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THE EXPANSION OF PATIENTS' RIGHTS IN EUROPE: A NEW PERSPECTIVE FOR HEALTHCARE ABROAD

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Abstract: *This article aims to reflect on the enlargement of patients' rights in Europe and the future effects of the application of the provisions of EU Directive 2011/24 on cross-border healthcare. These new rules, in fact, if properly implemented, could contribute to a more responsible management of health care, to counter the inefficiency of the health facilities, to contain the phenomenon of waiting lists and to allow a more concrete freedom of care. But they can fully achieve their goal only if really allowing all patients (regardless of income level, social standing, etc.) to be able to enjoy their effects.*

Key words: *patients' rights, cross border healthcare, effectiveness of treatment, networks of healthcare providers.*

1. Cross-border health care and the expansion of patients' rights

It is well known that, generally, people prefer to receive medical care and/ or health services near the place of residence. But there are certain circumstances in which it is possible for patients to draw benefits in using healthcare services elsewhere than the place where they usually live: not only in the event that the closest health center is across the border, but especially when you want to treat yourself in a center of excellence or when health treatments can be delivered faster. It is no coincidence, therefore, if for long time the Court of Justice has been facing the issue of healthcare abroad, by focusing - in particular - on the relationship between the right to movement of citizens and protection of the right to health [1]. It is hardly necessary to emphasize that the opening of borders to patients, although conceived according to market logic, is a reinforcement of the protection to health, as it strengthens the possibility of choosing the types of services and providers.

However, it is clear that the movement of patients, if it is not supported by sufficient resources, takes a very *elitist connotation* [2]: that's why the Court of Justice has immediately tried to identify the legal basis of reference relating to the financial support for treatment abroad, to the type of healthcare which can be redeemed and to conditions of reimbursement. In its judgments, the Court has enunciated principles that have been calling into question some of the assumptions underlying state of social

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protection systems, thereby considerably expanding the rights of European patients. In particular, it has switched from allowing patients to receive a reimbursement subject to obtaining an authorization from the health authorities of the state of origin of the patient, to the finding that the requirement of the authorization should not be an obstacle to the freedom to provide services [3]. In practice, over twenty years (thanks to the application of article 22 of Regulation EEC n. 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed and to members of their families moving within the Community), patients began enjoying the possibility of receiving treatment provided in another Member State, even outside of the margins provided for by Community legislation, except for hospital care [4]. For the latter, however, in accordance with the principle of proportionality, the Court has redefined the framework within which the authorization may be granted: namely, the authorization for hospital care cannot depend on the discretion of the national authorities but must refer to (international) requirements of objectivity established in relation to the type of refundable healthcare. The Court does not fail to introduce immediately a further theme that is bound to give rise to important developments in the future as well: the timeliness of treatment and therefore the importance of the time factor in the assessment of the need of treatment for which authorization is requested. In other words, the authorization is due when the treatment required, although expected in national hospitals affiliated, is not available within the time required by the clinical condition of the patient and by his antecedents [5]. You could note that, in this way, the interpretation of the rules on free movement of services (medical care) and people (patients) pushes in some way health services towards efficiency: this is because the state of origin is more likely to grant a higher amount for reimbursement (healthcare to be refunded are higher) than to obtain an economic advantage caused by the failure to provide healthcare for a citizen (or because treatments to be redeemed are lower). In the first place, in fact, the principle of fully refunding the costs of health treatments incurred abroad also applies when they are more expensive than domestic ones; secondly, the fact that the state of origin is obliged to grant to his patient the 'amount of health treatment costs incurred abroad does not subtract this state from supporting certain expenses for the maintenance of their hospitals. We agree, therefore, with those who have noted that the state of origin may be found actually having to pay - because of its inefficiency - twice for the same patient, with the perverse effect of undermining the financial balance [6]. Consequently, just the fear of negative effects on government finances has affected in later years the development of common rules on cross-border care.

The Court of Justice has sought to emphasize that, in assessing the conditions for granting an authorization for treatment abroad, considerations relating to excessively long waiting times, that may jeopardize the effectiveness of healthcare, must be accepted [7].

The argument at stake has become a central one when art. 22 of Regulation 1408/71 was changed, by providing for the obligation to grant an authorization if the treatment cannot be practiced in the state of origin “within a time frame which is medically acceptable”: although a system of waiting lists remains acceptable, this cannot come at the expense of the effectiveness of patient care [8]. A new balance is therefore

required between organizational and financial needs of the State and individual rights of citizens: in other words, economic and organizational needs can be taken into account if they are not detrimental to the patient. In essence, what the new rules want to ensure is the high quality of health services for patients: the issue is of primary importance, that's why the right to healthcare is recognized by the Charter of Fundamental Rights of European Union (art. 35 "Health care"). By now, in fact, health care systems and related policies of the Member States are increasingly interconnected and this is due to the movement of patients and professionals, as well as to the diffusion of new medical and software technologies.

The increased interconnections, however, amplify certain issues of health policy: the request for information for patients; the quality and access to medical treatment; background of professionals; health cooperation, harmonization of rules, etc. To this aim, by the time the European Commission has invited healthcare Ministers of the Member States and representatives of civil society to take part in a process of reflection on patient mobility and the development of the health system in Europe [9].

Following this consultation, in July 2004, the Commission entrusted a High Level Group the task of verifying the practical implementation of a Directive on collaboration between national health systems in the EU. On July 2008, it prepared a proposal for a directive on cross-border healthcare to provide a Community framework on patient mobility: common principles for all health systems of the Member States, specific rules for cross-border healthcare, cooperation among healthcare systems, taking into account the cases law of the Court of Justice. The idea behind the proposal was to enable European citizens to obtain health care in other Member States with a reimbursement of costs, without prior authorization in the event of non-hospital healthcare and with prior approval in case of hospital and specialized healthcare. The proposal also provided for: the recognition of prescriptions issued in another Member State, the development of European networks of healthcare providers, the realization of e-Health systems (e-Health) and a stronger cooperation on management of new technologies in health. The main aim of the proposal was to allow a patient not to suffer the consequences of a poorly working healthcare system, giving him a chance to go to a country where he believes there are better conditions.

The effects of such legislation, however, can have a strong impact on healthcare costs in each Member States and that's why these new rules continued to be postponed for a long time: the fear for an increase in large-scale of "health tourism" was great, and the proposal was hampered mainly by countries with less efficient healthcare systems or where there are long waiting lists in many areas.

2. The new European rules on cross-border healthcare

We can try below to highlight the main features of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 [10]: this Directive should have been transposed by 25 October 2013. The rules approved are mainly aimed at establishing a general framework to clarify patients' rights in relation to their access to cross-border healthcare and to have reimbursement of healthcare; the rules want to ensure the quality and safety of healthcare benefits provided in another EU Country and to

promote cooperation on healthcare among Member States. Each Member State of affiliation (i.e. a Member State competent to grant the insured person a prior authorization to receive appropriate treatment outside the Member State of residence) must designate one or more national contact points (NCPs) for cross border healthcare. These contact points (which shall consult with organizations of patients, health care providers and health insurance) have the task of providing patients with information about their rights when they decide to benefit cross-border healthcare, as well as the details of national contact points in other Member States (art. 5). The Member State of treatment (i.e. the Member State on whose territory healthcare is actually provided to the patient) organizes and provides healthcare, ensuring compliance with the rules concerning quality and safety in the provision of healthcare, especially thanks to the adoption of control mechanisms.

It also guarantees respect for the protection of personal data and the equal treatment of patients from other Member States. After the assistance, right the Member State of affiliation has to take charge of the reimbursement for the patient, provided that the treatment received falls within the list of reimbursable healthcare costs under the national legislation: more specifically, the Member State of affiliation shall ensure that the costs sustained by an insured person who receives cross-border healthcare are reimbursed, provided of course that person is entitled to that assistance (art. 7). The amount of the refund is equal to the amount that would be reimbursed by the social security, if the healthcare had been provided on the territory of origin of the patient. The amount should not exceed the actual costs of healthcare received. Anyway the Member State of affiliation has the possibility of reimbursing other related costs, such as travel or accommodation costs.

For coverage of a certain cross-border healthcare, the State of affiliation may provide for a system of prior authorization in order to avoid the risk of destabilizing the planning and/or financing of its healthcare system; however such authorization should systematically granted when the patient is entitled to the healthcare at issue and at the same time when such assistance cannot be provided on its territory within a time limit which is medically justifiable. By contrast, the State of affiliation may refuse to grant prior authorization to the patient for specific reasons (indicated in the Directive). If a patient asks for prior authorization and the conditions are satisfied, the authorization shall be granted in accordance with Regulation n. 883/2004 on the coordination of social security systems [11], unless the patient requests that the authorization be handled within the framework of this Directive.

Administrative procedures relating to the provision of healthcare must be necessary and proportionate; these procedures shall be implemented in a transparent manner, within the deadlines set out in advance and on the basis of objective and non-discriminatory criteria.

In the administrative review procedure for assessing a request of cross-border healthcare, the Member States must take in account primarily the specific medical condition of the patient as well as the urgency of the case and of individual circumstances. In short, then: with the new Directive if the patient's case will respect the foreseen conditions, the reimbursement of expenses incurred can no longer be denied.

2.1. The possible effects

The provisions of this Directive may increase - both in Italy and elsewhere - the phenomenon of emigration for healthcare - currently really not very significant in Italy - and influence the waiting lists [12]: the exasperation of patients for excessively long waiting times, the ease of displacement and lower costs than in the past to travel to the place chosen for the healthcare, may, in fact, stimulate greater mobility, especially from the Italian regions that have low levels of efficiency and effectiveness of the services provided: by exploiting the possibilities offered by a broader right of choice, patients would migrate towards more "attractive" destinations. From a certain point of view, such migration - and in some cases - could lead to a positive effect thanks to the "decongestion of waiting lists"; on the other hand there could be negative effects: namely a selection of patients (the migrating patient could be the most informed ones, the wealthiest people, etc.) and the risk that health authorities pay more for the performance required (not only because the cost is higher abroad but also because there could be a decrease of positive effects of economies of scale).

In order to avoid this situation, that is certainly possible under conditions of increased competition and differentiation (in quality and quantity of healthcare) among health systems of the different Member States, it is necessary to increase its efficiency, by trying to improve the cost/benefit ratio.

If a member State does not want to lose patients and therefore the pay-back of the factors of production, it will need to seek to increase their competitiveness and work tirelessly on the quality of the services offered. Some possible adverse effects resulting from the adoption of the new EU rules were clearly highlighted in the report attached to the proposal for the Directive. In this document, you could note that in order to avoid unsustainable impact, it is important to ensure a non-discriminatory treatment of patients regardless of whether or not they are enrolled in a national healthcare system. From an economic point of view, in this way you can avoid perverse incentives such as giving priority to foreign patients and not to national ones, and avoid compromising the long-term capital investments in healthcare. From an health point of view, treating patients equitably is essential if you want to ensure that the impact of cross-border healthcare, for example in terms of waiting lists, remains reasonable and manageable. Fears of negative impacts on health expenditure and in general on health systems – which fears have actually stuck for some time, as mentioned, the approval of the new EU rules – have been reduced in the Directive under consideration, through a series of recommendations immediately put forward in the first part. It is clear, in fact, that neither the transposition of this Directive into national law or its application should lead to a situation in which patients are encouraged to receive treatment outside their Member State of affiliation (see Recital 4). That is, with the directive, you do not aim to create an entitlement to reimbursement of costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person (see Recital 33). The Directive, therefore, tends to fully respect the differences between national health systems and the responsibilities of the Member States for the organization and delivery of health services and medical care (see Recital 35).

Given that Member States are responsible for the adoption of rules relating to the management, requirements, standards of quality and safety, and organization and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be up to the Member States to decide whether it is necessary to introduce a system of prior authorization and, if so, to identify the healthcare requiring prior authorization in the context of their system - according to the criteria established by this Directive and in the light of the case law of the Court of Justice (see Recital 42). In addition, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of healthcare provided, where this can be justified by an overriding reason of general interest relating to public health. The latter reason allows the Member State of affiliation also to take further measures to justify restrictions on the freedom of movement envisaged in the Treaties. You should note that the concept of 'overriding reasons in the general interest' to which certain provisions of the Directive refer, has been developed by the Court of Justice in its case law in relation to Articles 49 and 56 TFEU, and may continue to evolve: the Court - for example - has repeatedly held that the overriding reasons in the general interest are capable of justifying a restriction to the freedom to provide services, such as planning requirements relating to the objective of ensuring, in the territory of the Member State concerned, the possibility of a sufficient and permanent access to a balanced range of high-quality care or a wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources (see Recital 11-12). For the use of healthcare and the reimbursement of healthcare costs, Member States may maintain, also in relation to patients seeking healthcare in another Member State, general conditions, criteria of eligibility and regulatory and administrative formalities, such as the obligation to consult a general practitioner before consulting a specialist or before receiving hospital care, provided that such conditions are necessary and proportionate to the aim, not discretionary and discriminatory. It would therefore be appropriate to establish that these conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known, in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their member State of affiliation. This should be without prejudice - however – to the rights of Member States to lay down criteria or conditions for prior authorization in the case of patients seeking healthcare in their Member State of affiliation (see Recital 37). This was considered by the Court of Justice to be a necessary and reasonable requirement, since the number of hospitals, their geographical distribution, their organization and the equipment with which they are provided for and even the nature of the medical services which they are able to provide, must be connected with a plan, generally designed to satisfy various needs.

The Court of Justice has found that such planning seeks to ensure a sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. Moreover it assists in meeting a desire to control costs and to prevent, as far as possible, any waste of financial, technical and human resources (see Recital 40).

3. Future prospects. The Italian system

The implementation of these provisions is in progress in the various Member States: it will take years, however, to analyze concretely what kind of changes will affect health services. What you can do right now is trying to analyze the way of implementation, for instance in Italy, taking into account - where it is possible - a number of key-points which every Member State cannot ignore.

In Italy, the Directive has been timely transposed, but administrative tasks on its practical implementation are started late and– at the moment – the implementing decree is being prepared [13].

However, both the state level and the regional level have been set up in order to build the tariff, to define the authorization system (for instance, it is necessary to produce certificates and invoices in all EU languages), to arrange the contact points and to identify the structures that will provide the healthcare.

The activity is complex and is to be conducted in continuous connection between the two levels of government. The data available to the Ministry of Health show that at the beginning there will not be a mobility with high numbers although the development of the movement of patients in the international arena are not easily predictable.

It should be noted, however, that in Italy there is a high inter-regional mobility (the impact is about 3.7 billion euro), whereas the international mobility has a negative balance (equal to 25 million: the countrymen who go abroad for healthcare are more numerous than the patients who come from across the border: about € 75 million outflow for about 50 million inbound). These few figures give an idea of the small size of phenomenon which, at least in the short term, the application of Directive 24/2011 cross-border healthcare could have on the Italian public finance (national and regional) [14].

The implementing law clearly points out that this Directive does not replace but supplement the EU regulations n. 883/04 and n. 987/09 concerning the possibility for European citizens to have treatment in other Member States: unlike the previous legislation, the Directive 2011/24/EU is centered on the figure of the patient, defined as "any natural person who seeks to receive or receives healthcare in a Member State"; the Directive firstly aims to ensure concretely the freedom of movement.

The legislator seems to want to restrict the innovative potential of the new rules by taking care to monitor, in particular, high specialization treatments, that is the performances that more than others may be likely to push patients to go abroad in order to receive the best healthcare: at the moment, right this seems to be the weak point of the Italian health system, as it manages to attract an incoming flow of patients lower than the outgoing flow of patients (about three times). The high specialization will be the focal point of the Italian strategy to promote their excellence and transform the obligation to transpose the Directive into an opportunity. In any case the concrete implementation of the Directive will involve a big work on the organizational apparatus: the data have been received so far by the Directorate-General for Health and Consumers of the European Commission (DG Sanco) [15], which coordinates the implementation of the Directive, indicate that no Member State is really ready at the organizational level.

For Italy, the formal transposition deadline has been respected: this formality, however, made it possible to give a tighter timing to the concrete organizational activity that involves the

transposition. A first assessment of the state of affairs was made at the end of July when the Health Committee of the Regions has examined the investigation technique used to represent the lines of action that will form the content of the legislative decree implementing the Directive [16].

Among the most interesting points – which points could also be useful for a comparative assessment of the lines of implementation of the Directive by all the member countries of the EU - there is not only the definition of prior authorization for treatment abroad but also the construction of a specific web area for this purpose in the web page of the Ministry of health, and the establishment of the national contact point, which will be the key center and the information desk for insured patients in and out, as well as the reference for the regional contact points and health care facilities, both public and private [17].

Other crucial points are: register of the healthcare institutions, tariff system, the method of sending patients (whether or not related to an authorization system), the models of the prescriptions and the time of payment of the invoices, networks of centers of excellence (which the European Commission will draw up and periodically evaluate). All these aspects can actually decide the future effects of the Directive, which was introduced to ensure the free choice of care providers by the insured patient and the exchange of expertise between States. This Directive can fully achieve its goal only if really allow all patients (regardless of income level, social standing, etc.) to be able to enjoy its effects. At the moment, it is hoped that the implementation of the Directive may reactivate investment in health sector and inject innovation among healthcare professionals. In any case, several implementing decrees and a serious involvement of the Regions will be necessary, especially on the criteria for reimbursement of healthcare. The costs of cross-border healthcare, in fact, will be reimbursed on the basis of regional standards rates and regional policies: we should remember that the general rule refers to reimbursement whose coverage will not exceed the actual cost of healthcare received, but the Regions can choose to refund to patients other expenses, such as travel, accommodation, additional costs for people with disabilities: freedom of care could therefore end up being linked to the - better or poorer financial situation of the Italian Regions as well.

References and Notes

1. See Joined Cases C - 286/83 and C-26/83, *Graziana Luisi e Giuseppe Carbone c. Ministero del Tesoro* [1984] ECR I-377.
2. Dani, M.: *Il diritto costituzionale nell'epoca della circolazione dei fattori di produzione,* p. 14. Available at http://www.forumcostituzionale.it/site/images/stories/pdf/documenti_forum/paper/0030_dani.pdf**.**
3. For a long time, in fact, the right to reimbursement of medical expenses incurred in another Member State was governed by art. 22 of Council Regulation (EC) n.1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, repealed by art. 20 of Regulation (EC) n.883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems). The authorization used to be necessary if two cumulative conditions were met: healthcare

treatment received abroad had to be provided for under the national legislation of the home State and the required treatment could not be available within the normally timeframe to get it in the home State. If these conditions were met, the patient used to be entitled to get refund of expenses in the home State. See Case C- 117/77, *Bestuur Van Het Algemeen Ziekenfonds Drenthe-Platteland c. G. Pierik* [1978] ERC I-825. Cfr. about the freedom to provide services Case C-158/96, *Raymond Kohll c. Union des caisses de maladie* [1998] ECR I-1931 and CaseC-120/95, *Nicolas Decker c. Caisse de maladie des employés privés* [1998] ECR I-1831.

4. The issue was dealt with in *Smits e Peerbooms* (Case C-157/99, [2001] ECR I-5473).
5. The solution put forward by the Court clearly broadens the range of healthcare treatment available to patient, but it is also evident that it ends up affecting the financial sustainability of national health services and, in particular, of those national health services relying on limited financial resources.
6. See Davies, G.: *The Process and Side-Effects of Harmonisation of European Welfare States,* Jean Monnet Working Paper, no. 2, 2006. Available at http://www.jeanmonnetprogram.org /papers/06/060201.html, p. 30: "Therefore even if the bill for medical or educational services abroad is lower than it would be at home, reimbursement may be a drain on national resources. The domestic bill includes a large element for fixed infrastructural costs which one way or another must be paid anyway. The state will effectively be paying twice".
7. See Case C-385/99, *Müller-Fauré and Van Riet* [2003] ECR. I-4509. In this ruling the Court allows national authorities to deny the patient the permission to receive health care treatment abroad only if the same treatment, based on the clinical conditions of the patient requiring it, could be timely offered by national hospitals.
8. The wording oh the new art. 22 is applied to Case C-56/01, Patricia Inizan c. Caisse primarie d'assurance maladie des Hauts-de-Seine [2003] ECR I-12403; and Case C- 372/04, The Queen (on the application of Yvonne Watts) v. Bedford Primary Care Trust, Secretary of State for Health [2006] ECR I-4325).
9. *Consultation regarding Community action on health services, 26 September 2006*. Available at http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/ comm_health_services_comm2006_en.pdf.
10. *Directive 2011/24/UE of the European Parliament and of the Council of 9 march 2011*. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF.
11. *Regulation (EC) n.883/2004 of the European Parliament and of the Council of 29 April 2004*. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0883: EN:PDF.
12. The Eurobarometer has contributed to the study with a survey aimed at understanding the effective cross-border mobility of patients and benefits, as well as the problems associated with medical treatment

abroad. See at ttp://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/ebs_210_en.pdf. The intra EU patient flow issues are also stressed by the Directive's Preamble (recital 39).

13. L. 6 agosto 2013, n. 97 "Disposizioni per l'adempimento degli obblighi derivanti dall'appartenenza dell'Italia all'Unione europea - Legge europea 2013 in GU n. 194 del 20-8-2013.
14. Data drawn from B. Gobbi e R. Magnano, *Cure transfrontaliere: conto alla rovescia verso il 25 ottobre. Ministero e Regioni in affanno sulla direttiva Ue*, Il Sole 24 ore, 9 luglio 2013.
15. http://ec.europa.eu/health/cross_border_care/consultations/cons_implementation_ern_en.htm.
16. The sources are available at http://www.progettomattoneinternazionale.it/upload/mattone/documentiallegati/agenda_WS_Residenziale_2_3_luglio_2013_ultima_13660_1062.pdf.
17. The currently available ministerial sources foresee that setting up all necessary organizational and support structures (for implementing the main administrative procedures) will take at least one year.