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# The Cross-Border Health Services Market in EU

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**ABSTRACT:** Access to cross-border healthcare in the European Union (EU) is promoted by Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011. The aim is to promote patient mobility and the possibility of access to new treatment opportunities and an EU-wide health service. The focus of this paper is the analysis of the Directive, its scope and its consequences in Portugal. The concept of cross-border healthcare provision means the possibility for an EU citizen to have access to healthcare in another Member State, bordering the state of his nationality. The directive imposes rules for patients' access to cross-border healthcare. The idea is to ensure freedom of choice and access to high-quality cross-border healthcare in the EU, and to do so by ensuring patient mobility. As stated by the Court of Justice of the European Union (CJEU), the main objective is to promote cooperation on healthcare between member states, while respecting all national competences on the organization and delivery of healthcare. In this paper we analyze the assumptions of access to cross-border healthcare, from transparent information to the removal of administrative obstacles and treatment costs in host countries. We also analyze the terms of the transposition of the Directive into Portuguese law, and in particular the introduction of the mechanism of subordination to prior authorization.

The methodology adopted is based on a theoretical framework that includes the study of legislation, jurisprudence and reports from the European institutions. We also try to access some data on cross-border health care in times of pandemic from COVID 19. The results show some inconsistencies in the transposition of the Directive in Portugal and also regulatory flaws. The possibility of "reverse discrimination" between Portuguese and nationals of other member states is one example. Safeguarding the quality of this type of healthcare requires a more assertive intervention by EU health regulators.

**KEYWORDS:** Competition; Cross-border health services; EU health services market; Reverse discrimination; Services of general interest

## 1. INTRODUCTION

The Directive 2011/24/EU, of the European Parliament and of the Council, of 9 March 2011 (from now referred only as Directive) sets the rights of European Union citizens to cross-border healthcare, and guarante freedom of choice and access to high-quality healthcare in the European Union (EU). The Directive applies to the provision of cross-border healthcare from a Member State (MS) to another (ERS: Report 2017).

This Directive covers a wide range of healthcare broadly, public or not, but excludes the provision of continued care, organ transplantation and public vaccination. Its aim is to ensure patient mobility in accordance with the principles established by Treaty on Functioning of the European Union (TFEU) and the Universal Declaration of Human Rights (UDHR), which in Article 25 (1) recognises the right to health, medical care and safety in the disease. Similarly, the Convention on Human Rights and Biomedicine also protects human beings in their dignity and identity, promoting their well-being. The Charter of Fundamental Rights of the European Union, in article 35º, also presents access to health as an fundamental right.

The TFEU, in articles 4, 6 and 168, confers jurisdiction on the European Union to legislate on public health. The aim is to safeguard the security of the Member States by outlining a common strategy in the fight against the disease. To pursue this objective, it is up to the EU to adopt health information and education measures and to monitor threats and risks to public health.

The Directive was born in 2011 in this legal framework, so we can say that since then the EU has a legal mechanism that guarantees to european patients, in and from any member State, the access to quality healthcare in safe conditions, and their mobility in the EU. To this end, some social and health benefits have been established which the MS should guarantee on an equal way to all

european citizens. Nevertheless, the national competences of each MS in the definition and organisation of their health services are safeguarded.Despite its good intentions, over the years this Directive has not had the expected effect. The economic crisis, between 2008 and 2013, has put in first plan other priorities, and health, despite being a service of general interest, has been neglected.

The Directive enforce the idea of solidarity and efficiency in the management of health services among MS, which is very important, in particular, to fight against specific diseases as pandemic situations. However, we have observed daily disorientation and lack of coordination between Member States in the fight against the COVID 19 crisis, especially in the first and second waves of the pandemic

We believe that if MS had given greater importance to the implementation and improvement of the principles contained in the Directive, the means to face the current crisis acould be better more efficient and integrated, in order to do a better support to de MS with more dificulties.

### 1.1 The Investigation Goals

The aim of this work is to present the results of the investigation about the aplication of the Directive in the field, all over the last eight years. This study was developed within the scope of the research for the Master Thesis in law, realized by the Author Joaquim Cepeda with the scientific orientation of the Author Maria do Rosário Anjos. After the conclusion of the Master degree, it seems quite importante to share with the scientific community some of the results and conclusions of the work. The impact of the Directive corresponds only to one chapter of the master's thesis, but the situation motivated by COVID 19 pandemic crisis highlighted the importance of this issue.

In this work paper we abord the legal framework contained in the Directive and present some data, collected in order to show the real impact of the Directive in the last years and answer to the question about the (ir)relevance of this Directive in the field of healthcare services in the EU. This issue is indeed very important at a particularly critical time due to the global pandemic crisis that has paralyzed the world.

### 1.2 Methodology

Considering the theme and the rules of investigation on issues of law we did develope a theoretical study of the legal framework of the Directive. We have also used other sources such as documents, reports, recommendations and other documents from European institutions, including the Court of Justice of the European Union (CJEU) and the National Regulatory Authorities, and some doctrinal references. About the state of art, it is important to note that there are still no specific research papers on this issue. The research carried out focused primarily on the collection of some data on the levels of implementation of the Directive, in order to conclude about the degree of impact of the Directive in the EU. Finally, we considered the importance of its implementation in times of COVID 19 pandemic.

## 2. THE CROSS-BORDER HEALTHCARE DIRECTIVE

The healthcare provided for in the Directive covers health services provided by health professionals, including the prescription, dispensing and supply of medicines and medical devices. The concept of providing cross-border healthcare means the possibility for an EU citizen to have access to healthcare in another Member State, bordering the State of his nationality. The aim is to promote patient mobility and the possibility of access to new treatment opportunities and an EU-wide health service. However, Member States may prohibit their nationals from accessing healthcare in another member when the "*public interest*" impose it. For example, in case of danger to public health due to infectious diseases (paragraphs 11 and 12 of the Directive). The Directive also allows the exclusion from its application when the expenditure associated with medical treatment is of very high value, putting in danger the financial sustainability of the national health system. Actualy this is "*an open road"* to the MS do what they want.

### 2.1 The analysis of the Directive

A study by the European Commission (EC. 2014: Final Report) carried out with users and funding entities concluded that the main motivations for seeking cross-border care under the Directive are healthcare costs and waiting times in the patient's nationality country. The user's degree of confidence in the national health system is important, but it is not the main decision factor. According to this report, for the informed decision of the user, it is essential that information on prices and waiting times is made available, ideally online, and the information must be transparent about each member State providers in order to gradually the users get confidence in the all health systems of all EU member states.

Another study by the European Commission (EC. 2015: Final Report) published in September 2015, which involved a number of stakeholders (user groups, supervisory bodies, healthcare provider organisations and existing national contact points in each MS), has conclude that the Directive could have more benefit if the MS increased information to users. The results show that citizens

are not informed about the new treatment opportunities that the Directive recognises to them, neither about the existence of national information points.[1] In Portugal case these information points exist but it was found that they received a low number of requests for information and reimbursement requests, which may have occurred due to lack of knowledge of the citizens.

According to the same report, users interviewed in different Member States declare that the main reasons for the lack of cross-border care relate to administrative matters, in particular those relating to applications for prior authorisation denied or waiting for a decision for a long time. The interviewees also considered that the information available on most contact point *websites* does not provide sufficient detail. On the other hand, respondents revealed that the quality of healthcare is not a relevant factor for the decision to seek cross-border care (ERS. 2014.Annual Report: 6-7). In general, the users consider their healthcare services good, but sometimes are not fast enough or are not the best to care of some specific diseases.

A third European Commission study, published in 2015, presents the results of a survey conducted in the 28 EU MS countries on the demand for cross-border healthcare. This report concludes that only 5% of Europeans received medical treatment in another EU country (in Portugal the percentage was 7%) in the 12 months preceding the interview (held in October 2014).[2]

The majority of respondents indicated that the main reason for seeking health care in another country was the existence of care unavailable in their home country and care with a higher level of quality. Of those interviewed, 55% indicated satisfaction with the care provided in their home country as the main reason for not wanting to receive treatment abroad.

As for the degree of knowledge of citizens about the use of cross-border care, the majority of EU citizens know that they are entitled to reimbursement for treatments carried out in another EU country, although in Portugal this percentage has fallen to 41% between 2012-2014. Only 10% of EU citizens had heard talk about the existence of the national information contact point, but this time the percentage in Portugal rose to 13% between 2012-2014 (ERS.2014:7-8).

This Commission report about implementation of Directive 2011/24/EU, conclude that the exercise of patients' rights in cross-border healthcare had not a big success because some member States had not implemented the Directive in national legal framework in time. Because of that the patient mobility in scheduled healthcare remained low. Associated with the delay in transposing the Directive, european Comission considered that the lack of users knowledge, the lack of national information and the obstacles posed to users by local authorities are the reasons for the very low level of Directive impact in the field.

Among the obstacles are the situations requiring prior authorization, the lack of clarity regarding treatments requiring prior authorization, reimbursement for lower amounts than those used in the MS of origin and excessive administrative requirements (ERS. 2015:7-8).

In October 2016, a study by the European Commission found that in most of the 23 MS who participated in that study, requests for prior authorisation and claims for reimbursement were minute. (ERS. 2016: 8).

In September 2018, a new Commission report considers that cross-border mobility in the EU had a slight growth and the Directive had contributed to improving some legal certainty and clarity about rights and benefits of cross-border patients. It adds that cross-border patient flows are driven by geographical or cultural proximity and that patient mobility in the EU remains relatively low.

Finally, a January 2019 report, from European Parliament, about the implementation of the Directive, lists a number of relevant conclusions on the impact of the Directive on the EU, recalling that the health sector is a vital component of the EU economy, which amounts to 10 % of its GDP, and this figure could increase to 12.6 % by 2060 due to socio-economic factors (European Parliament report. 2019)

According to this report the main reasons for the low adherence of users to cross-border health services are: a) the reduced patient mobility; b) the delay of many MS in transposing the Directive; c) the lack of public awareness of their rights to reimburse expenditure; d) the several dificulties imposed by some MS to cross-border healthcare, such as administrative costs and prior authorizations; e) the lack of information guiven to the patients seeking cross-border healthcare and when existes some information it is incomplete or confused.

This Parliament report enforce the idea that EU Health systems, at an accessible price for all people, are crucial to ensuring public health, social cohesion and social justice, preserving and guaranteeing the right of universal access to healthcare. This is the «*leit motiv»* for §2, 106 article of TFEU, for preserve the protection of accessibility, quality and universality of services of general interest (Anjos. 2016: 214-2121).

The same report also mentions that the patients quality of life is an important component of the assessment of costs/benefits in the health sector.The report considers that healthcare can sometimes be better provided in another MS, due to proximity, ease

[1] In Portugal, the national contact point provides information on the Directive on the following website:http://diretiva.min-saude.pt/direitos/

[2] European Commission - *Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union*. May 2015. Available from: https://ec.europa.eu/commfrontoffice/publicopinion/ archives/ebs/ebs_425_sum_en.pdf

of access, specialised nature of care or lack of capacity, for example the lack of essential medicines, in the home Member State. In fact, this point of view is mentioned by some authors, reinforcing that this is a way to improve the quality and universality of the service and also its better management, and may result in some non-savings for member states by the synergy resulting from a common and more integrated management. (Mendes & André. 2017:34-37; Marques, 2015: 4-7)

The importance of EU cooperation is highlighted in ensuring efficient sharing of knowledge and resources in the fight against rare and chronic diseases. The report finds that Member State have not fully or correctly implemented the Directive, so citizens continue to struggle to know how they can benefit from the rights set out in the Directive. Greater clarity and transparency about the working conditions of healthcare providers is needed to ensure greater patient mobility. The right to information is crucial, but the Directive goes further and imposes a duty to inform. Local health professionals should clarify the user about the possibility to use the health service in any other Member State, in order to give the best support in health services to the citizen. (Anjos&Cepeda.2018:2-4).

In short, the European Parliament has declared the Member State's duty to ensure access to health care and to ensure that the costs associated with it are reimbursed. But it should be noted that in several Member States there are significant bureaucratic obstacles and it should be remembered that the Directive aims to ensure a high level of public health protection while respecting the principle of free movement of persons in the internal market.

**2.2 Transposing the Directive into the Portuguese legal system**

The Directive presented an ambitious schedule, establishing that Member States should put it into effect by October 25, 2013, but this was not the case. The transposition of the Directive into the Portuguese legal system occurred with Law No. 52/2014 of August 25, which defined the rules for access to cross-border healthcare, establishing the rules for access to cross-border healthcare. It excludes from the scope of the law integrated long-term care and the donation or harvesting of organs for therapeutic or transplant purposes. Article 4(1) provides that cross-border healthcare shall be provided in accordance with the principles of universality, access to good quality care, equity and solidarity, and states in paragraph 2 that such care shall be provided while respecting the patient's right to privacy. Article 6 imposes a duty to provide information in the relationship with the patient, including the right to use another Member State to obtain the healthcare allowed.

As for the right to reimbursement of expenses directly related to cross-border healthcare provided in another member state, we have expenses subject to a system of prior authorization by a general practitioner of national or regional health services, which determines the need for healthcare (article 11, Law 52/2014). Here, there is the possibility of "**reverse discrimination",** i.e. discrimination against nationals who internally see their freedom of choice limited to certain providers. On the contrary, a citizen of another Member State will be able to choose access to any provider, public or non-public.

**2.3. Reverse Discrimination**

The transposition of the Directive into Portuguese law has led to a situation of "reverse discrimination", which means that it is possible that Portuguese citizens may have worse conditions of access to health services than nationals of other Member States. In other words, in some situations it is possible that health care for Portuguese citizens may be more expensive than for nationals of other Member States.

Reverse discrimination arises when a European citizen cannot be a beneficiary of certain provisions guaranteed by EU law in his country of origin, but a citizen of another Member State, in the same situation, can do so. In this case, we can say that the treatment is more beneficial for migrant citizens of EU Member States than for nationals (Duarte,2015:11-12).

The point is that when a national needs access to hospital health care, everything depends on the decision of the doctor who examines, decides and guides the patient. Thus, the patient does not benefit from the freedom of choice, which is imposed by the geographical dictates and administrative organization of the national health system. On the contrary, the patient from another member state, who needs health care and decides to seek such services in another member state, is not subject to the need to resort to referral from the health center, with the added advantage of being able to be assisted in any hospital unit in any member state of his choice.

**3. THE ANALYSIS OF THE HEALTH REGULATORY AUTHORITY OF PORTUGAL**

The Portuguese Health Regulatory Authority, in a 2012 study, analyzed the potential economic and financial impact of increased cross-border care following the Directive, predicting that 32,000 users of the Portuguese healthcare system would not have their healthcare needs met and that 10% of users (3,200 users), would be willing to seek healthcare abroad. In 2017, it considered that the reduction in demand for cross-border healthcare by Portuguese users resulted from the following reasons:

- users may not be aware of the existence of the Directive;
- users may not have enough information to make the decision to seek care abroad;

- the national health service provided on Portuguese territory reasonably satisfies the needs of its users;
- payment in advance for health care and costs associated with travel and residence in another member state are not covered.

The study points out that the difficulty of making claims against medical errors or negligence and the possibility of these being rejected with the consequent need for costly legal action may discourage seeking cross-border healthcare.
The same study shows that users fear the costs associated with prospecting (search costs) to find the right provider and the costs of lack of knowledge of another country's health system. (switching costs). (ERS. 2017:Annual Report).
The Portuguese Health Regulatory Authority revealed that 80% of Portuguese users do not intend to use cross-border health care and the level of knowledge about cross-border care is very low. The causes of low demand for cross-border care include lack of information about using such care, difficulty in understanding the procedures, and financial constraints. The costs of traveling abroad that are not reimbursed. Thus, this study concludes that the impact of the Directive in Portugal has been low so far.

**4. PRIOR AUTHORIZATION AS A LIMIT TO THE PRINCIPLE OF FREE MOVEMENT**

The Directive allows Member States to establish a prior authorization mechanism. The Portuguese State has made use of this prerogative by transposing the Directive into our domestic law No. 52/2014 of August 25, imposing on national citizens the requirement of prior authorization to be able to access cross-border healthcare.
Law No. 52/2014, in article 14, establishes the prior authorization process, stating in paragraph 1 that "the prior authorization request and the respective clinical evaluation report are sent by the hospital unit that issued the report to the Central Administration of Health Systems, I.P. (ACSS, I.P.), or to the competent services of the autonomous regions, for appreciation".
The same article 14, paragraph 3, states that the request for prior authorization must be rejected in the following cases:
"if the clinical evaluation indicates with reasonable certainty that the patient is exposed to a safety risk that cannot be considered acceptable taking into account the potential benefit to the patient of the cross-border healthcare sought;
if there is a reasonable degree of certainty to conclude that the population is exposed to a significant safety risk as a result of the cross-border healthcare sought
if the healthcare in question is provided by a healthcare provider where there are serious and specific concerns about compliance with standards and guidelines on quality of healthcare and patient safety
if the healthcare in question can be provided in Portugal within a reasonable and medically justifiable time limit, taking into account the patient's state of health and the probable course of the illness".
Thus, there are several situations where the patient or the general population may be denied access to cross-border healthcare for safety reasons. Subordination to prior authorization requirements may constitute an undue limitation on the free movement of citizens, a violation of the Treaty (TFEU), which in Article 20 (1) establishes a true European citizenship, adding in paragraph 2(a) that citizens of the European Union have the "right to move and reside freely within the territory of the Member States".
This legal provision is reiterated in §1 of Article 21 TFEU which stipulates that "every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and to the measures adopted to give them effect."
Portuguese law provides for reimbursement in exceptional cases, whenever the Portuguese national health system does not have a treatment solution available for the patient. This condition is, by its very nature, likely to severely limit the chances of obtaining prior authorization. It should be noted, however, that this restriction is not justified on budgetary grounds, such as the alleged serious threat to the financial balance of the social security system. This motivation has already been invoked by the Portuguese State in its defense, but the European Commission has warned that this argument is not acceptable.
The European Court of Justice also considers that prior authorization cannot be denied on the grounds of risk to the financial balance of the Portuguese social security system. Except in urgent and exceptional cases, travel takes place mainly in border regions or for treatment of specific diseases, so this argument is not justified (CJEU; Kholl; EU:C-158/96). This position of the court is old, long before the directive under review.

**4.1 Results of research into the implementation of the Directive**

The data collected and the analysis of the European Commission's Final Report on the implementation of the 4/9/2015 Directive on Cross-Border Healthcare show:

a. Until July 1st 2015, only four infringement proceedings have been open by European Commission because of violation in the transposition of the Directive;
b. The system of prior authorisation for healthcare has been an impediment to the effective exercise of citizens' rights;
c. In fourteen Member States, the patients are unaware of which treatments are subject to prior authorisation;
d. Only seven Member States do not use the «*prior authorisation*» system;

e. Some Member States with prior authorisation systems had not received any applications for authorisation between 2012 and 2017;
f. Twenty-six Member States provided data on patient flow in 2014;
g. Of the twenty-one Member States that introduced a prior authorisation scheme only seventeen provided data on the number of applications for prior authorisation;
h. In these seventeen Member States there were five hundred and sixty applications for authorisation, of which three hundred and sixty were granted;
i. Two of these seventeen Member States did not refuse or grant a single application;
j. Two of these seventeen Member States approved only one application each;
k. Of this universe of seventeen Member States, only in two of them more than 100 applications have been submitted.

**4.2.The European Commission's Final Report 2018**

This report on the implementation of the Directive provides an overview of the data received between 2015, 2016 and 2017, and states that:

a. Six Member States do not have any prior authorisation system and, therefore, they give patients freedom of choice;
b. The system of prior authorisation should be limited to what is necessary and proportional and cannot constitute a mean of arbitrary discrimination or an unjustified obstacle to the free movement of patients;
c. In 2015 data was received from twenty-three Member States, in 2016 from twenty-eight Member States and in 2017 data was received from twenty-six Member States;
d. Aggregated data on applications for prior authorization in 2015, 2016 and 2017 show that this number remains low;
e. However, there was a steady increase and in 2017 more than twice as many applications for prior authorisation as in 2015;
f. In 2015, Member States issued around fifty-five thousand planned treatment authorizations abroad;
g. Among the three years under review, the number of claims for reimbursement was relatively low.
h. France has the highest number of patients seeking healthcare abroad;
i. Spain, Portugal and Belgium are the three countries most seeked by French citizens to receive healthcare;
a. There are a very frequent patients mobility from Denmark to Germany, mostly for dental treatments;
b. Patients from Poland usually seek healthcare in Czech Republic;
**c.** Finally, the case of patients from Norway seeking medical care in Spain still deserves reference (the reason of that demand is mostly associated to climate conditions for recovered from some diseases).

**In the end, the report conclude that:**

1st: Patient mobility is mainly based between neighboring countries, which shows that people generally prefer to receive healthcare close to home.

2nd: About half of patient mobility corresponds to movements of patients from France to neighboring countries, and the other half of this flow consists of a small number of patients traveling across the EU to receive healthcare in neighboring countries.

This evidences suggests that many patients wish to return to their birth country for healthcare.Also indicates that many patients on mobility only seek specialist skills not available in their country of origin.

**4.3. Directive impact in times of COVID 19 Pandemic in EU**

Finally, the impact of this Directive in times of Pandemic COVID 19 must be analyzed.

In this moment we have no precisious statistics to refer. But we can say that it was the first time in the EU that we saw real solidarity between border countries, using all the means at their disposal to take care of COVID patients. We can mention the help from Germany to France, with a significant number of users being transferred from France to Germany. But the most important cases of aid were mainly aid to Italy and Spain provided by several countries, especially Germany.

This research should continue to study statistics when they are available after the pandemic. Only then will we be able to assess the real impact of this directive. In any case, we have no doubt in stating right now that the Directive was fundamental to face the pandemic of COVID 19 at the most critical moments in many EU member states.

**5. CONCLUSIONS**

The Directive underlines the European Union's concern to strengthen the possibilities of access to cross-border healthcare for all, in order to promote mobility and freedom of choice for European citizens.

Close cooperation between Member States is essential, particularly in terms of reimbursement of healthcare costs incurred as a result of healthcare provided in another Member State.

## The Cross-Border Health Services Market in EU

Unless there are compelling reasons, Member States should not put obstacles in the way of the right of patients to seek medical treatment in another Member State.

This also contributes to reducing the so-called 'waiting lists', which in some Member States are significant, particularly in Portugal.

Cross-border mobility within the EU shows a slight upward trend over the years analyzed, but does not appear to be very significant.

Cross-border patient flows show a stable pattern, being mainly motivated by geographical or cultural proximity.

The figures from the reports we analyzed show that many mobile patients wish to return to their home country for care and only seek another MS for specialized skills not available in their home country.

Overall, patient mobility and the financial dimension of this mobility in the EU remain low and the Directive has not had a significant budgetary impact on the sustainability of health systems or the wellbeing of patients.

Safeguarding the quality of this type of healthcare in the EU requires a more assertive intervention by EU health regulators to increase the effective impact of the Directive.

This research shows, even without statistics available at this time, that the impact of this Directive has been and continues to be very important in tackling the pandemic of COVID 19 at the most critical moments in many EU Member States.

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