THE CROSS-BORDER HEALTHCARE AT THE EUROPEAN LEVEL: THE DIRECTIVE 2011/24/EU ON THE APPLICATION OF PATIENTS' RIGHTS

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1. Introduction: cross-border healthcare mobility, European welfare state, European citizenship.

The right to health, as a fundamental and non-compressible right, was badly affected by the economic crisis, the *welfare* crisis and austerity policies that prevent the EU Member States to guarantee patients and users the same levels of services and benefits they ensured in the past.

Despite the clear difficulty in continuing to secure the universal and solidarity values of European social protection systems, some recent measures introduced by the European legislator in the healthcare field offer a cause for serious reflection on the re-evaluation of the development of the so-called European Welfare State.

In this perspective, the right to health symbolizes the "litmus test" to understand the current role of welfare in Europe. In fact, the right to health rep-

resents both the paradigm and the prerequisite of all social rights, so that its applications can also be extended to the others, since belonging to the European community depends on the effective use of social rights and, consequently, of a social citizenship that goes beyond national borders.

The adoption by the European Parliament and the Council of the European directive 2011/24/EU of 9 March 2011, concerning the application of the patients' rights related to cross-border healthcare, is the most significant outcome of the in- depth analysis on this subject that started at a jurisprudential level beginning with the *Decker* e *Kohll* sentences in the mid-90s of the last century [1].

This directive shows how the guarantee of cross-border healthcare – and, more generally, social rights – mobility can be subject to different systems of logic: namely, on one hand, the protection of human dignity and, on the other hand, the goal of market laws implementation, sometimes strongly contrasting each other and therefore suitable to give rise to divergent results in terms of health protection and access to care.

The above-mentioned directive, as a harmonization act, represents a valuable "intrusion" by the EU law in one of the typical sectors of the social form of rule of law.

In particular, the directive aims at harmonizing the different national legislations on the right of European citizens to obtain health care in a Member

[1] The reference is to the two famous cases *Decker v. Caisse de maladie des employés privés*, 28 April 1998 (case C-120/95) and *Kohll v. Union des caisses de maladie*, 1998 (case C-158/96), within which the right to cross-border care is totally functional to the implementation of the European market and the free provision of services. In fact, we read that «articles 30 and 36 of the Treaty preclude national legislation under which a social security institution of a Member State denies the flat-rate reimbursement to an insured person for a pair of eyeglasses with prescription lenses purchased from an optician established in another Member State for the reason that the purchase of any medical product abroad must be authorised in advance. [Because] this legislation must be classified as an obstacle to the free movement of goods because it encourages the insured person to purchase the products at issue on the national territory rather than other Member States and, therefore, is liable to curb import». For the subsequent jurisprudence see also the sentence: *Vanbraekel* of 12 July 2001 (case C-368/98), *Müller-Fauré and Van Riet* 13 May 2003 (case C-385/99), *Yvonne Watts* 16 May 2006 (case C-372/04), *Stamatelaki* 19 April 2007 (Case C-444/05), *European Commission v. French Republic* 5 October 2010 (case C-512/08); *Elchinov* 5 October 2010 (case C-173/09) and the sentence *Petru* 9 October 2014 (case C-268/13). The limits and criticalities of the European jurisprudence on the point in issue were recently highlighted by T. HERVEY, *Patient mobility, Solidarity, and Equal access*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 19 ss.

State other than that of residence [2]. In this way, it supports the previous regulations on the coordination of social security systems (Regulation 883/2004/EC and the subsequent Regulation 987/2009/EC), that provide the possibility of obtaining health services in a Member State other than the one of origin, but only for workers and students temporarily abroad [3].

The directive did not replace the previous regulations, but it is placed next to it, resulting in a substantial expansion of the possibility of accessing cross-border care in Europe.

In particular, the latter exceeds the previously applicable rule of the prior authorization by the State of origin and introduces the "new" mechanism for the reimbursement of the sustained expenses: article 7 states that the Member State of affiliation ensures 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 [4].

The directive reflects the evident effort by the European Union to «open a gap in its traditional closure with respect to the guarantee of social rights» [5].

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[2] One of the most delicate problems is to guarantee drugs prescribed by the State to which one belongs, especially for vulnerable patients because they suffer from chronic diseases, rare diseases or because they reside in border towns or do not have an adequate health system.

[3] First, the system of regulations provides for a "subjective" limitation, since it is formally intended to guarantee the benefits connected with the working position of the European citizen, thus favouring more the part linked to the freedom of movement for the workers, than that of the general access to care. Secondly, Regulation 883/2004/CE is based on the mechanism of the prior authorization, by the State of origin, to obtain direct healthcare in another EU Member State. In any case, it is important to underline that, despite the obstacle of the authorisation mechanism, Regulation 883/2004/EC continues to represent one of the access routes to intra-European healthcare mobility and, indeed, the closest one to configuring a real right to receive healthcare abroad.

[4] Considering this provision about the "limit of care basket", the Italian legislator implemented the Directive with the legislative decree 38 of 4 March 2014, in which a considerable clarification was made with regards to the reimbursement issue. In fact, Article 8 of Legislative Decree 30/2014 provides that «the costs incurred by a person insured in Italy that made use of cross-border healthcare [...] are reimbursed if and to the extent that the service provided is included in the Essential Assistance Levels of which at Article 1 of Legislative Decree 502 of 30 December 1992 and following amendments».

[5] It has to be underlined the importance of this opening in light of the most recent tendency to «want to relaunch the social dimension of the Union through the use of soft law with an uncertain destiny», like the new European Pillar of Social Rights, referred to in the *Inter-institutional Proclamation on the European Pillar of Social Rights*, COM (2017) 251 final of 26 April 2017.

There is no doubt that the directive steps forward in reinforcing the guarantees of social rights in Europe. However, in spite of the recurring statements according to which equal access to medical care is an essential goal for the European integration process, the new discipline on cross-border care does not seem to allow an appropriate empowering of the right to health within the EU, especially if considered in the light of its social part. Nor can it be considered suitable to consolidate the foundations of a utopian European welfare state. Indeed, on one hand, the state level matrix of social rights is given by the principle of countries sovereignty, by the substantial equality and by the corresponding duty of solidarity that allow the redistribution inherent in social rights; instead, on the other hand, the social face of the European Union shows a different base of development: it originates from the non-discrimination principle instrumental in the realisation of the internal market, as well as, in general, the freedom of movement seems to be regulated more by hospitality than by solidarity. Consumers more than patients have a prominent role.

By the way, it should be noted that the most critical point in the concrete implementation of the Directive lies in the balance between the sustainability of financial systems and the protection of the right to health, where the satisfaction of the patient's need to seek healthcare in another Member State is likely to affect the financial, technical and human resources of the health system of the State of affiliation [6].

[6] This profile was examined by the Court of Justice in the deliberation already mentioned, relating to the *Petru* case (case C-268/2013). In particular, as was pointed out in the doctrinal context, the Court of Justice seemed to go beyond the limits set by the Directive, deriving from the "imperative reasons of general interest" to outline a "federal-like perspective" on health protection founded on the principle of subsidiarity. Therefore, the patient must always, firstly, turn to the State of residence to obtain medical treatment and then can turn to the health system of another Member State, thus obtaining the reimbursement of the costs incurred if in their own State (of affiliation) it is not possible to obtain the treatment that is needed within a reasonable time, due to occasional or structural deficiencies of the national health system. For assessments and comments on the sentence at issue, especially with reference to the repercussions of the ruling regarding the definition of concepts such as the "reasonableness of the treatment times" and "occasional or structural deficiencies of the national health systems", see: L. BUSATTA, *La cittadinanza della salute nell'Unione europea: il fenomeno della mobilità transfrontaliera dei pazienti, dalla libera circolazione alla dimensione relazionale dei diritti*, in www.dpce.it, 2015/3, 148 ss.; M. FRISCHHUT, R. LEVAGGI, *Patient mobility in the contest of austerity and an enlarged EU: the European Court of Justice's ruling in the Petru case*, in *Health policy*, 2015/119, 1293, ss.; ed A. FERRARI, *La carenza di materiali medici giustifica la possibilità di ricevere prestazioni sanitarie in un altro Stato membro: la sentenza della Corte di giustizia nel caso Petru*, in www.Eurojus.it, of 3 March 2015.

As we'll see below, one of the most problematic factors of the new discipline consists in the new mechanism of reimbursement. In fact, since the expenses to access cross-border care must necessarily be paid beforehand by those using it and reimbursed only later, this approach would seem to hinder – if not even exclude – people who have the greatest difficulties in accessing health services because they are in a not good economic condition.

These considerations would seem to be the consequence not only of the choices made by the European legislator, but also the attitude of the Member States, perhaps not fully willing to give up on margins of sovereignty in the protection of the right to health, as denoted by the telling reluctance of the Italian government to extensively implement directive 2011/24/EU (the problems of the complementary reimbursement and of the reimbursement of accommodation and travel costs are meaningful in this regard).

2. What is cross-border healthcare. The European regulatory framework.

Cross-border healthcare is an economic and social phenomenon and it needs a specific and clear set of rules.

By and large, the European Union institutions don't take direct care of social services such as healthcare, except in cases where the State organizes the social services like a business: taking into account that economic activity is defined as a production or exchange of goods and services.

The State must respect the European rules about freedom of competition and the internal market, namely: a) the four fundamental freedoms: freedom to provide services, free movement of persons, goods and capitals; b) the ban of State's aid, under which States can't help or finance their own national companies nor refinance their companies' debts.

Cross-border healthcare means healthcare provided or prescribed in a Member State other than the Member State of affiliation. The State of treatment is the Member State where healthcare is indeed provided to the patient. More generally, healthcare means 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 [7].

[7] According to Preamble to the Constitution of the World Health Organization, "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".

As regards the specific European regulatory framework, we must first consider article 168 of the Treaty on EU, from which we can infer four indications:

1. The entire political action of the EU Institutions (in all fields: e.g. customs union, monetary policy, environmental protection, energy sources, transportation, consumer protection, agriculture and fishing, etc.) is subjected to an indirect aim to protect citizen's health: in other words, there is an obligation of results;
2. The EU carries out a restricted competence directly in health matters, for example to fight the epidemics which have a transnational diffusion;
3. The assignment of promoting the cooperation between Member States is given to the EU;
4. A safeguard clause is however established to make Member States' direct and main competences untouchable: in fact, the EU respects the power of choice of each Member State about the way in which the care is organized, administered and financed.

Also, worth mentioning:

a) Article 35 Charter of Fundamental Rights, according to which everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. At the meantime, a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities;
b) Article 56 Treaty of the EU, which states that on the basis of the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended;
c) Article 20 Treaty of the EU, which establishes that the citizens of the Union shall enjoy the rights and be subject to the duties provided for in the Treaties, having, inter alia, the right to move and reside freely within the territory of the Member States.

3. The contribution of the EU Court of Justice.

On the one hand, it's important to analyze the most important judgments adopted by the EU Court of Justice about the main problematic aspects re-

lated to cross-border healthcare; on the other hand, it's useful to compare the earlier interpretations provided by the EU Court of Justice on this subject with the rules included in the following Directive 2011/24/UE.

Traditionally, the EU Court of Justice was called to check if the Members States' rules were compatible with the regulatory European framework, especially art. 56 Treaty of the EU and the Regulation 1408/71/EEC.

The first question on background regards how to conciliate the power of choice assigned to the State with the provisions of Treaty of the EU. In particular: is it important or irrelevant the way in which States organize, manage and finance the healthcare system? Is it important or irrelevant the nature, public or private, of the entities which provide health services, keeping in mind that each State organizes its own system differently (some country has a mixed system)? Is it legal the practice based on the prior authorization? Must the Members States refund all costs to the patient, including accommodation and travel costs and the excess costs?

All these problems were addressed and resolved by the Court of Justice which adopted a lot of sentences following in most cases, where possible, a substantial approach.

In general, healthcare services must be qualified as services according to the article 56 Treaty of the EU: «The freedom to provide services includes the freedom, for the recipients of services, to go to another Member State in order to receive a service there, without being obstructed by restrictions … persons receiving medical treatment are to be regarded as recipients of services» [8].

Furthermore, discrimination related to the place where the treatment is administered isn't allowed: «The dispute before the national court concerns treatment provided by an orthodontist established in another Member State, outside any hospital infrastructure. That service, provided for remuneration, must be regarded as a service within the meaning of Article 60 of the Treaty, which expressly refers to activities of the professions» [9].

In other words, the Court clarified that the place of healthcare is irrelevant.

In the same way, it is irrelevant the way in which the two States (State of affiliation and State of treatment) manage the methods of administering: one of them provides for benefits in kind, and the other one provides for a reimbursement of the costs of the treatment [10].

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[8] Justice Court, judgment 31.1.1984, C-286/82 e 26/83, Luisi and Carbone, point 16.

[9] Justice Court, judgment 28.4.1998, C-158/96, Kohll, point 29.

[10] «With regard more particularly to the argument that hospital services provided in the

4. The crux of the prior authorization.

The central issue in CJEU rulings is the prior authorisation requirement, which is conditional for reimbursement of health care provided abroad, restricts free movement of patients and health services [11].

After all, the key issue in negotiations for the adoption of the directive within and between the EU legislative institutions concerned prior authorization [12].

The Court of Justice pointed out the conditions under which the provision of a prior authorization by the Member States is legal: 1) the States' power of choice must be adequately circumscribed; 2) a list of the types of treatment that States guarantee and finance needs to be predetermined [13].

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context of a sickness insurance scheme providing benefits in kind, such as that governed by the ZFW, should not be classified as services within the meaning of Article 60 of the Treaty, it should be noted that, far from falling under such a scheme, the medical treatment at issue in the main proceedings, which was provided in Member States other than those in which the persons concerned were insured, did lead to the establishments providing the treatment being paid directly by the patients. It must be accepted that a medical service provided in one Member State and paid for by the patient should not cease to fall within the scope of the freedom to provide services guaranteed by the Treaty merely because reimbursement of the costs of the treatment involved is applied for under another Member State's sickness insurance legislation which is essentially of the type which provides for benefits in kind. Furthermore, the fact that hospital medical treatment is financed directly by the sickness insurance funds on the basis of agreements and pre-set scales of fees is not in any event such as to remove such treatment from the sphere of services within the meaning of Article 60 of the Treaty» (Justice Court, judgment 12.7.2001, C-157/99, Smits and Peerbooms, points 55 e 56).

[11] *See* A. DEN EXTER, *Introduction: patient mobility after the* Decker & Kohll *rulings*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 1.

[12] *See* D. SINDBJERG MARTINSEN, *The politics of the Cross-Border Care Directive*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 5.

[13] «It likewise follows from settled case-law that a scheme of prior authorisation cannot legitimize discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings (see, to that effect, Joined Cases C-358/93 and C-416/93 *Bordessa and Others* [1995] ECR I-361, paragraph 25; Joined Cases C-163/94, C-165/94 and C-250/94 *Sanz de Lera and Others* [1995] ECR I-4821, paragraphs 23 to 28, and Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 37). Therefore, in order for a prior administrative authorisation scheme to be justified even though it derogates from such a fundamental freedom, it must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circum-

Other aspects about authorization were made clear by the same Court: the authorities must carry out an objective medical assessment of the patient's medical condition and they can't justify the refusal of the authorization on: a) the existence of a waiting list; or b) a distorted order of priorities in giving treatment; or c) the fact that the treatment is administered as free of charge in the State of affiliation; or d) an obligation to make available specific funds; or e) a comparison between the cost of that treatment in two different States [14].

The "medical necessity" test is designed to secure equal access to health services on the basis of medical need if the treatment cannot be provided effectively in the country of residence. Moreover, authorization shall be granted in any event when treatment cannot be provided without undue delay.

In this way, the Court's rulings opened a fierce debate touching the heart of health care policy making, namely the organisation and financing of

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scribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (*Analir and Others*, paragraph 38). Such a prior administrative authorisation scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings. The actual system of sickness insurance laid down by the ZFW is not based on a pre-established list of types of treatment issued by the national authorities for which payment will be guaranteed. The Netherlands legislature has enacted a general rule under which the costs of medical treatment will be assumed provided that the treatment is 'normal in the professional circles concerned'. It has therefore left it to the sickness insurance funds, acting where necessary under the supervision of the Ziekenfondsraad and the courts, to determine the types of treatment which actually satisfy that condition» (judgment Smits and Peerbooms, paras 90 e 91).

[14] «A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed. Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State» (Justice Court, judgment 16.5.2006, C-372/04, Watts, point 123).

health care [15]. Therefore, the authorization, as an exception from the general rule, must be justifiable: e.g. when treatments are defined as 'highly specialized' or 'cost-intensive', if included on a specific list, and there is an evidence that outflow of patients would seriously undermine the State financial balance, planning, or rationalization of the hospital sector [16].

In other words, in those judgements prior authorization came up for legal challenged, accused to be in breach with EU law and the free movement principles of the internal market [17]. It is against this judicial background, the policy-making process of the cross-border care directive kicks off [18].

5. The problem of reimbursement ceiling.

Regarding the reimbursement, rules designed to protect the financial bal-

[15] *See* A. DEN EXTER, *Introduction: patient mobility after the* Decker & Kohll *rulings*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 1.

[16] The proof must be provided case-by-case: in this perspective, the EU Court of Justice stated that a single patient seeking to receive cross-border dental services does not jeopardise the financial arrangements of Luxembourg's system sufficiently to constitute a reason to restrict free movement (Kohll ruling, para 42). Rules designed to protect the financial balance of social security systems are instead allowed: rules determining the 'basket of care' covered by a national health system are permissible (Case C-173/09 *Elchinov*; Case C-187/80 *Petru*); arrangements for expensive medical equipment are also permissible (Case C-255/09 *Commission v Portugal*). As we see below, pursuant to Article 8 Directive 2011/24/UE, Member States may provide a system of prior authorisation of reimbursement of costs of cross-border health care where planification, cost control, and the need to avoid waste of 'financial, technical and human resources' to secure 'sufficient and permanent access to a balanced range of high quality treatment' necessitate it, if the health care concerns either over-night hospital treatment, or use of cost-intensive medical infrastructure.

[17] The conflict between prior authorization and freedom to provide services has been clearly pointed out by the European Court in Kholl ruling (paras 34 e 35): «while the national rules at issue in the main proceedings do not deprive insured persons of the possibility of approaching a provider of services established in another Member State, they do nevertheless make reimbursement of the costs incurred in that Member State subject to prior authorisation, and deny such reimbursement to insured persons who have not obtained that authorisation. Costs incurred in the State of insurance are not, however, subject to that authorisation. Consequently, such rules deter insured persons from approaching providers of medical services established in another Member State and constitute, for them and their patients, a barrier to freedom to provide services».

[18] *See* D. SINDBJERG MARTINSEN, *The politics of the Cross-Border Care Directive*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 6.

ance of social security systems are permissible as well. In general, reimbursement rules that limit the amount to be reimbursed to mobile patients to the level of reimbursement that would be received if the patient had received the service in the home Member State, are permissible [19].

Nevertheless, the Court resolved some other specific issues.

Which legislation must be applied to quantify the costs of reimbursement? Is it a legal practice, according to the Treaty of the EU, when in another Member State the patient gets a lower refund compared to the level of coverage ensured in the State of residence?

In an important sentence it was clarified that if a patient has less coverage in the host State that in his own, he would be discourage from seeking treatment abroad: hence, it must be avoided that the disparity in costs becomes a barrier to crossborder healthcare [20].

And what happens when for the same treatment the costs in the host Member State are higher than in the State of residence? Is the patient entitled to have the entire reimbursement? Taking into account the usual sequence of steps, where at the beginning the patient receives the preliminary authorization from his public authorities while the problems of the costs and related reimbursement will rise in a later date. In fact, the patient is basically interested in going abroad for treatment without considering the economic question, also because the foreign fares not always are known beforehand. Therefore, the difference in costs will be discovered by the same patient during the treatment abroad and the amount of the refund is decided on by the home authorities at the end of the care.

The Court's verdict is clear: in such a case, the patient is not required to make any financial contribution to the cost of that treatment. He is entitled to have the cost of that treatment reimbursed in full pursuant to the provisions of the legislation of the host Member State [21].

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[19] Case C-211/08, *Commission v Spain*.

[20] «The costs must be quantified in accordance with the provisions of the legislation of the State in which the benefits are provided, as if the covered person were insured in that State. There is no doubt that the fact that a person has a lower level of coverage when he receives hospital treatment in another Member State than where he undergoes the same treatment in the Member State in which he is insured may deter, or even prevent, that person from applying to providers of medical services established in other Member States and constitutes, both for insured persons and for service providers, a barrier to freedom to provide services» (Justice Court, judgment 12.7.2001, C-368/98, Vanbraekel, points 32 and 45).

[21] «In the context of national rules which provide that hospital treatment in establishments belonging to the national health service instituted by those rules is to be free of

In closing, what about the accommodation and travel costs? Is the patient entitled to be refunded? The Court's position is also clear with regard to this aspect: «The obligation imposed on the competent institution ex art. 22 Reg. EU relates exclusively to the expenditure connected with the healthcare received by the insured person in the host Member State, which includes the costs of medical services strictly defined and the inextricably linked costs relating to stay and meals in the hospital» [22].

6. The present framework: the reimbursement of costs according to the Directive 2011/24.

As noted above, the directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross border healthcare replaces the previous EC Regulations (1408/71/EEC and 883/2004/EC) for specific sectors (social security) or categories of persons (e.g. workers).

According to the same Directive, the basic sequence is: European citizenship → freedom of movement → increase in the level of health.

The principle of freedom is the fundamental premise: in accordance with Article 7, par. 8, the Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorization except in the cases set out in Article 8.

The aim of the new rules is to reduce or overcome the patient's natural resistance to go in another Member State due to several causes, namely: the costs of treatment, accommodation and travel; the sense of belonging to his or her own country; the knowledge of only one's own healthcare system; the lack of information about the specific characteristics of treatments provided in other Member States [23]; the linguistic barrier; the proximity between hospital and patient's and his family's house.

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charge, it must be found that there is no restriction of the freedom to provide services where the patient registered with that service, who was authorized to receive hospital treatment in another Member State pursuant to Article 22(1)(c)(i) of Regulation No 1408/71 or who received a refusal to authorize subsequently held to be unfounded, will be reimbursed for all the costs provided by the legislation of the host Member State» (judgment Watts, point 130).

[22] Justice Court, judgment 16 June 2006, C-466/04, Herrera, point 28.

[23] In *Smits* and *Peerbooms* CJEU case, quality of care is considered one of the barriers to patient mobility. About that, M. FRISCHHUT, *Standards on quality and safety in cross-border healthcare*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*,

In other words, there are many economic, social and cultural factors that push the patient to renounce seeking healthcare abroad.

After all, it's meaningful that currently planned cross-border healthcare is much less developed than unscheduled and unexpected cross-border healthcare (e.g. urgent treatment given abroad to the tourists).

Article 7 of the Directive fixes some important points:

a) Each Member State has a discretional power to establish the level of financing nationally as much as cross-border healthcare: it is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided;

b) Only the actual costs of healthcare received can be refunded: 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: from this point of view, the Directive appears to conflict with the EU Justice Court's case law according to which the costs of treatment must be reimbursed in full (mentioned judgment Watts);

c) This rule allows waivers: where the full cost 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;

d) There are some rigorous conditions under which the State could refund other costs (accommodation and travel costs or extra costs which persons with disabilities might incur): 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 the condition that there be sufficient documentation setting out these costs;

e) The criteria to calculate the costs have to be suitable: Member States

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2017, Erasmus University Press, Rotterdam, 60, noticed that quality of care can also be a barrier, for instance if a patient does not get reimbursement of costs of treatment in another Member State of the European Union, based on the argument that the Member State of affiliation considers the therapy used in the Member State of treatment as being experimental, and thus "not regarded as normal within the professional circles concerned".

shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level:

f) Principle of mutual recognition: Member States may adopt provisions in accordance with the Treaty on EU 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. Pursuant Article 11, the same principle is implemented for the prescriptions dispensed in another Member State [24]: mutual recognition of cross-border prescriptions aims to improve patients' access to medicines abroad and also facilitates co-operation initiatives on eHealth. As noted [25], reading the patient's history in his/her electronic health record or patient's summary record (country of origin) allows the physician in the Member State of treatment to continue medical treatment without duplicating all kinds of – expensive – diagnostic tests, treatment methods and thus to ensure continuity of care, increase efficiency and save costs. Facilitating cross-border access of electronic health records/patient summary records by both the treating physician and the patient, is therefore a key element in realising cross-border care. Nevertheless, numerous obstacles, some of which are legal, to this exchange of information hamper the deployment of eHealth on a large scale. Among these, the issue consisting in patients' personal data protection must be mentioned, taking into account that «the right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patients' health. These personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded» (Whereas 25 of directive 2011/24/EU) [26].

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[24] *See* J. CAYÓN DE LAS CUEVAS, *Mutual recognition of cross-border prescriptions at EU level: concerns and challenges*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 117. About ethical implications *see* T. FRISCHHUT, *The Ethical Spirit of EU Law*, Springer, Cham, Switzerland, 2019, 75.

[25] *See* A. DEN EXTER, *e-Health challenges under EU law*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 106.

[26] According to Whereas 35 of General Data Protection Regulation EU 2016/679 of 27 April 2016, «personal data concerning health should include all data pertaining to the health

7. The main provisions of the Directive 2011/24: the limits to the prior authorization.

The State's choice to request a prior authorization is allowed only for the purpose of respecting the budget and consequently ensuring all citizens a good level of health protection. In particular, healthcare that may be subject to prior authorization shall be limited to healthcare which is made subject to planning requirements relating to: a) the goal of ensuring sufficient and continual access to a balanced range of high-quality treatment in the Member State; or b) the control of costs avoiding, as far as possible, any waste of financial, technical and human resources. Furthermore, the care must involve overnight hospital accommodation of the patient in question for at least one night and must require use of highly specialized and cost-intensive medical infrastructure or medical equipment (Article 8, par. 2, lett. a).

Availability and time are the only two factors that may justify the refusal of authorization. In fact, the Member State of affiliation may refuse to grant prior authorization for the following reason: this healthcare can be provided on its territory within a time limit which is medically justifiable, considering the current state of health and the probable course of the illness of each patient concerned (Article 8, par. 6, lett. d).

Ultimately, it's clear that the refusal of authorization for reimbursement of health care services abroad costs is considered an important barrier to free movement. This is even more the case when the claimed service is covered by the patient's NHS. The justification of refusal can be based on the general or public interest argument raised in social security issues, i.e. the risk of uncontrolled health expenditure. In fact, although purely economic reasons cannot justify any restriction of the fundamental freedoms, in *Kohll*

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status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test». On this topic, *see* J. HERVEG, *Data protection and patient mobility in Europe*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 191.

CJEU ruling the Court accepted the argument that 'the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest' justifying such a barrier (para 41) [27].

8. The main provisions of the Directive 2011/24: the administrative procedures regarding cross-border healthcare.

Pursuant Article 9, the rules and criteria of the procedure are of great importance.

On one hand, the Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved. In other words, Member States has to respect basic legal principles [28].

On the other hand, Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and made public in advance. When considering a request for cross-border healthcare, Member States shall take into account the specific medical condition and the urgency and individual circumstances. The obligation to justify the way in which patient's request is approved or refused and the obligation to make an appropriate set of remedies available for patients are essential too: Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are reasonable and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

Thus, the member State of affiliation is obliged to have "publicly available" information regarding administrative procedures concerning prior authorisation. Article 9 is partly requiring some procedures to exist and is

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[27] *See* A. DEN EXTER, *Cross-border reproductive care: Low expectations from European (Union) law*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 147.

[28] *See* A. SANTUARI, *Patient mobility and Health SPAs in the EU: legal implications and future challenges for patients and users*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 131.

partly setting quality standard for the procedures [29].

As noted [30], one of the hoped-for outcomes from the directive and the CJEU's case law relates to its obligations to provide procedural entitlements and information to patients. Article 9 entitles patients to individual, timely, transparent, and judicially reviewable decision on whether they may receive cross-border health services that are paid for by their home health system. Through its transparency rules, the directive may *indirectly* to increased awareness of poor-quality health services, or unsafe health care practices.

9. The main provisions of the Directive 2011/24: the national contact points for cross-border healthcare.

It was clear in the preparation of the directive in order to facilitate cross-border care for patients, not only reimbursement questions needed to be addressed but also the availability of information about other non-financial issues surrounding the enjoyment of care in another Member State needed to be improved. On these grounds, cooperation became integral to the design of the Directive to addressing "flanking measures" to create trust for patients. The information duty covers various aspects of relevant information, transparency about quality and safety standards, facilitation of continuity of care, and knowledge about mechanisms for redress and compensation in the case of harm [31].

Article 6 of the directive requires the obligation for the Member States to establish one or more National Contact Point-NCP; moreover, specific relationships must be developed with stakeholders. In particular, each Member State shall designate one or more NCP for cross-border healthcare and communicate their names and contact details to the EU Commission. The Commission and the Member States shall make this information publicly availa-

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[29] The wording of the provision is expressing well accepted principles of administrative law: *see* K. HARALD SØVIG, *Convergence and divergence in patients' rights*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 43.

[30] *See* T. HERVEY, *Patient Mobility, Solidarity, and Equal access*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 32.

[31] *See* T. CLEMENS, *Information for patients and health system cooperation by means of the National Contact Points for cross-border healthcare*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 89.

ble. Member States shall ensure that the NCP consult with patient organizations, healthcare providers and healthcare insurers.

As regards the role and the functions of National Contact Points – NCP, they shall facilitate the exchange of information referred to in paragraph 3 and shall cooperate closely with each other and with the Commission. Furthermore, the homeland contact point provide patients on request with contact details of NCP in other Member States.

The kind of information that NCP must give to the patients are significant too. In fact, to enable patients to make use of their rights in relation to cross-border healthcare, NCP in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including any possible harm arising from cross-border healthcare.

The two goals of NCP for information and collaboration are aimed to help patients in order to make decisions about various aspects of their healthcare.

The provisions in directive specify responsibilities for Member States in three areas: a) on the setup and establishment of its own NCP, including design and functions; b) on information to be provided, distinguished for Member States of treatment and Member States of affiliation; c) for cooperation with relevant stakeholders and among NCPs themselves.

It has been proposed to extend the NCPs' functions [32]. These bodies, designed to be the information portal for own citizens and patients from other Member States seeking care abroad, could potentially benefit domestic patients in general as well by pooling and presenting information in an understandable way about patients' rights in the home country's health system. Moving beyond the function of an information portal to patients, NCPs could act as the communication hub for professionals and decision makers to provide detailed insights into national practices across the border. To facilitate a fruitful cooperation could benefit the smooth operation of cross-border care and domestic health systems in the EU in general.

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[32] *See* T. CLEMENS, *Information for patients and health system cooperation by means of the National Contact Points for cross-border healthcare*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 101.

10. Conclusions.

The EU directive in issue deserves a high and low judgment.

It has been adopted late by many Member States and, in some cases, it hasn't been adopted yet.

Apart from this aspect, national systems are proceeding slowly: only some working groups were formed to develop guidelines; national contact points and other cooperation tools still have to be implemented; the measures aimed to establish list of treatments for which payment will be guaranteed by the State were often not adopted by public authorities in charge.

Statistic is eloquent. The number of citizens claiming reimbursement for medical care received abroad under the Directive is low (approximately 200 000 claims a year – fewer than 0.05 % of EU citizens) compared to those making use of the Regulation on the coordination of social security systems (approximately 2 million claims a year for unplanned treatments abroad).

Member States have too wide discretion in granting or denying prior authorization to reimbursement. Too much bureaucracy in administrative proceedings, long lead times and a defensive approach by States to protect financial and budgetary balances are not very encouraging figures.

Then, costs are a strong barrier to patients' rights implementation. And the requirement for upfront payment by patients, while intrinsic to the design of the Directive, is widely recognised as a significant challenge that patients face.

Complexity of the procedures and uncertainty about the reimbursement are held as a deterrent against patients' cross-border mobility. It's not easy for patients to calculate in advance the costs for their medical mobility, given that in each country rates and criteria for expenses contribution are different. Moreover, the single State may decide to reimburse the supplementary costs, namely costs not strictly related to medical care.

Other different fences can be listed: 1) no suitable treatment should be available as an alternative for the patient in a reasonable time; 2) services provided abroad can be reimbursed only if and to the extent that they are included in the national basket of care (basic healthcare levels); 3) the treatment required must be evidence-based; 4) temporal continuity in the cares and urgent medical needs are for patients preconditions useful to be authorized.

In turn, the EU Commission, currently hardworking in this field, will have to do more as well.

The launch of the European Reference Networks is an ambitious innova-

tion in cross-border healthcare cooperation, particularly as healthcare is a Member State competence. Nevertheless, EU Commission could assess the results achieved for cross-border exchanges of health data via EU-wide eHealth Infrastructure (for ePrescriptions and Electronic Patients Summaries). Furthermore, it should provide more support for National Contact Point along three lines: a) building on former actions, support the work of National Contact Points, including on how best to communicate the relationship between the Cross-border Healthcare Directive and the Social Security Coordination Regulation pathways; b) provide guidance on presenting information about European Reference Networks on the National Contact Points websites, in particular with regard to rare disease strategy [33].

The adoption and the implementation of good and clear guidelines is essential in order to increase the performance of the National Contact Points. Furthermore, it's necessary to involve, inform and consult all stakeholders (patients, providers and insurance companies).

Other important goals are: to create a core of information available to patients; to realize good practices of cooperation between the Member States; to build a solid network among the health structures operating in the Member States.

The knowledge of migratory reasons, at the same time, can allow the State of origin to better organize the exit of patients seeking treatment in another State of destination to structure and improve the offer to make it more competitive with a view to increase the level of competition and efficiency of the system and, consequently, to decrease the need for patients to seek care abroad.

As noted, EU patient mobility law moves national health systems away from collective welfare-based approaches, towards an individual rights approach. For this reason, equal access according to professionally determined medical need is unlikely to be secured. Moreover, too strong a 'health rights' basis of EU law entitlements to patient mobility would result in political and administrative chaos, as individual legal claims to particular health services were pursued. Member States would struggle to provide equivalent entitlements to all, including those who do not move to another Member State to receive health services: that being able to determine a downward pressure on the more generous Member States and, ultimately, a lowering of standards overall (a sort of 'regulatory race to the bottom'). Consequently, according

[33] *See* European Court of Auditors, *Special Report on "EU actions for cross-border healthcare: significant ambitions but improved management required"*, Luxembourg, 2019.

to this critical interpretation, «the best way to understand the relationships between patient mobility, equal access to health care, and solidarity is that they are not directly related in a significant way» [34].

Patients' mobility is just one of the dimensions of healthcare mobility, which also includes: a) the provision of services from one Member State within the boundaries of another Member State (telemedicine, remote diagnosis and prescriptions, laboratory services); b) the fact that companies provide health services within territories of another EU country; c) the mobility of professionals. These areas include admissions to the hospitals, specialist cares, spa treatments, medical transportations, basic medicine and pharmaceuticals.

Getting healthcare in one's country and near their family is surely better for patients; nevertheless, they could prefer to seek treatment abroad in the following cases [35]:

✓ for highly specialized care that requires so many resources and expertise that goes beyond the possibilities of a single State;
✓ for rare diseases;
✓ for citizens residing in border regions where the nearest hospital could be on the other State and nursing populations of both two countries be efficient;
✓ because of inability of their own local health services or higher costs compared to providers in other countries;
✓ due to personal choices that lead European citizens to work, study or live in other member countries.

Consequently, it's possible to recognize different types of patient who resort to seeking healthcare from other Countries. This list includes: tourists; pensioners who move to another State with lower taxation; foreign students; citizens who prefer the better treatment provided abroad and therefore ask for authorizations; citizens who have cultural or linguistic links with countries where they go to be treated.

In this framework the following aspects are to be considered fundamental:

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[34] *See* T. HERVEY, *Patient Mobility, Solidarity, and Equal access*, in A. DEN EXTER (edited), *Cross-border health care and European Union law*, 2017, Erasmus University Press, Rotterdam, 33.

[35] *See* Impact Assessment of the 2011/24/EU directive: http://ec.europa.eu/health-eu/doc/commsec_20082163_en.pdf.

✓ the competition between Member States healthcare systems in order to increase their complementarity and homogeneity in the respective efficiency level;

✓ the subsidiary function of cross-border healthcare compared to national healthcare, which remains the priority choice, considering that each country establishes recipients, qualified operators, basket of cares and financial coverage;

✓ the cooperation between Member States, given that the only EU principle of subsidiarity is not enough;

✓ patients' legitimate expectations of good healthcare organization in EU countries in order to better satisfy their right of access to treatments;

✓ States responsibility for citizen's trust in their organizational set-up;

✓ coordination of States' initiatives and EU actions based on art. 114, paragraph 1, TFEU and not on art. 168 (although it has indirect effects on the latter).

After all, the purpose of the directive is not and could not be that to encourage European patients' mobility by overlapping the States jurisdictions in managing national healthcare systems. The goal isn't to introduce additional services and higher costs at the expense of the State of residence; rather, the aim is to enhance the added value of the European dimension of health policy by integrating and improving, according to a consumer model, the organizational competence of the States in health services supply and provision, in order to make the European citizens' access to care more informed and less discriminatory, in accordance with provisions of Article 35 of the Charter of Fundamental Rights of the European Union.

In other words, the harmonizing European act in issue is justified by the dimension and the effects of the action to be carried out, given that the lack of a support from European Union would undermine the efficiency and safety of the healthcare at European level. Therefore, the directive aims to eliminate the regulatory uncertainties that would affect the competitiveness of the EU. The uniformity of healthcare and pharmaceutical procedures facilitates the improvement of organizational standards and increases the level of competition between Member States, that patients evaluate by exercising their freedom of choice of cares and professionals.

In conclusion, the basis for regulating patients' mobility rights at European level is Article 52, more than Article 168, TFEU: considering that the Member States' competence to arrange, manage and freely finance their social and healthcare systems doesn't remove the duty for them to respect the

principles on fundamental freedoms established by the European Treaty.

Articles 52 and 168 represent two different but at the meantime accessory perspectives: Article 52 exceeds the limits of Article 168 and makes the opportunities of health protection grow, considering that patients take advantage of the transition from the social law side, referring to the "patient-citizen", to the fundamental freedoms' level, referring to the "patient-consumer" instead [36].

This transition can be described as follows: from the positive limit (what the States can do in the organization of their healthcare services, according to Article 168) to the negative limit (what the States cannot do in the management of their healthcare services, according to Article 52).

In this way, the user becomes a "tool for European legal integration in the field of health policy" [37].

The rules on cross-border healthcare aspire to put European systems into virtuous competition by raising the general level of care efficiency and promoting the freedom to choose the most effective "place of care" by the European citizens, patients and consumers.

In practice, the inefficient State cannot deny the patient to go abroad to obtain the same treatment he would have received on the national territory if his or her healthcare system had been efficiently organized and managed. States may only complain about an uncontrolled effect of demand for cross-border care, demonstrating that the generalized opening could result in a prejudice to public health in terms of unsustainable social expenditure and subsequent risk of breaking the financial balance. In fact, in that case the objective to maintain a balanced medical-hospital service accessible to all would be jeopardized.

Member States remain the keystone in the regulating system insofar they subordinate the patient's mobility rights to the same national conditions for enjoying the right of health. However, the only freedom to organize healthcare service can not constitute an overriding reason of public interest: on the contrary, to refuse the reimbursement State must demonstrate that it's necessary to respect the budget constraints if a good organization of healthcare is

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[36] *See* A. ERRANTE PARRINO, *La consumerizzazione del paziente 2011/24 sull'assistenza sanitaria transfrontaliera*, in *Europa e diritto privato*, 2017, 329.

[37] *See* C. COLAPIETRO, *I diritti sociali oltre lo Stato. Il caso dell'assistenza sanitaria transfrontaliera*, in *Costituzionalismo.it*, 2018, no. 2, 45; D. MORANA (ed.), *Cross-border Healthcare in EU: towards a European Welfare State?*, Edizioni Scientifiche Italiane, Napoli, 2018.

demonstrable as well: emblematic is, in this perspective, the case of waiting lists [38].

The current rather minimalistic implementation of the NCPs in many countries is not facilitating objectives pursued by the directive [39]. More in general, the directive has only in part implemented the CJEU interpretations while Member States have often adopted a regrettable approach that resizes both the CJUE rulings and the directive provisions.

[38] *See* L. KLESTA, *L'assistenza sanitaria transfrontaliera*, in *Nuove leggi civili commentate*, 2014, 729.

[39] *See* G. BOGGERO, *Gli ostacoli alla mobilità sanitaria transfrontaliera in Italia*, in *Corti supreme e salute*, 2018, 2.

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