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Cross-border healthcare: problems concerning the "medical error"

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ABSTRACT: The Directive on cross-border healthcare reflects the concern of the EU with the human right to health, in terms of universality, equity, access and quality. Through this Directive, Member States cannot prohibit free access for non-nationals to their health systems. All Member States of the EU are, therefore, mandated to provide the same standard of healthcare to non-nationals as they do to its nationals. The question raised in this paper is related to the "medical error" with disregard for the leges artis ad hoc medicinae or the violation of EU principles contained in the Directive and treated in the course of the practice of cross-border healthcare. In other words, what legal regime is applicable and what are the legal mechanisms that the injured patient may operate with a view to compensation for damages? Legislation on medical liability of the "Member-State of treatment" and simultaneously the European dispute mechanisms shall apply or, alternatively, only the latter because we are in EU cross-border care legal character?

KEYWORDS: right to health - border healthcare - medical liability - obligations of States - patients' rights.

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1. The Directive 2011/24/ EU: concept

Article 1 of the Universal Declaration of Human Rights (UDHR) states that all human beings are free and are endowed with rights, in conditions of full equality and dignity. The principle of equality is reinforced by provisions embedded in Articles 7 and 10. The right of access to health to all individuals without discrimination of any kind is the ultimate expression of respect for the dignity of a human being.

The right to healthcare is enshrined in Article 25 (1) UDHR. It states that all persons are entitled to welfare achieved through access to sickness insurance, old age and disability. Inspired by the vernacular of the UDHR, the Convention on Human Rights and Biomedicine was created and ratified by the Portuguese State by Resolution of the Portuguese Parliament. In this legal instrument, Articles 1, 2 and 3 expressly establish access to healthcare in conditions of equality and dignity, with a view to welfare and respect for the integrity and fundamental rights and freedoms of the individual.

Under Article 4 (2) (k), in conjunction with precepts enshrined in Articles 6 (a) and 168 of the Treaty on the Functioning of the European Union (TFEU), the EU has competence to legislate on public health, with the purpose of safeguarding the common security of Member States by implementing measures that will strive to minimize the impact of illness and disease on the economies of EU Member States. In this vein, it is for the EU to strive for the adoption of political, legal and administrative measures for, inter alia, health information and education, surveillance[1] dedicated to serious threats and risks to public health. Based on this concern, the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the exercise of patients' rights in cross-border healthcare is developed.

The notion of *cross-border healthcare* identifies with the mobility of patients, including the *provision or prescription* of healthcare in a Member State other than the Member State of affiliation, being designated by the Directive as "Member State of treatment." In fact, this Directive calls *cross-border healthcare* the situation in which the patient takes medicine and medical devices in a Member State other than the Member State of affiliation, as well as the situation in which the patient gets these medication and medical devices in a Member State other than that in which the prescription was issued.[2]

According to Article 3 (a) under the heading *"Definition"*, it is understood by *healthcare*, health services provided by health professionals,[3] including the prescription, dispensation and provision of medicines and medical devices. On the other hand, in accordance with Article 3 (e), *cross-border healthcare* is the one provided or prescribed in a Member State other than the Member State of affiliation. In other words, in a State from the European area different from the State of the citizen in which the patient is a resident, insured, or where he is entitled to sickness benefits under the law of that Member State.

The primary aim of the Directive is to prevent the States from imposing

[1] In particular on the monitoring of threats and warning of health risks to public health, see Sara Vera Jardim and Diana Grilo, "A União Europeia e as políticas de Saúde em Portugal", in *40 Anos de Abril na Saúde*, Coimbra: Almedina, 2014, 337 ff.

[2] See paragraph 16 of the Directive.

[3] For the purposes of this Directive, a health professional is qualified as a doctor, nurse, dentist, midwife or even a pharmacist or other professional whose activity in the health sector is a regulated profession, such as a psychologist, physiotherapist, etc. [see paragraph f) of Article 3 of the Directive].

restrictions on the freedom to provide medical services in the European Union area, ensuring that a patient could choose to receive the health service that is in another Member State.[4] In this sense, it seeks to provide access to healthcare to patients of the Member States on security and quality conditions, allowing their mobility within Europe. Also, it promotes collaboration between Member States regarding the definition of social security benefits relating to health and the organization and delivery of healthcare and medical care as well as other benefits related to the disease.[5]

The Court of Justice of the European Union (hereinafter, CJEU) has contributed significantly to this legislative progress, in the path of the attempt to resolve the issue on the reimbursement of healthcare costs incurred in another Member State. The jurisprudence of this Court has always striven for the defense of freedom of the provision of services and movement of goods, *inter alia*.

Among the solutions mentioned in the Directive, we can highlight the following: *(i)* the provision of health care is covered by the scope of protection as the freedom to provide services; *(ii)* the Directive has affixed a broad meaning to *"the provision of healthcare"* and what acts that it comprises. This can include, *inter alia*, providing specialized care (in hospitals) and undifferentiated (primary care, but no long-term care); *(iii)* the freedom to provide medical services include the very freedom of the service recipients (i.e. the patients) to go to another Member State to receive the same; *(iv)* the right to be treated equally in another Member State exists both in the universal public health system (in the case of the Portuguese system) and in health systems based on private insurance; *(v)* it remains the prerogative of the Member States to organize their individual social security and health systems; *(vi)* it may exceptionally be admitted a prior authorization mechanism for States – as a rule is seen as an impediment to the freedom to provide services – on grounds of *"compelling reasons in the public interest."*[6]

The Directive clearly states that patients, who decide to seek treatment in another Member State other than that of affiliation, should not be denied access to them, except in certain circumstances *relating to the public interest*. There may be a number of reasons why a Member State might wish to evoke this safeguard: *(i)* first, the *risk to public health*,[7] emerging from doubts about how to proceed with infectious diseases, assuming that they are excluded from the range of medical procedures being performed in another Member State; *(ii)* second, *the risk of financial collapse* of the health system of the "host" State, which seems likely evocable by most Member States, because the public expenditure with the health sector is high. There are medical and surgical treatments that may involve excessive structural planning and sophisticated infrastructure by the States, justifying the refusal to accept patients who cast doubt on the sustainability of the health system of the Member State of treatment.

1.1. The scope of application and restrictions

The provision and prescription can take place in health facilities, public and private. These are included in all health care, public and private, regardless of how

[4] See Maria João Estorninho and Tiago Macieirinha, *Direito da Saúde. Lições,* Lisboa: Universidade Católica Portuguesa Publisher, 2014, 282.

[5] See paragraph 10 of the Directive.

[6] See Maria João Estorninho and Tiago Macieirinha, *Direito da Saúde, Lições, cit.,* 283.

[7] See paragraphs 11 and 12 of the Directive.

it is organized, delivered and financed.[8] It also includes prescribing, dispensing and supplying medicines and medical devices.

The scope and objective of this Directive is to provide health care as defined by Article 1 (1), in conjunction with Article 3 (a). However, there are restrictions under the precept embedded in Article 3 (3). First, in the case of *continuing* or *supportive care,* i.e. support for patients in their daily lives, in the minimum hygiene care, home-based, usually provided at home or in nursing homes. Second, the *transplants are* excluded from the scope of cross-border healthcare, as a result of the particular complexity around the collection and allocation of organs. Finally, *public vaccination* programs against infectious diseases which are intended to protect only the health of the population of a given Member State.

2. Obligations of Member States

2.1. Member States of treatment

From this Directive results – in the legal sphere of the Member State of "treatment" understood as that State in whose territory healthcare is actually provided to the patient[9] – a significant number of certain positive and negative obligations.

In the terms established by Article 4, the following tasks belong to the Member State of treatment. First, the provision of clear, objective and relevant information that allows the patient to decide whether to opt for the use of the provision of health care in that State. This should be about standards and guidelines on quality and safety, such as those relating to monitoring, evaluation of health care providers and the accessibility of hospitals for persons with disabilities.[10]

Another obligation placed on the Member State of treatment is to give patients access to appropriate complaint procedures that are transparent and provide them with the opportunity to voice any grievance(s) they may have if they suffer harm resulting from the healthcare they have received.[11]

The Member State in which healthcare is provided is also required to ensure the existence of a professional liability insurance or other guarantees to safeguard damage and risks to health and physical integrity of the patient.[12]

On the other hand, recognition and zeal for the right to privacy of personal data, as well as ensuring continuity of care associated with clinical and computer records of the treatment carried out, are priorities to be considered.[13]

Treatment in conditions of non-discrimination, in accordance with the principles of universality, quality, equity and solidarity are key obligations for which the State of treatment should guide their actions.

One manifestation of the principle of equality or of non-discrimination on grounds of nationality between nationals and non-nationals patients is the application of pre-set scale of charges to comparable medical conditions or similar clinical conditions.

However, the Directive itself has a proviso: *"Taking into account all mentioned herein duties, it is not undermined or restricted the possibility of the Member-State of treatment to adopt*

[8] See Sara Vera Jardim and Diana Grilo, "A União Europeia e as políticas de Saúde em Portugal, *cit.* 356.
[9] See Article 3, paragraph d) of the Directive.
[10] See Article 4(2) (a) and (b) of the Directive.
[11] See Article 4(2) (c) of the Directive.
[12] See Article 4(2) (d) of the Directive.
[13] See Article 4(2) (e) and (f) of the Directive.

measures concerning the treatment...and avoid as much as possible, the waste of financial, technical and human resources. Such measures should be (yet) limited to what is necessary and proportionate and may not constitute a mean of arbitrary discrimination."[14] In fact, the Directive sets a limit of proportionality and reasonableness, related to the principle of financially possible, serving as a safeguard clause to the enforcement and implementation of the obligations imposed as it may be seen as too costly for the Member State concerned.

2.2. Member State of affiliation

The competent State to authorize the *insured persons*[15] to receive treatment outside the Member State of residence is called the "Affiliate Member State". According to the regulations of coordination of social security systems, it has the following obligations. First, the repayment obligation of the amounts related to the costs of cross-border healthcare [Article 5 (a)], together with the duty of information on patients' rights related to receiving cross-border healthcare including on the reimbursement of costs.[16]

The State of Affiliation should also guarantee medical follow up to patients that receive cross-border care when this is required, as it would have been if the healthcare had been provided on its territory.[17] Furthermore, it is also imperative that they ensure that all their patients, in obtaining cross-border healthcare, have access to their medical records.[18]

It is important to point out that the State of Affiliation is bound to pay the reimbursement of the costs of health care, only in the exact terms that they would have if these medical procedures were performed in their territory. It will never have to pay the excess of the actual costs of care received.[19] But in some cases, it may decide to pay the costs of travel and accommodation.[20]

The obligation to repay the costs of medical care has exceptions contemplated in Article 7 (9) and Article 8, by being subject to prior authorization. This authorization has generated some reservations and earned criticism, including by the Health Regulatory Authority,[21] but we will not focus on this issue, because it is not the subject of this study.

3. The specific case of "medical error"

We believe that "medical error" is any kind of lack of compliance in the performance of a medical procedure, either by action or omission, characterized by the violation *of the leges artis ad hoc medicinae*[22] (understood as a set of clinical guidelines

[14] See Article 4(1) and (3) of the Directive.

[15] According to Article 3, (b) of the Directive, "insured person" includes the person, but also members of his family and his survivor, covered by Article 2 of the EC Regulation No. 833/ 2004 and third-country nationals covered by Regulation EC No. 859/2003 or that fulfill the conditions laid down in the laws of the State member of affiliation regarding the entitlement to benefits.

[16] See (Article 5, paragraph b) read in conjunction with Article 7, No. 6).

[17] See Article 5(c) of the Directive.

[18] See Article 5(d) of the Directive.

[19] See Article 7 paragraphs 3 and 4 of the Directive.

[20] See Article 7(4) of the Directive.

[21] See in detail the opinion of the Health Regulatory Authority on the Directive No. 2011/24/EU of the European Parliament and of the Council of 9 March 2011.

[22] *'Leges artis ad hoc medicinae'* refers to those rules by which the health professionals would have to guide themselves in the development of their activity: particularities of medical activity, multiple

that the current state of the art of medicine and science impose as the most appropriate and more reliable, applicable to a given clinical condition at a particular time of technological advancement and knowledge).

In turn, we can define generally *"medical act"* as follows: *"It is all the direct or indirect action on a human body by a physician (or medical staff) in the exercise of their profession, to which has proper academic university degree in medicine and surgery..."*[23] Alfonso de la Osa gives us the definition of *"medical procedure"* which is *"…an act performed by a doctor whose purpose, directly or indirectly, promote or ensure the conditions for human health and which generally has an effect on the human body."*[24] We believe that this concept should be upheld as the standard reference to define, in turn, what is meant by *"medical error"* in the light of Directive 2011/24/EU on cross-border healthcare.

By virtue of the existence of "medical errors" happening during the execution of cross-border healthcare, the aforementioned Directive states[25] that there must be clear obligations for providing mechanisms to respond to harm resulting from the carriage of health care in order to prevent the lack of confidence in those mechanisms by the patient which could result in an obstacle to the use of cross-border healthcare.

National legislation of each Member State on the liability for damages caused in the exercise of medical activity cannot limit the extension of coverage of national health systems to patients from their country wishing to receive healthcare abroad, whenever this is the more appropriate mean to address the clinical condition of the patient.

In this vein, Member States should ensure protection regimes of patients and compensation in case of injury or loss of health care provided in their territory. The legal system of each Member State shall, if necessary, be subject to a legislative amendment in order to adapt to the *risk*, in terms of *extent and nature*.[26] However, it is always the exclusive prerogative of States to determine the characteristics and modalities of such legal liability regimes for medical procedures caused by cross-border healthcare.

We raise, in this regard, the following question: in case of medical error, resulting in damage to health, life, physical integrity or patient safety, which national legislation should apply? How and on what terms can the patients demand compensation for

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factors that influence it, the complexity of their interventions, the relevance at a given time of the patient´s treatment, etc. Thus, it is understood by *'leges artis ad hoc medicinae'*, the application of general medical rules to the same or similar cases to ensure an objective performance with due care. It can still be regarded as the evaluative criterion of correctness of one determined medical procedure performed by a medical professional (science or medicine) that takes into account the particularities of its author, profession, complexity of its activity and expertise, as well as external factors as it is the particular condition of the patients, the potential involvement of their families, the hospital organization and sanitary conditions, etc. to qualify the medical procedure in question as consistent or inconsistent with the required technique (taking into account the legitimate requirements and lawful medical action, the effectiveness of performed proceeding, and the possible responsibility of the author-physician as a result of its intervention). See Isa António, *A responsabilidade da Administração Pública por atos médicos*, Master's thesis, Catholic University of Porto, 2008, 95. See also José María González and Andrea Macía Morillo, "La responsabilidad médica en el ordenamiento español", in *Responsabilidade civil dos médicos*, Centro de Direito Biomédico da Faculdade de Direito da Universidade de Coimbra, No. 11. Coimbra: Coimbra Editora, 2005, 44 e 45.

[23] See Pedro Rodríguez Lopez, *Responsabilidad médica y hospitalaria*, Bosch, 2004, 34 and 35.

[24] See Alfonso Lopez de la Osa Escribano, *La convergence de la responsabilité hospitalière en France et en Espagne. Étude compare,* Marseille: Presses Universitaires d'Aix, 2005, 232 et seq.

[25] See paragraph 23 Directive 2011/24/EU.

[26] See paragraph 24 of the Directive 2011/24/EU.

their damages for cross-border healthcare? What legal mechanisms are at their disposal?

The patient may, in our view, resort to legal mechanisms for the recovery of their legal status *in status quo ante* to injury in the following ways: First, he can use the mechanisms at his disposal entitled by his European citizenship, via the European Ombudsman (Article 228 TFEU), by lodging a complaint under which all the relevant facts are exposed. The European Ombudsman will, then, conduct a phase of investigation or inquiry, checking with the Member State of treatment, the accuracy of the facts set out by the patient. If it is considered that the facts submitted have grounds, the Ombudsman will decide to forward the case to the European Commission. In the exercise of its functions, as guardian of the Treaties and caretaker of good compliance with European law, it may bring the competent action for failure (Articles 258 to 260 TFEU) against the non-compliant State of the treatment. The European Ombudsman may alternatively decide to refer this situation immediately to the CJEU if it considers that the facts are lined with *obvious seriousness and difficult voluntary return by the offending Member State*.[27]

Another hypothesis that may be added to the previous one is the admissibility of the Affiliated Member State to bring, *in itself*, a contentious case before the CJEU against the Member State of treatment on grounds of discrimination and denial of their national as sick, for unqualified and insufficient treatment, or for disregarding the collaboration rules established by the Directive. The Member State of Affiliation files, prior to the legal action, a well-grounded complaint to the European Commission,[28] in order to attempt an amicable, expeditious and efficient settlement of the situation with the offender Member State of treatment.

The pleas put forward in both judicial proceedings before the CJEU as well as with the European Commission may be of various kinds, such as: *i)* the disregard for *fundamental principles:* the principle of non-discrimination on grounds of nationality, the principle of equality, the principle of solidarity, principles of universality and equity in access to health care; *ii)* violation of *Treaties* (primary or originating legislation), particularly the Charter of Fundamental Rights of the European Union and the TFEU;[29] *iii)* violation of the Directive on cross-border healthcare (secondary legislation); iv) violation of citizen rights, while "sick", such as health, life, psychological integrity, security, medical and health "hygienic and healthy" environment, respect, protection of private intimacy, personal data protection, etc.

Assuming that the State of treatment is Portugal, the legal regime of Law 67/2007, of December 31[30] applies, whether by active conduct (for action) or negative

[27] We believe that the legal action before the CJEU should be the last resort in the activities of the European institutions, in order to assign only situations with legal significance to this court, under penalty of contributing to the slow pace of European justice and the subordination of the European judges to matters of minor importance. Moreover, the route of amicable settlement, by giving the opportunity to the offending Member-State to redeem itself, restoring the legality or compensating the damages, contributes to a higher level of trust, collaboration and inter-state diplomacy, along with more efficient and expeditious settlement of disputes.

[28] See João Mota de Campos/João Luiz Mota de Campos, *Manual de Direito Europeu. O sistema institucional, a ordem jurídica e o ordenamento económico da União Europeia*, 6th ed. Coimbra: Coimbra Publisher, 2010, 443 et seq.

[29] Miguel Gorjão-Henriques, *Direito da União. História, Direito, Cidadania, Mercado Interno e Concorrência*, 6th ed,. Coimbra: Almedina Bookshop, 2010, 307 et seq, as well as, João Mota de Campos/João Luiz Mota de Campos, *Manual de Direito Europeu, cit.,* 345 et seq.

[30] Extra-contractual Civil Liability Act of the State and other public entities.

(by omission, abstention) from which results a loss or injury, property damage and/or personal injury. Therefore, on a second level, a patient injured abroad, due to cross-border health care in public health facilities in Portuguese territory, use the means made available by the Portuguese State, with a view to fair and adequate compensation.

Regarding the healthcare liability of hospitals, one will have to consider not only the nature of the act in question but also a myriad of factors such as the qualification of the agent, the legitimacy of its action, the legality and appropriateness of delegation entrusted, the difficulty and urgency of the intervention itself, the existent material, personal and organizational means, etc.

More specifically, it is crucial to consider that, except for cases of urgency or duly justified of proven force majeure, technical personnel and medical students shall only perform a medical act, no matter how easy or complex it may be, under the direct and effective monitoring and responsibility of the Director, head of service or head of the medical team, or by delegation expressed or implied, and provided that with such intervention the "medical guarantees" of patients are not violated or disregarded. The assessment regarding the risk and skills and practical experience of the involved agents already would be, in itself, a *"medical procedure"*, and therefore part of the diagnostic or therapeutic. As such, this part should also be examined by the courts for the purposes of responsibility within the general principles laid down aiming at reconciling patients' rights, proper training of medical and paramedical personnel, as well as the demands of medical progress.[31]

In our view, without disregarding the application of individual or collective criminal and disciplinary action to the doctor, medical team or other health professional, the liability regime against public and private institutions that are part of the legal relationship for providing health care to the patient would also apply.[32] According to a certain doctrine, the most appropriate legal institution to respond to disputes arising out of medical errors is the Extra-contractual Civil Liability [*"...the violation of legal health requirements can also be a source of aquilian liability or non-contractual liability, since the rights concerned...are…absolute rights..."*].[33] On the contrary, there are other doctrinal positions such as Sinde Monteiro's who advocates the contractual liability as the most appropriate institution, whether at stake is a public or private institution.[34]

Any hospital service must act with care and diligence appropriate to the particular situation of its users, under the penalty of being guilty for dismissing this legal obligation and by consequently causing damage to their patients, having the public hospital to compensate them when the following cumulative conditions are present:[35] volunteer fact, illegality, guilt (intent or negligence), injury, causal link between the act committed or omitted, and the damage or injury specifically suffered by the patient.

On the other hand, by having the status of *"respect of public service"*, the public hospital incurs in an extra-contractual nature of liability, consequently responding

[31] See Isa António, *A responsabilidade da Administração Pública por atos médicos, cit.,* 87-88.
[32] See Maria João Estorninho/Tiago Macieirinha, *Direito da Saúde. Lições, cit.,* 293 and 294.
[33] *Idem.*
[34] On this subject see Nuno Pinto Oliveira, "Responsabilidade civil em instituições privadas de saúde: problemas de ilicitude e de culpa", in *Responsabilidade civil dos médicos*, Centro de Direito Biomédico da Faculdade de Direito da Universidade de Coimbra, Coimbra: Coimbra Editora, 2006, 142.
[35] See Maria João Estorninho and Tiago Macieirinha, *Direito da Saúde, Lições, cit.,* 295 to 302.

under Law No. 67/2007,[36] in situations where Portugal is the Member State of treatment. Paragraph 1 of Article 11, Law No. 67/ 2007 states the following: *"The State and other legal persons governed by public law are liable for damage arising from activities, things or especially dangerous administrative services...."*

We advocate the position that medical activity is *a particularly dangerous activity*, given the abnormal and special risks, the specificities of the service itself and the organization of health facilities, combined with the characteristics of each human body or the disease itself. Therefore, medical liability caused by cross-border healthcare should dismiss the assumption of "guilt"[37] and require only the objective inconsistency of the performed care with clinical standards and *leges artis ad hoc medicinae*, and the relationship between the volunteer event and the injury suffered.

We welcome the ruling doctrine that advocates the *objectivity trend* of State´s civil liability, reflected in the statement of Carla Amado Gomes: *"The scheme approved by Law No. 67/2007, of 31 December, implementing Article 22 of the Portuguese Republic Constitution, points to a mixed model of administrative responsibility function, which, while maintaining the route of subjective accountability, considerably widens the lens of accountability and quite tinting the first."*[38]

Especially in regard to medical activities in public establishments providing health services their main purpose is to drive the proper performance of the *leges artis ad hoc medicinae* and a strict conduct, with the diligence of the c*riterion of the average man as referred* to in Article 487, paragraph 2 of the Civil Code, which is also adopted in the context of administrative activity.

According to the provision of article 4, paragraph 1, Law No. 52/2014 of August 25 – which transposes the Directive 2011/24/EU and Directive of Execution 2012/52/EU[39] – cross-border healthcare is provided in accordance with the principles of universality, access to quality health care, equity and solidarity in compliance with *national legislation standards on quality and safety of the Member State of treatment* and according to EU legislation on the safety standards.

Therefore, when the Member State of treatment is Portugal and an injury or property or material damage is caused, by virtue of "medical error" in cross-border health care in compliance with the Directives mentioned, Portuguese law shall apply in order to compensate the patient. The legal regime of non-contractual liability of the State and other public entities, enshrined in Law No. 67/ 2007 – liability for the risk form – will be therefore applicable, notwithstanding EU law on the violation of security rules associated with medical care and the structural principles of equality, non-discrimination on grounds of nationality, solidarity and rights as enshrined in the Charter of Fundamental Rights of the European Union.

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[36] However, it was revised by Law No. 31/2008, of 17 July.

[37] On this topic see Carla Amado Gomes, "A responsabilidade civil extracontratual da Administração pelo risco: uma solução arriscada?", in *Textos dispersos de direito da responsabilidade civil extracontratual das entidades públicas*, Lisbon, 2010, 83 ff.

[38] See Carla Amado Gomes, "Nota breve sobre a tendência de objectivação da responsabilidade civil extracontratual das entidades públicas no regime aprovado pela Lei 67/2007, de 31 de Dezembro", in *Responsabilidade Civil do Estado*, Centre for Judicial Studies, Lisbon: July 2014, 83, consulted in January 2016: http://www.cej.mj.pt/cej/recursos/ebooks/civil/Responsabilidade_Civil_Estado.pdf.

[39] See Implementation Directive 2012/52/EU of the European Commission of 20 December 2012 on measures to facilitate the recognition of prescription issued in another Member State.

4. Critical reflection on the weaknesses of the healthcare transboundary

We consider the "right to health", and its universal access in terms of quality and equity, a true integral human right and a *sine qua non* of citizenship.[40]

The legal protection provided by this right is of universal significance and results from the *spirit* of the fundamental law of all Western European countries, the Universal Declaration of Human Rights, the UN Charter, and the Charter of Fundamental Rights of the European Union (hereinafter, CFREU). The Directive 2011/24/EU shows the concern of European countries with this human right and the difficulties with the implementation and enforcement of these provisions.

In any case, it is important to take a critical reflection on the weaknesses of the healthcare transboundary due to the risks that it entails. States with better conditions could be submerged with clinical cases stemmed from countries where the health system does not have as much quality and where there are many waiting lists. Moreover, we could see an increase in waiting times of the patients in the host countries, where they previously did not exist, associated with more acute problems in health systems, due to the increase of patients from other countries.

There is a danger of encouraging "health tourism" due to the induction of demand for medical services in the Member State of treatment, that is to say, the risk of hospitals tending to prescribe all kinds of treatment, tests or perform surgery or other medical acts, increasing the invoice of the State of origin/affiliation. Cross-border health care may come to be regarded by Member States as a source of income via "export of medical services" or a way of boosting their national economy, as it is the case with "tourism".

It seems only essential to acknowledge the danger of this resulting in a "disincentive" for improving the health system of the various Member States, since they might fear to become too attractive for patients. The issue of financial sustainability of the Member States' health systems and social security, due to the increase of health care costs and the consequent rise in the public deficit of the Member States of affiliation, which must reimburse patients, may also be a cause of concern.

Moreover, there is the considerable danger of adverse selection leading to the possible "refusal" and "discrimination" of the more expensive patient, whose pathology ensures "less financial return". Associated with this risk there is also a possibility of asymmetry regarding the information exchanged among the various Member States with regard to their health systems, equally harmful to the universal and equitable access patients have to health.

According to our understanding, the question about the contours of medical liability is undoubtedly the one that raises more challenges on this subject: how to ensure the liability of health facilities in which "medical errors", either by action or by omission, occur? As mentioned above we defend the theory of "strict liability" or "based on risk" in terms of the non-contractual civil liability of the Member States in hospital matters or "medical procedures" on the ground that it is very difficult for the patient to prove guilt and the causality nexus between the fact and the damage suffered by him, when considering the specificities of the medical science. In the context of liability for "medical errors" caused by cross-border healthcare, medical

[40] See Isa António, *As parcerias público-privadas no sector da Saúde*, Coleção Teses, Coimbra: Almedina, 2015, 64 ff.

liability should be based on *"présomption de faute',*[41] *similarly* to what is done in France by means of the reversal of the burden of proof in favor of the patient.

In turn, it becomes imperative to implement a strong independent regulation[42], at the supra-State level, European-oriented and able to oversee issues relating to competition within the activities of insurers and private providers. In view of the above, in our opinion it appears that there is a need to create a European mediation centre dealing exclusively with proceedings related to medical liability or to other disputes arising from the practice of cross-*border* health care. To overcome this problem, it would be useful to set up inter-state conciliation boards, in case of dispute or disagreement over the terms of the application of medical care to their nationals, or on the "price" applied in a particular case. Despite there being pre-fixed price lists, it is always likely that the dissonance about their application or interpretation on the need to have brought that particular medical procedure to the patient may raise questions or disputes. By this order of reasons, the articulation and dialogue between the European Commission and/or hypothetical Regulatory European Health Authority and the national health regulatory authorities is imperative to achieve the goals of the Directive.

Finally, while praising the commendable objectives of this EU Directive, imbued with the spirit of true solidarity and respect for the human right of access to health, we cannot fail to note our reservations about its problematic application, which raises complex legal and financial dilemmas. In our view, it has indeed revealed the absolute need for the institutionalization of a High Authority for the Regulation and Supervision in the "European Health System," now harmonized by the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011, on the exercise of patients' rights in cross-border healthcare, and the implementing Directive of execution 2012/52/EU of the Commission of 20 December 2012 on measures to facilitate the recognition of medical revenue issued in another Member State.

[41] See Alfonso Lopez de la Osa Escribano, *La convergence de la responsabilité hospitalière en France et en Espagne, cit.,* 232 et seq.

[42] AAVV, "A Reforma do Sector da Saúde. Uma realidade iminente?", Institute for Economic and Financial and Tax Law. Coimbra: Almedina, 2010, as well as Rui Nunes, *Regulação da Saúde,* 3rd edition, Porto: Economic Life, 2014.