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Rules and Practical Challenges of Cross-Border Healthcare in the European Union

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One of the building blocks of the functioning of the single market and the free movement of persons is the coordination of Member States' social security systems at EU level. Due to the coordination rules, EU citizens in any Member State belonging to the European Economic Area and Switzerland have equal access to healthcare, whether unplanned, i.e. urgent or planned. A multi-level regulation of planned care has emerged in the European Union with the entry into force of the Patient Mobility Directive. The purpose of the creation of the Directive is to facilitate access to planned healthcare and thus overcome certain restrictive measures in the coordination rules. However, the enforcement of the Directive depends to a large extent on the adequacy of Member States' implementing measures, so the European Union places great emphasis on monitoring the implementation as well. In addition to the multi-level regulation of healthcare abroad, the rules of the Patient Mobility Directive related to cross-border healthcare, as well as certain aspects of the implementation and future challenges of the Directive are presented in the study.

Keywords: coordination, European Union, free movement, healthcare, healthcare service, patient mobility, patients' rights, regulation, social security

Introduction

In the European Union, social security coordination bridges the gap between national social security systems and ensures cross-border social protection for EU citizens. Regulation (EC) No. 883/2004[2] (hereinafter referred to as

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2 Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Coordination Regulation) and Regulation (EC) No. 987/2009[3] (hereinafter referred to as Implementing Regulation) (hereinafter jointly referred to as coordination rules) therefore regard equal treatment, exportability of benefits, counting of insurance periods and the principle of belonging to the jurisdiction of a Member State as fundamental principles. Accordingly, the coordination arrangements provide EU citizens with the possibility to enjoy equal access to healthcare services in other European Economic Area Member States[4] and Switzerland under the same conditions as nationals of the host Member State. This is of paramount importance for the functioning of the single market and for the free movement of persons since health is undoubtedly one of the most important values of human society. Thus, it is important that EU citizens have access to adequate and high-quality healthcare while staying in another Member State, which goes beyond Member States' obligations and requires EU involvement.[5] The coordination rules cover both unplanned, urgent care and planned care. Regarding the latter, the coordination rules make the reimbursement of the costs of healthcare services subject to the possession of prior authorisation.[6] Among other things, this rule gave rise to several disputes, which since the 1980s have increasingly required the ruling of the Court of Justice of the European Union. As a result, it was declared, among other things, that healthcare services also qualify as services, so their free movement must be ensured. However, one of the barriers to the free movement has proved to be the requirement of prior authorisation for the financing of planned healthcare. This led to Directive 2011/24/EU[7] (hereinafter referred to as Patient Mobility Directive or Directive), which made the rules more flexible in several respects. Within the framework of the study, after a brief outlook, the system of multi-level regulation of medical treatment abroad and the detailed analysis of the rules of the Patient Mobility Directive will be presented. We will then look at the Commission's 2022 report monitoring the implementation of the Directive, as well as the Committee of the Regions' opinion issued in 2020, which make forward-looking statements on the functioning of the Patient Mobility Directive and the insurability and future challenges of cross-border healthcare. Although the Patient Mobility Directive contains essential provisions on the cooperation between the Member States, in particular with regard to the European Reference Networks, the diagnosis of rare diseases and the capacity building of care, or the cooperation in the field of eHealth and health technology assessment, these provisions will not be examined given the limitations of the scope of this study.

3 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) 883/2004 on the coordination of social security systems.

4 The territorial scope of the coordination regulation covers the whole European Economic Area as well as Switzerland.

5 Strban 2013: 392.

6 De Wispelaere 2019: 159.

7 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.

A multi-level regulation of medical treatment abroad in the European Union

As mentioned in the introductory part, access to cross-border healthcare is possible as a result of the European Union's work on social security coordination. The regulations summarising the coordination rules ensure, inter alia, that every EU citizen has access to healthcare in the territory of any Member State. With the creation and entry into force of the Patient Mobility Directive on 24 April 2011, a multi-level regulation of planned healthcare in the European Union has emerged. The coordination rules remain in force and, where they contain more advantageous provisions, the Coordination Regulation applies.[8] However, the Directive clarified and made the rules for planned healthcare more flexible, both in the case of prior authorisation and the rules for the reimbursement of the costs of care.

Relationship between the Patient Mobility Directive and the coordination rules

To illustrate the multi-level regulation and the relationship between them, it is also important to include a brief overview of the coordination rules for medical treatments abroad. The coordination rules allow the use of planned and unplanned health services. *Unplanned health services* are provided for in Articles 19 and 27 of the Coordination Regulation and Article 25 of the Implementing Regulation.[9] In this sense, an unplanned health service is when an EU citizen has an unexpected accident while staying in a Member State and needs urgent, immediate care. This treatment is provided free of charge by the publicly funded healthcare provider in the Member State of stay, provided that the EU citizen holds a European Health Insurance Card. Reimbursement of healthcare costs is settled between the insurance bodies of the Member States.[10] By contrast, *a planned healthcare service* occurs when an EU citizen travels to another Member State for the express purpose of receiving healthcare. In this case, prior authorisation must be given by the competent body of the Member State of affiliation, only then can the costs of treatment be reimbursed.[11] The Patient Mobility Directive introduced changes to this rule compared to the coordination rules, as it removed the requirement for prior authorisation for the reimbursement of the costs of planned treatment abroad, with a few exceptions. The detailed regulation is described in the next part of the study.

8 Directive 2011/24/EU (31).
9 Kristó–Borbás 2021: 144.
10 Cornelissen – De Wispelaere 2020: 152.
11 De Wispelaere et al. 2019: 53.

The coordination rules also determine the rules *for entitlement to healthcare in case of residence in another Member State.* Pursuant to Article 17 of the Coordination Regulation, insured persons and their family members who reside in a state other than the Member State where they work, may also receive healthcare in the Member State where they reside. In order to use the aforementioned right, they are obliged to register at the social security institution of the Member State of residence. The EU citizen also needs a certificate proving the right to healthcare in the Member State of residence. This certificate is issued by the Member State of the place of work.[12]

Regarding the relationship between the coordination rules and the Directive, the Directive states in its introductory provisions as follows:

> "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 Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems are met […]."[13]

In other words, the Directive underlines that unplanned healthcare services available with a European Health Insurance Card remain governed solely by the rules of the Coordination Regulation, and the Directive does not contain any provisions in this regard.[14]

Furthermore, the rules established by the Directive are not exclusive to planned health services, as beneficiaries can still receive healthcare services under the conditions laid down in the Coordination Regulation. Thus, in the latter case, the rules of the Coordination Regulation also apply to the reimbursement of costs.

> „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

12 Kristó–Borbás 2021: 145.
13 Directive 2011/24/EU (28).
14 Directive 2011/24/EU (30).

> 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."[15]

Legal basis and purpose of the Directive

The Patient Mobility Directive aims to ensure and facilitate access to safe and high-quality health services and encourage cooperation between Member States on prescriptions, rare diseases, eHealth and health technology assessment. The Directive has been drafted in line with the case law of the Court of Justice of the European Union (hereinafter referred to as CJEU) and, in some respects, as a summary thereof.[16] The basis for establishing the Directive is that the CJEU ruled in the cases of Kohll and Decker[17] that the principle of the free movement of services must also apply to health services.[18] In addition, the CJEU has ruled on numerous cases involving cross-border healthcare services[19] since the 1980s.[20] In the course of their practical application, there has been an increasing need to incorporate their content into secondary legislation. The European Commission first submitted a blueprint for implementing EU-wide legislation in 2004. It was planned to include the rules on the free movement for healthcare services in the draft Directive on services in the internal market. Neither the European Parliament nor the Member States agreed with this draft, as the specificities of health services were not fully reflected in it. As a result, the Commission presented a new draft in 2008, which resulted in the Patient Mobility Directive, which Member States had to transpose into their legislation by 25 October 2013.[21]

Among its introductory provisions, the Patient Mobility Directive sets out the main principles and objectives that have justified its creation. It cites Articles 114 and 168 of the Treaty on the Functioning of the European Union (TFEU) as its primary legal basis.

15 Directive 2011/24/EU (31).

16 Quinn – De Hert 2012: 30.

17 Case C-158/96, *Raymond Kohll v. Union of Sickness Funds*; Case C-120/95, *Nicolas Decker v. Private Employees' Sickness Fund.*

18 Carrascosa Bermejo 2014: 361.

19 Case C-158/96, *Raymond Kohll v. Union des caisses de maladie;* Case C-120/95, *Nicolas Decker v. Caisse de maladies des employés privés;* Case C-157/99, *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M., Peerboms v. Stichting CZ Groep Zorverzekeringen;* Case C-385/99, *V.G. Müller-Fauré c/ Onderlinge Waarborgmaatschappij O.Z. Zorgverzekeringen UA and E.E.M. Van Riet c/ Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*; Case C-372/04 *Watts;* Case C-444/05 *Stamatelaki.*

20 For more information Van Nuffel 2005: 253–270.

21 Gellérné Lukács – Gyeney 2014: 5.

The Article 114 of the TFEU defines provisions related to the approximation of the laws of the Member States, the purpose of which is to create and operate the internal market:

> "(1) Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, 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."

In relation to public health, Article 168 of the TFEU provides, among other things, the following:

> "(1) A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
>
> Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health."
>
> "(2) The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.
>
> Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed."
>
> "(6) The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article."

> "(7) Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

It is clear that the aim of the Directive is to promote maximum protection of human health by laying down rules for cross-border health services, while respecting the competence of the Member States to develop their own health systems.

> "This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness."[22]

> "This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States."[23]

At the same time, the Directive highlights that, although the legislation allows free use of cross-border services, Member States remain responsible for organising safe, efficient, and high-quality healthcare on their territory. Furthermore, this Directive does not aim to encourage patients to seek care outside the territory of the Member State of affiliation.

> "Notwithstanding the possibility for patients to receive cross-border healthcare under this Directive, Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. Furthermore, the transposition of this Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation."[24]

22 Directive 2011/24/EU (10).
23 Directive 2011/24/EU (7).
24 Directive 2011/24/EU (4).

Rules of the Patient Mobility Directive

The structure of the Directive is as follows. Following the introductory provisions discussing the legal basis, the purpose, and the relationship of the Directive with the coordination rules, Chapter 1 contains general provisions. It sets out the subject and scope of the Directive, its relationship with other EU provisions, as well as the definitions. Chapter 2 sets out the competences of the Member States, including the responsibilities of both the Member State of treatment and the Member State of affiliation. Chapter 3 sets out the provisions on the reimbursement of cross-border healthcare, including the rules on healthcare subject to prior authorisation and the administrative procedures for cross-border healthcare. Chapter 4 describes the rules for cooperation between Member States in the field of healthcare. This includes standards for mutual assistance, the establishment of European Reference Networks, the recognition of prescriptions issued in another Member State, the cooperation to develop capacities for diagnostics and care for rare diseases, the establishment of an eHealth network and the cooperation on health technology assessment.[25] The significance of these latter provisions is not in question, but, as already mentioned, they are not described in detail in this study. Finally, Chapter 5 of the Directive contains the implementing and final provisions.

In this chapter of the study, the rules of the Directive for cross-border healthcare services are presented, with special reference to the definition of Member States' competences, the rules on prior authorisation and reimbursement of costs, and the provisions on administrative procedures.

Competences of Member States

The Directive defines under the article 'Definitions' what is meant by the terms of Member State of treatment and Member State of affiliation.

> "Member State of affiliation means: for persons referred to in point (b)(i), 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;"[26]

> "Member State of treatment means 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."[27]

25 Baeten 2009: 159.
26 Directive 2011/24/EU Article 3 (c).
27 Directive 2011/24/EU Article 3 (d).

Under the rules of the Directive, regardless of whether the Member State is a provider or an insurance undertaking for a given cross-border healthcare, it must operate a national contact point.[28] One of the most important tasks of the *national contact points* (of which there may be several per Member State) is to keep in touch and provide information. This applies to contacts with healthcare providers, health insurers and patients. Contact points play a particularly significant role in enforcing patients' rights in relation to cross-border healthcare services, providing them with information, inter alia, on healthcare providers, patients' rights, complaint procedures and means of redress.[29]

The Directive specifically includes the following responsibilities of the *Member State of treatment.* It requires the national contact points they operate to provide, at the request of patients, appropriate information, inter alia, on quality and safety standards set by the Member State, on the assessment of healthcare providers or on accessible hospitals for disabled people. It requires, inter alia, healthcare providers to provide patients with adequate information on care options and availability, clear bills, and accurate price information. The Member State of treatment should also provide complaint procedures and mechanisms to which patients can seek redress in case of any harm they may suffer. It should also operate professional indemnity insurance schemes that are proportionate to the nature and extent of the risk associated with the care provided on its territory and ensure patient access to care documentation in order to ensure the continuity of care.[30] The Directive also provides for the prohibition of discrimination on grounds of nationality, which covers, inter alia, that healthcare providers apply to patients from other Member States the same scale of fees as they apply to domestic patients. However, it is important that overriding reasons of public interest, such as to avoid wasting financial, technical or human resources, the Member State of treatment may restrict access to treatment for cross-border patients, but such measures should not go beyond what is necessary and proportionate.[31]

It refers to the competence of *the Member State of affiliation* to reimburse the costs of cross-border healthcare services, to provide any subsequent follow-up medical treatment and to provide remote access to medical records. It also provides for mechanisms to be in place to inform patients about their rights, entitlements, appeals and remedies, and rules on reimbursement of costs in relation to cross-border healthcare.[32]

28 Panurjasz 2014: 69.
29 Directive 2011/24/EU Article 6.
30 Directive 2011/24/EU Article 4 (2).
31 Directive 2011/24/EU Article 4 (3)–(4).
32 Directive 2011/24/EU Article 5.

Rules on prior authorisation

One of the major changes brought about by the directive to the EU treatment system is that it no longer makes the reimbursement of planned healthcare services subject to prior authorisation. However, as explained in more detail in the next subsection, there is also a change in the level of reimbursable costs when healthcare services are provided under the rules of the Directive. To ensure the sustainability and rational operation of health systems, there are healthcare services for which prior authorisation may continue to be required.[33] It is for Member States to determine the scope of these benefits subject to prior authorisation, but the Directive calls for the application of the *principle of proportionality* as follows:

> "[…] The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients."[34]

In summary, the Directive waives the obligation of prior authorisation for simpler, routine care, but for care that requires more serious planning, infrastructure or poses a risk to the patient, the use may be subject to prior authorisation by Member States. These cases include:

- care requiring a hospital stay of at least one night, or services requiring the use of medical equipment or infrastructure that are extremely costly and specialised
- treatments presenting a particular risk for the patient or the general public
- or where there are serious concerns about the quality or safety of the service provided by the healthcare provider[35]

The importance of the Directive's provisions on benefits subject to prior authorisation is also indicated by the fact that we already find rules on this in the introductory provisions. For example, in paragraph 40 it refers to the case law of the CJEU providing for prior authorisation for hospital care, arguing, inter alia, that planning for such care is of paramount importance, both from a cost-effectiveness point of view and from the point of view of ensuring diverse, balanced, and multi-faceted hospital care, avoiding a waste of technical and human resources.[36]

The issue of high-cost medical infrastructure was dealt with by the Court *in the case of the Commission v France,*[37] where the ruling is an important addition to that

33 Pennings 2011: 439.
34 Directive 2011/24/EU Article 8 (1).
35 Directive 2011/24/EU Article 8 (2).
36 Directive 2011/24/EU (40).
37 C-512/08. *European Commission v French Republic.*

legislation. In this case, the European Commission opened infringement proceedings against France on the ground that French social security legislation was contrary to Community law by requiring prior authorisation for the use of care requiring the use of significant medical equipment outside hospital settings. However, the CJEU dismissed the Commission's action on the grounds that the requirement for prior authorisation was realistic in this case with a view to maintaining the financial balance of the social security system. Thus, by that judgment, the CJEU classified the use of MRI and PET scanners as particularly costly care.

Therefore, it is up to the Member States to determine which benefits are subject to prior authorisation; this list shall be forwarded to the European Commission.[38] The Directive provides that the scope of benefits on the list must be limited to what is necessary and proportionate and that Member States should be able to *"set up different criteria for different regions or other relevant administrative levels for the organisations of healthcare, or indeed for different treatments, as long as the system is transparent and easily accessible and the criteria are made public in advance"*.[39]

As provided for in the coordination regulations, if the necessary care cannot be provided within the medically justified time limit in the Member State of affiliation, prior authorisation for the planned healthcare must in any event be granted to the patient. However, there are cases where, although care cannot be provided within the medically justified time limit, authorisation may be refused, and the patient may need to be directed towards other viable solutions. The Directive provides an exhaustive list of these cases:

- where the patient would be exposed to a patient safety risk which, taking into account the benefits of cross-border healthcare, cannot be considered acceptable
- where cross-border healthcare would result in the population being exposed to a serious safety risk
- where the healthcare service is provided by a provider with serious and specific concerns regarding the quality of care and patient safety
- where the healthcare in question can be provided in the Member State of affiliation within a medically reasonable period[40]

Overall, therefore, the Patient Mobility Directive recognises that requiring prior authorisation for healthcare services constitutes an obstacle to the free movement of services, but there are overriding reasons of public interest where any national measure requiring prior authorisation to receive cross-border healthcare services is acceptable.

38 Directive 2011/24/EU Article 8 (7).
39 Directive 2011/24/EU (44).
40 Directive 2011/24/EU Article 8 (6).

Rules for reimbursement of costs

In addition to relaxing the rules on prior authorisation, the Patient Mobility Directive also introduced significant changes to the rules on reimbursement compared to the coordination rules. While the total amount of the treatment received in another Member State is reimbursed by the Member State of affiliation under the coordination rules when prior authorisation is granted, under the rules of the Directive, i.e., if the treatment is received without prior authorisation, the costs may only be reimbursed ex post, and the full cost of the treatment may not be covered. Indeed, the Patient Mobility Directive lays down the following rules in this regard:

> "The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.
>
> Where the full costs of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.
>
> The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on condition that there be sufficient documentation setting out these costs."[41]

Thus, one of the main changes introduced by the Directive is that, although it is now possible to receive planned healthcare services without prior authorisation, reimbursement of costs can only be made ex post or to the extent that the Member State of affiliation would have assumed if the treatment had been provided on its territory. Member States should put in place a transparent mechanism for calculating the costs to be reimbursed, based on objective, non-discriminatory criteria known in advance.[42]

Rules of administrative procedures

The enforcement of the rules of the Directive on cross-border healthcare services depends to a large extent on cooperation between Member States. The administrative procedures they have developed allow beneficiaries to enforce their rights, which

41 Directive 2011/24/EU Article 7 (4).
42 Directive 2011/24/EU Article 7 (6).

must comply with certain rules set out in the Patient Mobility Directive. The Directive requires that national rules of administrative procedures are to be objective and non-discriminatory, and that information concerning them should be easily accessible and publicly available.[43]

Member States should set reasonable time limits for the examination of requests for cross-border healthcare and should take into account the applicant's medical status and the urgency and specific circumstances of the treatment. The Directive also provides that decisions on reimbursement of costs must be properly reasoned and open to challenge before the courts.[44] The directive provides for the possibility of introducing a so-called prior notification system, which gives the patient a confirmation in advance of the estimated reimbursable amount of care, considering the patient's clinical history.[45]

Monitoring the implementation of the Directive

Rules for monitoring the Directive

The Patient Mobility Directive provides for a separate section on how to monitor the operation of the Directive and on reporting obligations for the European Commission. This includes requiring the Commission to report to the European Parliament and to the Council on the implementation of the Directive by 25 October 2015 and every three years thereafter.[46] The report shall address the following aspects:

- patient flow
- financial aspects of patient mobility
- restrictive measures introduced by Member States on the reimbursement of costs incurred for cross-border healthcare services and healthcare subject to prior authorisation by Member States
- the functioning of the European Reference Networks and national contact points[47]

The preparation of reports requires cooperation between Member States and the Commission, since the Commission can only evaluate the systems and practices put in place by Member States if they provide assistance and all information to the Commission. As regards the methodology for preparing the reports, the Commission reviews the websites operated by each Member State, in addition to theoretical research and literature analysis, and uses participatory research methods.

43 Directive 2011/24/EU Article 9 (2)–(3).
44 Directive 2011/24/EU Article 9 (4).
45 Directive 2011/24/EU Article 9 (5).
46 Directive 2011/24/EU Article 20 (1).
47 Directive 2011/24/EU Article 20 (2).

These include interviews with health insurers, healthcare providers, patients' rights representatives, patient advocacy groups, etc., and often use the so-called 'bogus patient' research method to assess the adequacy of the information provided by national contact points.

So far, the Commission has produced a total of 3 reports in 2015, 2018 and 2022. In this chapter, we review the latest Commission report published in 2022.

Commission Report 2022[48]

The Commission's 2022 report concludes that patient mobility data remains low and that there has been no significant increase compared to the periods covered by previous reports. The report highlights that when assessing the number of healthcare received under the rules of the Directive, it should not be overlooked that restrictions to free movement as a result of the 2020 Covid–19 pandemic also play a significant role in this. As regards the direction of patient mobility, it has been identified that it is more significant among neighbouring countries and France remains one of the largest countries of origin in this respect.

The Commission also explains in the report that consideration should be given not to introduce a prior authorisation requirement, even where the Directive allows for this. This is justified by the fact that due to the low level of patient mobility, its impact on national health budgets remains marginal – so a system of prior authorisation is not strictly necessary to protect health budgeting. However, if a Member State does apply one, a well-defined and exhaustive list of treatments subject to prior authorisation should be drawn up and made publicly available so that those entitled can easily identify the applicable rules. Regarding reimbursement, the Commission has still encountered some Member States' practices that apply lower reimbursement levels for cross-border healthcare services received by private/non-contracted healthcare providers compared to public health systems. The Commission has also initiated proceedings against these Member States for failure to fulfil their obligations.

The report highlights the cumbersome and disproportionate administrative procedures applied by some Member States as an obstacle to the operation of the Directive. In doing so, it recommends that national competent authorities avoid unnecessary requests for information from patients, such as information on the estimated cost of healthcare or waiting times for a particular treatment.

Regarding the adequacy of patient information, the report notes that accessibility for persons with disabilities is not ensured on several websites operated by national contact points and that information on accessible hospitals is still lacking in several

48 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 (12.5.2022).

places. To help inform patients, the Commission has produced a specific handbook[49] on their rights in cross-border healthcare, available in several languages, which national contact points are encouraged to publish. Patients' understanding of the relationship between the Directive and the Coordination Regulation remains a major problem, particularly as the responsibility for making decisions lies with patients.[50]

Regarding the cooperation between Member States, the report highlights that the Covid–19 pandemic situation has clearly transformed the focal point of cooperation and has had a positive impact on developments in many situations. For example, the report highlighted that the eHealth Network greatly facilitated the development of contact tracing and warning applications and the development of the EU Digital Covid Certificate. Cooperation on health technology assessment was also useful in countering the pandemic, as it provided ongoing assessments of a range of pharmacological and non-pharmacological therapies. Another major step forward in eHealth was the adoption of the proposal for a regulation on the European Health Data Space (MyHealth@EU),[51] which can help EU citizens ensure continuity of care while abroad by expanding the eHealth service infrastructure.

Furthermore, as the report states, the epidemiological situation has further highlighted the need for cross-border regional cooperation. Thus, intensive care sites have been set up in several EU regions, which have proved vital during the rage of the pandemic. The report sees the significance of the Directive in the post-pandemic period as helping to overcome the huge backlog of routine, non-urgent treatments postponed by utilising the free healthcare capacities available across the border.

The report concluded that, although patient mobility at European level is still low,[52] there is no doubt about the positive effects of the directive, which has encouraged cooperation between health systems, particularly in the areas of rare diseases and eHealth.

Cross-border healthcare provision and future challenges

In addition to the Commission's implementation monitoring report, it is also important to mention the *Opinion of the European Committee of the Regions issued in 2020*[53] on the provision and prospects of cross-border healthcare. The opinion highlights that cross-border patient mobility is a particularly important policy issue where many problems offer complex solutions: For example, access to information on

49 Guiding Principles and Indicators for the practice of National Contact Points under the Cross-border Healthcare Directive 2011/24/EU.

50 For more information of the development opportunities: Kristó 2022: 169.

51 Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM (2022) 197 final.

52 For more information: Gellérné Lukács 2020: 1366.

53 Opinion of the European Committee of the Regions (2020/C 440/03) on the provision and future prospects of cross-border healthcare.

treatment abroad, continuity of care, exchange of information between medical staff on both sides of the border, and logistical and administrative challenges affecting how many citizens want to exercise their right to cross-border healthcare. The opinion also draws attention to the fact that border regions are the main focus of cross-border healthcare services, as many patients living there seek treatment in neighbouring countries and therefore particular attention should be paid to these areas. Of course, the experiences learned from the health crisis caused by the Covid–19 pandemic also feature prominently in the document. Like the Commission's 2022 report, the opinion highlights that the biggest lesson of the pandemic is the need for closer cooperation in Europe. Thus, it proposes the creation of an EU Emergency Health Mechanism, linked to the EU Solidarity Fund and the European Centre for Disease Prevention and Control. This is necessary to support local and regional leaders in providing health services and supplies to hospitals and schools, buying medical devices or hiring medical staff in future outbreaks. The opinion recalls the solidarity clause enshrined in Article 222 of the TFEU, according to which the European Union and its Member States act together in a spirit of solidarity when dealing with different crisis situations. It also proposes the creation of so-called health corridors between border regions, which will allow both patients and healthcare professionals to cross the border during restrictions. The opinion also addresses the issue of patient mobility and mentions Commission opinions showing that patient mobility is low and cross-border healthcare services are most used in border regions, targeting neighbouring countries. However, it highlights that low patient mobility is not a problem in itself, as the Patient Mobility Directive only aims to complement healthcare service options available at national level and clarify the rights of European patients travelling to another Member State to receive healthcare. Thus, the effectiveness of the Directive should not be measured in terms of the number of cross-border healthcare services, but in terms of improving the situation of patients. Like the Commission's reports, the European Committee of the Regions stresses that information is of paramount importance for the implementation of the Directive, so that the Commission could help the information mechanism of Member States that perform worse by raising awareness of practices in different countries, and that national contact points could also improve their activities by setting up regional agencies. Regarding the application of the prior authorisation system, it explains that, although in some cases it constitutes an obstacle to cross-border patient mobility, it provides financial security for patients and opens access to healthcare services abroad for less well-off citizens. Thus, it considers that the possibility of introducing a prior authorisation requirement in the Member States remains justified, but stresses that Member States should process applications for prior authorisation with the shortest possible administrative time and should not unnecessarily delay treatment. It also calls for the introduction of a mechanism for prior notification of reimbursable costs as a form of certainty for patients.

Conclusion

With the creation of the Patient Mobility Directive, a multi-level regulation of treatment abroad has emerged in the European Union. The coordination regulations ensuring coordination of national social security systems allow cross-border access to healthcare but make reimbursement of planned healthcare conditional on prior authorisation. By contrast, the Patient Mobility Directive removed the obligation to provide prior authorisation for reimbursement of costs for planned treatment abroad, with a few exceptions. For care requiring more serious planning in terms of organisation, technology, resources, or financing, as well as a hospital stay of several days, Member States may maintain the requirement of prior authorisation in order to preserve the financial sustainability of the systems and avoid wasting resources. Furthermore, Member States may also require prior authorisation where there are certain overriding reasons relating to the public interest. If beneficiaries make use of the Patient Mobility Directive and receive planned care without authorisation, they can only claim reimbursement of costs ex post and only to the extent that the Member State of affiliation would have taken over if the treatment had been provided on its territory. If, on the other hand, a person entitled to benefits is received under the rules of the coordination regulation and receives the benefit with prior authorisation, the full cost will be reimbursed by the Member State of affiliation and need not be advanced by the recipient. The regulation thus gives EU citizens the opportunity to access adequate and high-quality health services, but real effectiveness depends on Member States' implementing measures.

The Commission's 2022 monitoring report on the implementation of the Directive highlights that some Member States' practices still make it significantly more difficult for beneficiaries to access cross-border healthcare services. The biggest problem mentioned in the report is still in relation to administrative procedures, as in many cases they continue to impose unnecessary administrative burdens on patients. The study also reviewed the opinion of the Committee of the Regions issued in 2020, which also makes interesting findings on the provision and future challenges of cross-border health services.

Summing up the study, the Patient Mobility Directive has removed all possible barriers to cross-border healthcare services, but the number of EU citizens making use of the legislation remains low. Analysing the Commission's 2022 report and the Committee of the Regions' opinion issued in 2020, the problem could be alleviated by improving information to EU citizens and strengthening cooperation between border regions. However, in conclusion, it is important to underline – as described in the opinion of the Committee of the Regions discussed in the study – that the effectiveness of the Patient Mobility Directive should not be measured in terms of the number of benefits received, but in terms of improving the situation of patients.

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