

The Proposed Directive on the Application of Patients' Rights in Cross Border Healthcare: Postponed or Suppressed?*

Introduction

A fundamental freedom to receive cross border medical treatment is granted to citizens of the European Union under the internal market provision in the European Community Treaty on the freedom to provide and receive services.¹ This has been confirmed in a sequence of rulings by the European Court of Justice.² At the behest of the Member States, who called for legal certainty in the form of a political initiative and not as result of Court judgments,³ the European Commission engaged in an open Consultation exercise,⁴ on the need for Community action on health services, and proposed to adopt a draft Directive with an internal market legal basis on the Application of Patients' Rights in Cross Border Healthcare. This Directive has positive implications for an internal market in healthcare systems in the European Union, opening up competition in healthcare, and, in fact, would go much further in this regard than the *Watts* case and previous Court rulings.

The adoption of the draft Directive which was scheduled for 19 December 2007 was postponed until early 2008 because of 'a series of open and controversial questions needing further discussion'.⁵ Since 7 February 2008, the proposed draft Directive has been withdrawn pending 'further analysis'.⁶ It is the intention of this paper to

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¹ Article 49 EC.

² Joined Cases 286/82 and 26/83 *Luisi and Carbone*; Case C-158/96 *Kohll*; Case C-120/95 *Decker*; Case C-368/98 *Vanbraekel*; Case C-157/99 *Geraets Smits and Peerbooms*; Case C-385/99 *Müller-Fauré and van Riet*; Case C-56/01 *Inizan* and Case C-372/04, *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*. Judgment of the Court (Grand Chamber), 16th May 2006.

³ See Council Conclusions on Common Values and Principles in EU Health Systems, 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006, 3rd conclusion, <http://www.consilium.europa.eu/Newsroom> OJ C 146, 22.6.2006, p. 1. The Council recognised the particular value of an initiative on health service ensuring clarity for European citizens about their rights and entitlements when they move from one Member State to another in order to ensure legal certainty. Healthcare services were excluded from the scope of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, [2006] OJ L 376/ 36.

⁴ Commission Communication, Consultation regarding Community action on health services, SEC(2006) 1195/4, 26 September 2006. The Commission received 280 responses to this consultation from a wide range of stakeholders, including health professional organisations, healthcare providers, national and regional governments, insurers, industry, and individual citizens. The full list of contributors and their responses may be consulted directly on the Commission's website:

http://www.ec.europa.eu/health/phooverview/cooperation/mobility/results_open_consultation_en.htm The proposal is also based on an independent expert analysis conducted by the European Observatory on Health Systems and Policies, which focused on seven aspects of cross border healthcare: pre-authorisation and access to healthcare; quality and safety; patients rights; cross border collaboration; healthcare baskets and tariffs; past impacts of cross border healthcare; and cross border healthcare data. Wismar M, Palm W, Figueras J, Ernst K and Van Ginneken E, *Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity*, European Observatory on Health Systems and Policies, 2007. See the Executive Summary to the Draft Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross Border Healthcare, pp. 2 and 3.

⁵ 'Brussels postpones landmark bill on EU cross-border healthcare until 2008', Lucia Kubosova, EU Observer/Brussels, 19 December 2007, <http://euobserver.com/9/25361/?rk=1>

⁶ 'EU health bill faces indefinite delay', Renata Goldirova, EU Observer/Brussels, 7 February 2008. <http://euobserver.com/9/25618/?rk+1>

examine the provisions of a leaked copy of the draft Directive,⁷ to pose some questions and to draw some conclusions.

The Proposed Draft Directive on the Application of Patients' Rights in Cross Border Healthcare

Three elements

The Commission's proposed Community framework for cross border healthcare is comprised of three elements: firstly, common principles in all European Union health systems; second, a specific framework for cross border healthcare, clearly delineating the entitlements of patients to have healthcare in another Member State and also the limits that Member States can place on cross-border healthcare; and thirdly, a framework for European cooperation on healthcare.

Internal market legal basis

The draft proposal for the Directive is based on Article 95 of the European Community Treaty. The Commission maintains that this legal basis is justified by both the objective and content of the proposal. Measures adopted under Article 95 EC should have as their object the establishment and functioning of the internal market.⁸

Aim

The aim of the draft proposed Directive is to establish a general framework for the provision of safe, high quality and efficient cross border healthcare⁹ in the European Union.¹⁰ Community action is deemed necessary to address barriers to the provision of cross border healthcare. The uncertainty about the general application of rights to reimbursement for healthcare provided in other Member States creates obstacles to the free movement of patients and health services in practice. The European Commission maintains that greater clarity and certainty regarding Community law on the freedom to receive cross border healthcare cannot be addressed by the Member States alone. By reason of the scale of the action, the proposed objectives can better

⁷ Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross Border Healthcare, as yet unpublished. In a reply dated 4 March 2008, from the Secretary, European Commission Health and Consumer Protection Directorate-General, Health Strategy Unit, to this author's request for transparency and access to the formal Commission proposal, the following reference was attributed to this proposed draft Directive: COM(2007)810.

⁸ Executive Summary, *ibid.*, p. 6.

⁹ Defined as 'healthcare provided in a Member State other than that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established. Article 4 ((b).

¹⁰ CHAPTER I Article 1.

be achieved at Community level. This draft proposal, according to the Commission, thus complies with the principle of subsidiarity.¹¹

Scope

The draft proposed Directive will apply to the provision of healthcare¹² regardless of how it is organised, delivered and financed or whether it is public or private.¹³ This consolidates the rulings of the European Court of Justice: The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service ... does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply.¹⁴ Article 49 EC applies where a patient receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates.¹⁵

Relationship with other Community provisions

When an insured person¹⁶ seeks healthcare in another Member State in circumstances *other* than when an authorisation must be granted under the coordination of social security Regulation¹⁷ - the proposed draft Directive¹⁸ will apply, - and the

¹¹ In accordance with Article 5 of the European Community Treaty. Executive Summary, *ibid.* pp. 6, 7 and 8.

¹² 'Healthcare' means a health service provided by or under the supervision of a health professional in exercise of his profession according to the legislation of the Member State on whose territory the service is provided and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private. Article 4(a) of the draft proposed Directive.

¹³ Article 2.

¹⁴ See to that effect *Smits and Peerbooms*, paragraph 55, and *Müller-Fauré and van Riet*, paragraph 39.

¹⁵ There being no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is itself a service within the meaning of Article 49. *Watts*, para. 90.

¹⁶ 'Insured person' means:

(i) until the date of application of Regulation (EC) No 883/2004: a person who is insured in accordance with the provisions of Articles 1, 2 and 4 of Regulation (EC) 1408/71;

(ii) as from the date of application of Regulation (EC) No. 883/2004: a person who is an insured person within the meaning of Article 1(c) of Regulation (EC) No. 883/2004. Article 4(g) of the draft proposed Directive.

¹⁷ Article 22 of Regulation (EC) No 1408/71 of the Council on the application of social security schemes to employed persons and their families moving within the Community, [1971] OJ L 149/2; and Article 20 of Council Regulation (EC) No. 883/2004 of the European Parliament and of the Council on the coordination of social security systems, [2004] OJ L 200/1. Regulation (EC) No. 1408/71, as since amended by Regulation (EC) No. 883/2004, are based on Article 42 of the European Community Treaty and entitle persons to medical treatment which becomes necessary during a stay in the territory of another Member State, using the European Health Insurance Card. Reimbursement between the Member State and the providers is regulated by national rules. The Regulations ensure assumption of costs for planned treatment in other Member States, subject to prior authorisation, and deal with the settlement of financial claims between receiving and sending Member States. See further, European Commission, "Summary report of the responses to the consultation regarding 'Community action on health services'", (SEC(2006)1195/4, 26 Sept. 2006). *Ibid.*

Article 22 of Regulation 1408/71 provides:

(1) An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits ..., and:

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it;

coordination of social security Regulation will not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No. 1408/71 are fulfilled, the authorisation must be accorded and the benefits provided in accordance with that Regulation.¹⁹

The draft proposed Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. Neither does the draft Directive affect patients' rights to necessary treatment in another Member State where they cannot be given such treatment in their home Member State within a time limit which is medically justifiable, taking into account their current state of health and the probable cause of their illness. These two situations are already covered by the European Community Regulation on the coordination of social security schemes, which Regulation would also apply in instances where the authorisation is granted after an administrative or judicial review of the request and that person concerned has received the treatment in another Member State.²⁰

Provisions regarding entitlements provided for by the draft proposed Directive and provisions regarding entitlements provided for by the coordination of social security would be *alternative* mechanisms for coverage of the costs of cross border healthcare. When the prior authorisation is sought and granted within the framework provided for by the coordination of social security Regulation, the provisions of that Regulation apply and sickness benefits will be granted and calculated according to the rules established by that Regulation on the basis of national legislation. The draft proposed Directive requires patients who go for healthcare to another Member State outside the system for coordination of social security schemes to be able to benefit from the

(2) The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided by the legislation of the Member State on whose territory the person resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of his disease.

¹⁸Articles 6, 7, 8 and 9.

¹⁹ In that case Articles 6, 7, 8 and 9 of the draft proposed Directive will not apply. 'When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No. 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of article 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No. 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No. 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.' Article 3(2) of the draft proposed Directive. 'Member States shall apply provisions of this Directive in compliance with the rules of the EC Treaty.' Article 3(4).

²⁰ See Recital 31 to the draft proposed Directive.

principles of free movement of services in accordance with the Treaty, case law and the provisions of that Directive.²¹

*Responsibilities of authorities of the Member State of treatment for compliance with common principles for health care*²²

The draft proposed Directive places the responsibility on the authorities of the Member State of treatment,²³ while respecting principles of universality, access to good quality care, equity and solidarity, to ensure that healthcare is provided according to clear quality and safety standards of healthcare defined by *that* Member State. Furthermore, mechanisms must be in place in the Member State of treatment for ensuring that healthcare providers²⁴ are able to meet these standards, taking into account international medical science and generally recognised good medical practices. Moreover, the application of quality and safety standards by healthcare providers in practice must be monitored regularly and the authorities of the Member State of treatment must take corrective action when appropriate standards and outcomes are not met, taking into account progress in medical sciences and health technology.

The draft proposed Directive further requires the authorities of the Member State of treatment to ensure that healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of any insurance cover or other means of personal or collective protection with regard to professional liability. Patients must have a means of making complaints and be guaranteed remedies and compensation when they suffer harm resulting from the healthcare they receive. In accordance with the draft proposed Directive, healthcare providers would have to subscribe to professional liability insurance appropriate to the nature and extent of the risk, or provide a guarantee or similar arrangement which is equivalent or essentially comparable as regards its purpose for the treatment provided on their territory. Responsibility would also be placed on the authorities of the Member State of treatment to ensure that the fundamental right to privacy with respect to the

²¹ Recitals 19, 20 and 21 to the draft proposed Directive.

²² CHAPTER II Article 5.

²³ 'Member State of treatment' means the Member State on whose territory cross border healthcare is actually provided. Article 4(i) of the draft proposed Directive.

²⁴ 'Healthcare provider' means any natural or legal person legally providing healthcare on the territory of a Member State. Article 4(e) of the draft proposed Directive.

processing of personal data is protected, and finally, that patients from other Member States enjoy equal treatment with the nationals of the Member State of treatment.²⁵ Thus the draft proposed Directive, in the first instance, clarifies the fact that it is the Member State of treatment who would be responsible in any given case of cross border healthcare for ensuring compliance with common principles for healthcare. In the second instance, there would be a minimum degree of certainty since there would be a minimum core set of common principles on which patients and professionals from other Member States would know they could rely.²⁶

*Use of healthcare provided in another Member State; the responsibilities of the Member State of affiliation*²⁷

The Member State of affiliation²⁸ would have to ensure that insured persons travelling to another Member State with the purpose of receiving healthcare or seeking to receive healthcare provided there, would not be prevented from receiving such healthcare - where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation would also be required to reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory, without exceeding the actual costs of healthcare received.²⁹

In accordance with the draft proposed Directive, the Member State of affiliation may impose on a patient seeking healthcare provided in another Member State the same conditions and formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or similar healthcare were provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons. Thus the draft proposal would not alter the right of Member States to apply conditions to their benefits, such as going through a general practitioner for referral to specialist treatment or hospital care.³⁰

²⁵ Article 5(1)(a) – (h). In so far as it is necessary to facilitate the provision of cross border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, shall develop guidelines or standards to facilitate the implementation of paragraph 1, points (a) and (b). Article 5(2).

²⁶ Executive Summary, *ibid.* p. 10.

²⁷ CHAPTER III Article 6.

²⁸ 'Member State of affiliation' means the Member State where the patient is an insured person. Article 4(h) of the draft proposed Directive.

²⁹ Article 6(1) and (2).

³⁰ Article 6(3). The Commission is of the view that this proposal thereby complies with the principle of proportionality in Article 5 EC in that it does not go beyond that which is necessary to achieve its objective. See the Executive Summary, *ibid.* p. 9 and Recital 27 to the draft proposed Directive.

Member States would be required to have a mechanism for calculation of the costs to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism must be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism must not be less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.³¹

Furthermore, patients travelling to another Member State with the purpose of receiving healthcare or seeking to receive healthcare provided there must be guaranteed access to their medical records.³²

Non-hospital care

In the light of the case law of the European Court of Justice, the draft proposed Directive would not establish or maintain the requirement of any prior authorisation for reimbursement by the social security system of a Member State of affiliation for non-hospital care provided in another Member State. The Commission confirms that in so far as the reimbursement of such care remains within the limits of the cover guaranteed by the sickness insurance scheme of the Member State of affiliation, the absence of a prior authorisation requirement will not undermine the financial equilibrium of social security systems.³³ The reimbursement of the costs of non-hospital care provided in another Member State must not, therefore, be subject to prior authorisation, where the cost of that care, if it had been provided in the territory of the Member State of affiliation, would have been paid for by its social security system.³⁴

Hospital and specialised care

The draft proposed Directive does not introduce a general prior authorisation requirement but allows Member States to provide for a system of prior authorisation for assumption of costs for hospital care provided in another Member State, provided however, that Member States can provide evidence that the outflow of patients for cross border healthcare has such an impact that it undermines all the planning and

³¹ Article 6(4).

³² Article 6(5).

³³ See in particular *Kohll*, paragraph 42, *Müller-Fauré and van Riet*, paragraphs 76-80. See the Executive Summary, *ibid.* p. 13.

³⁴ Article 7.

rationalisation carried out in the hospital sector. The draft proposed Directive defines hospital care for the purposes of reimbursement of healthcare provided in another Member State as meaning healthcare which requires overnight accommodation of the patient in question for at least one night.³⁵ A list of additional healthcare that does not require overnight accommodation of the patient but which is assimilated with hospital care for the purposes of the draft proposed Directive may be adopted by the Commission. This list, which will be updated regularly, will be limited to healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or involving treatments presenting a particular risk for the patient or the population.³⁶

It would be the general rule that the Member state of affiliation would *not* make the reimbursement of the costs of hospital care or defined additional healthcare provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in their territory, would have been assumed by their social security system.³⁷ By way of derogation, however, Member States *may provide for a system of prior authorisation* for reimbursement by their social security system of the cost of the hospital care or defined additional healthcare provided in another Member State, *where the outflow of patients has such an impact on the planning and rationalisation carried out in the hospital sector in order to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage as to undermine the financial balance of their social security system, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on its territory.* The prior authorisation system must be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.³⁸

Concerning hospital care, the European Court of Justice has recognised that it cannot be excluded that the possible risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of

³⁵ Article 8(1).

³⁶ Article 8(2). The Commission reports that there is no consistent definition of what constitute hospital care throughout the different health systems of the European Union. The difference of definition could therefore constitute on the one hand an obstacle to the freedom for patients to receive health care services because patients would be subject to different provisions in this Directive depending on the definition of hospital care. In order to overcome that obstacle, the Commission is of the opinion that it is necessary to provide a minimum definition of hospital care. See the Executive Summary, *ibid.* pp. 14 and 15.

³⁷ Article 8(3).

³⁸ Article 8(4). An obligation is placed on the Member State of affiliation to make available to the public information on the prior authorisation systems introduced pursuant to the provisions of paragraph 4. Article 8(5).

justifying a barrier to the principle of freedom to provided services. The European Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible.³⁹ The aims of such planning are to ensure, within each Member State, access to a balanced range of quality hospital care, to secure efficient cost management and, so far as is possible, to avoid wastage of financial, technical or human resources.⁴⁰

Procedural guarantees regarding use of healthcare in another Member State

Under the draft proposed Directive, the Member State of affiliation must ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation, reimbursement of costs of healthcare incurred in another Member State and such conditions as, for example, general practitioner referral, are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. Any such procedural systems must be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within the time limits set out and made public in advance by the Member States. Member States must specify in advance and in a transparent way the criteria for refusal of the prior authorisation.⁴¹ In addition, Member States are required, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, to take into account: the specific medical condition; the patient's degree of pain; the nature of the patient's disability; and the patient's ability to carry out a professional activity.⁴² The Commission is of the opinion that procedures regarding cross border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This applies also to actual reimbursement of costs of healthcare incurred in another Member State after the patient's return. The Commission believes that patients should normally have a

³⁹ See in particular *Smits and Peerbooms*, paragraphs 76-80.

⁴⁰ *Ibid.*, paragraph 82. Executive Summary, pp. 11-14.

⁴¹ Article 9(1). See Recital 27 to the draft proposed Directive.

⁴² Article 9(2).

decision regarding the cross border healthcare within fifteen calendar days or a shorter period where warranted by the urgency of the treatment in question.⁴³ Member States must also ensure that any administrative decisions regarding the use of healthcare in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.⁴⁴ The ruling of the European Court of Justice in the *Watts* case purported to circumscribe the potential for arbitrary discretionary decisions of national health authorities concerning the grant or refusal of prior authorisation and the regulation of their waiting lists.⁴⁵ The Court noted that the National Health Service regulations in the United Kingdom do ‘not set out the criteria for the grant or refusal of the prior authorisation necessary for the reimbursement of the cost of hospital treatment provided in another Member State, and therefore do not circumscribe the exercise of the national competent authorities’ discretionary power in that context.’ Moreover, ‘the lack of a legal framework in that regard also makes it difficult to exercise judicial review of decisions refusing to grant authorisation.’⁴⁶ The Court further ruled, ‘... a refusal to grant prior authorisation cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in question an objective medical assessment of the patient’s medical condition, the history and probable cause 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.’⁴⁷ The *Watts* ruling shed light on the fact that the National Health Service in the United Kingdom is deficient in all of these regards.

⁴³ Recital 32 to the draft proposed Directive.

⁴⁴ Article 9(3).

⁴⁵ Case C-372/04 *Watts*, *ibid.* ‘It is settled case-law that a system of prior authorisation cannot legitimise 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 Case C-157/99 *Smits and Peerbooms*, para. 90, and Case C-385/99 *Müller-Fauré and van Riet*, para. 84). Thus, in order for a system of prior authorisation to be justified even though it derogates from a fundamental freedom of that kind, it must in any event be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities’ discretion, so that it is not used arbitrarily. Such a system must furthermore 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 (*Smits and Peerbooms*, para. 90, and *Müller-Fauré and van Riet*, para. 85).’ paras. 115 and 116 of the judgment.

⁴⁶ *Ibid.*, para. 118.

⁴⁷ *Ibid.*, para. 119. See further, D Ryland, ‘Freedom, Solidarity and Citizenship’, paper presented at the International Conference on ‘The European Constitution and National Constitutions’, organised by Andrzej Frycz Modrzewski Kraków University College, the Jagiellonian University in Kraków, the University of Hull and the Consulate of the Republic of Poland in Beverley, held in Kraków, Poland, 21 to 24 October 2007. See also, D Ryland, ‘Patient Mobility in the European Union: A Freedom to Choose?’ Paper presented at the 7th International Academic Conference held on 28 May 2007 at Andrzej Frycz Modrzewski Kraków University College. Both papers are published on the Internet at <http://www.fom.com.pl>

Information for patients concerning the use of healthcare in another Member State

The Member State of affiliation would be required to ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, including in case of harm⁴⁸ caused by cross-border healthcare.⁴⁹ The information must be made easily accessible, including by electronic means, and must include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.⁵⁰ Such information about the process for having access to cross border care (eg.: procedures to be followed, timetable for reimbursement) is distinct from information about the content of the health care itself (e.g.: cost, timetable for availability, outcomes), which should be provided by the healthcare providers in the Member State of treatment. According to the Commission, information on all essential aspects of cross border healthcare is necessary in order to enable patients to exercise their rights to cross border healthcare in practice, i.e. to facilitate freedom of movement to receive healthcare.⁵¹ The current practice in providing information to patients on aspects of cross border healthcare in the Member States was found to be rather limited. For example, a study conducted by the Health Consumer Powerhouse in France, Poland, United Kingdom, Spain and Germany showed that 25 percent of citizens believed that they do not have the right for treatment abroad and 30 percent were unsure.⁵² This was confirmed by the recent Eurobarometer survey,⁵³ which showed that 30 percent of citizens in the European Union are not aware of the possibility to receive health care outside their country of affiliation.

National contact points for cross border healthcare

For cross border healthcare the most efficient mechanism for providing such information is deemed by the Commission to be the establishment of central contact points within each Member State to which patients can refer, which will cooperate with each other and which can provide information on cross border healthcare. The

⁴⁸ 'Harm' means adverse outcomes or injuries stemming from the provision of healthcare. Article 4(1) of the draft proposed Directive.

⁴⁹ Article 10(1).

⁵⁰ Article 10(2). The Commission may develop a standard Community format for the prior information. Article 10(3).

⁵¹ Recital 33 to the draft proposed Directive.

⁵² http://ec.europa.eu/health/ph_overview/co_co-operation/mobility/docs/health_services_co147.pdf

⁵³ Flash Eurobarometer Series #210, Cross border health services in the EU, Analytical report, conducted by the Gallup Organisation, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate General (DG SANCO), 2007.

form of these national contact points, as well as their numbers would be left to be decided by the Member State. The national contact points may also be incorporated in, or build on activities of, existing information centres provided that it is clearly indicated that they are also national contact points for cross border healthcare.⁵⁴ Member States are thus required to designate national contact points for cross border healthcare and communicate their names and contact details to the Commission.⁵⁵ According to the draft proposed Directive, the information to be provided and disseminated to patients by the national contact points must specify their rights related to cross border healthcare.⁵⁶ The national contact points, in accordance with the draft proposed Directive, would have the further remit of helping patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State.⁵⁷

Cooperation on health services

To achieve the objective of realising the internal market, the Member States are placed under a duty of cooperation to render such mutual assistance as is necessary for achieving implementation of the draft proposed Directive and to facilitate cross border healthcare provision at regional and local level.⁵⁸ Since the national, regional and local administrative practices in the health care sector differ significantly, the Commission is of the opinion that mutual cooperation between different health systems will help to avoid unnecessary obstacles to the free movement of health services.⁵⁹

Recognition of prescriptions issued in another Member State

Member States will be required to ensure that prescriptions issued by an authorised person in another Member State for a named patient can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they are limited to what is necessary and proportionate to safeguard human health and

⁵⁴ Recital 34 to the draft proposed Directive.

⁵⁵ Article 11(1).

⁵⁶ and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable. Article 11(2)(a).

⁵⁷ The national contact point must in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary. Article 11(2)(b). See further Articles 11(2)(c) and (d) and 11(3).

⁵⁸ CHAPTER IV Article 12(1). See Article 12(2).

⁵⁹ Executive Summary, *ibid.* p. 17.

are non-discriminatory or are based on legitimate and justified doubts about the authenticity or content of an individual prescription.⁶⁰

European reference networks

Member States will also be required under the draft proposed Directive to facilitate the development of European reference networks of healthcare providers.⁶¹ The objectives of European reference networks will be, *inter alia*: to help realise the potential of European cooperation regarding highly specialised healthcare for patients; and to help to promote access to high quality and cost-effective healthcare for all patients with conditions requiring a particular concentration of resources or expertise.⁶²

Data collection for statistical and monitoring purposes

It is significant that Member States will be required to collect statistical and other complementary data for monitoring purposes on the provision of cross border healthcare, the care provided, its providers and patients, the costs and the outcomes. Member States must then transmit the data to the Commission at least annually.⁶³ The Commission concluded that data on cross border health care was not sufficiently available or comparable to enable long term assessment and management of cross border health care.⁶⁴

Some Questions

*National Health Service concerns*⁶⁵

Four particular issues are of potential concern to the NHS. Firstly, Member States will be required to abide by the numerous principles for healthcare systems, which include, *inter alia*, patient information, quality and safety, complaints procedures, rights to privacy of data, and professional liability insurance. Would the failure to abide by these principles lead to enforcement actions either before the European Court

⁶⁰ Article 13(1).

⁶¹ See further Articles 14(1) and 14(3).

⁶² Article 14(2) (a) and (b). Furthermore, the Commission undertakes to adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field whenever Member States decide to introduce them. Article 15.

⁶³ Article 16(1) and (2).

⁶⁴ Executive Summary, *ibid.* p. 19. Article 17 of the draft proposed Directive would facilitate cooperation on management of new health technologies.

⁶⁵ The NHS Confederation Company Limited, 'Forthcoming EU Directive on cross border healthcare', December 2007, <http://www.nhsconfed.org/specialist/specialist-3088.cfm>

of Justice or in the national courts? In the second instance, European Union Member States would only be able to justify prior authorisation for hospital care on the basis that, without it, the financial sustainability of their healthcare system would be undermined. Where prior authorisation is not a requirement to receive hospital or non-hospital care abroad, would Primary Care Trusts face unmanageable uncertainty in financial planning? In the third instance, there would be, potentially, a risk of exacerbating inequalities in access to care when patients who can afford to pay travel costs and advance treatment costs may receive care more quickly in another Member State than those without such funds. Fourthly, the principle of equal treatment with residents of the country where cross border healthcare is provided could also pose significant difficulties concerning capacity planning for the NHS.

Reasons for withdrawal: postponement or suppression?

Why was the draft proposed Directive withdrawn at the last minute before its scheduled publication? A plethora of reasons have been put forward.

‘Ministers are concerned that the changes could lead to too much cash flowing out of the NHS [and] potentially a significant loss of control for Whitehall’.⁶⁶

‘The bill has been postponed until early January as several questions are expected to prompt further debate between Commissioners, including on how and when patients who opt for treatment abroad should be reimbursed.’⁶⁷

‘The official reason for withdrawing the bill has been the Commission’s heavy agenda.’⁶⁸ “Several Commission officials have informally acknowledged, however, that the legislative proposal was ‘not foreseen for the adoption in the near future’ because it is not supported by all 27 Commissioners. ‘Many cabinets intervened’ against the bill, one official said, citing high costs and the negative impact on national health systems during internal discussions. In addition, some wanted to avoid opening a highly-sensitive issue during ratification of the EU’s Lisbon Treaty.”⁶⁹ Kathy Sinnott, Irish MEP and member of the Committee on Public Health, has expressed ‘no doubt that this proposal has been temporarily buried because of the Lisbon Treaty

⁶⁶ ‘Patients to beat NHS queues in EU plan for open health market’, David Charter, The Times, December 18, 2007.

⁶⁷ ‘Brussels postpones landmark bill on EU cross-border healthcare until 2008’, Lucia Kubosova, EU Observer/Brussels, 19 December 2007, <http://euobserver.com/9/25361/?rk=1>

⁶⁸ ‘The Commission then promised a draft Directive by the end of January, but said at the beginning of February that proposals on climate change and renewable energy had dominated that month’s agenda. ‘Just a matter of time?’ Sarah Collins, Parliament Magazine, 18 February 2008.

⁶⁹ ‘EU health bill faces indefinite delay’, Renata Goldirova, EU Observer/Brussels, 7 February 2008, <http://euobserver.com/9/25618/?rk+1>

ratification, especially in relation to the referendum in Ireland, where an overstretched under-funded public health service is of major concerns to voters.’⁷⁰ She goes on to say: ‘When a home country cannot supply needed medical care, people must travel, but to make this a normal occurrence by making it an entitlement paid for at the expense of the home revenues – that is, from public hospital systems – will result in a diminishment of both services and quality. Of course, this legislation will be a boon to private medical providers as medical treatment becomes a very big and competitive business.’ By comparison, Paolo Giordano, secretary general of the European union of private hospitals, says that the public sector will not be financially disadvantaged because of the principle of the country of origin. A patient who chooses to receive healthcare in another Member State would only be entitled under the draft proposed directive to the reimbursement of the cost of that treatment as determined by national law and not any extra costs incurred in the Member State of treatment. He believes that the proposed Directive would ‘open up the private sector and choice for the patient.’⁷¹

This author had requested access to the unpublished draft proposed Directive in accordance with the Regulation⁷² regarding public access to European Parliament, Council and Commission documents. This request could not be met, the stated reason being that the Commission had not yet taken a decision on the proposed Directive and ‘Disclosure of the document would seriously undermine the institution’s decision-making process.’⁷³ Maybe all of the reasons hold water! Nevertheless, the lack of transparency renders the decision making process flawed in this author’s opinion, whose request for formal access to the unpublished Directive is still ongoing.⁷⁴

The new Cypriot Commissioner Androula Vassiliou has stated her determination to submit a European Union health Directive addressing patients’ rights for adoption by the Commission in June of this year, despite the subject’s controversy, stating that the draft proposal had been withdrawn because of strong opposition from several

⁷⁰ Parliament Magazine, 18 February 2008, *ibid*.

⁷¹ *Ibid*.

⁷² Regulation (EC) No. 1049/2001, [2001] OJ L145/43.

⁷³ (Article 4, paragraph 3 of Regulation (EC) No. 1049/2001).’ Letter dated 4 March 2008, from Robert Madelin, Director General, European Commission Health and Consumer Protection Directorate-General, Brussels.

⁷⁴ European Commission Secretariat – General, SG-E-3 Transparency, Relations with Stakeholders and External Organisations, Mark Maes, Deputy Head of Unit, Letter dated 7 April 2008. Subject: Confirmatory application for access to the Proposal for a Directive on the application of patients’ rights in cross border healthcare. ‘Your application is currently being handled. However, since we still have not been able to gather all the elements we need to carry out a proper analysis of your request in order to take a final decision, we will not be able to reply to your confirmatory request within the prescribed time limit. Therefore we have to extend this period by another 15 working days in accordance with Article 8(2) of Regulation 1049/2001. The new deadline expires on 28 April 2008. I apologise for any inconvenience this delay may cause.’ This period has since extended as per letter dated 28 April 2008.

Commissioners, as well as Member States and Members of the European Parliament. The Directive will be presented along with the Commission's pending social legislation, 'promoting access, opportunities and solidarity for all EU citizens.'⁷⁵

Adopted in June?

It will be interesting to see if a proposal for a Directive on the application of patients' rights in cross border healthcare will be adopted by the Commission in June 2008, and, more significantly, to compare its provisions with those in the unpublished version which have been highlighted in this work. It will be then that conclusions may be drawn.

Concluding comments

Balance

Suffice to say, in the interim, that the draft proposed Directive does strive to achieve a balance between: the stated interests of the Member States, on the one hand; in its provision on costs of reimbursement, the country of origin principle, the definition of hospital care, and the maintaining of such conditions as general practitioner referral; and, on the other hand, the entitlement of patients to receive healthcare in another Member State, with its strong procedural requirements and guarantees which will facilitate the removal of unnecessary barriers to freedom of movement to receive healthcare services in the European Union.

Administration

It should be emphasised that the draft proposed Directive would increase the administrative burdens of the Member States. This is evident from a reading of its provisions, such as, for example: the requirement to work out the costs of health treatments provided by the NHS so as to be able to reimburse patients for care received abroad; the establishment of national contact points responsible for disseminating information to patients on their rights to cross border healthcare; the collation of statistical data on cross border healthcare; the provision of access to medical records; verifying the authenticity of prescriptions *etc.*

⁷⁵ 'New Commissioner pledges to tackle disputed EU health bill', Lucia Kubosova, EU Observer, 1 April 2008, <http://euobserver.com/9/25899/?rk=1> This has been confirmed. The 'social package' ... 'is to include a long-awaited proposal on patients' cross border healthcare rights.' 'Barroso to focus on social agenda ahead of elections', Honor Mahony, EU Observer/Brussels, 30 April 2008, <http://euobserver.com/9/26071/?rk=1>

Raise standards and facilitate freedom of movement

In this author's opinion, the draft proposed Directive on the application of patients' rights to cross border healthcare clearly would open up access to what is currently a heavily controlled service, which potentially would raise standards in the provision of healthcare services in the European Union and facilitate patients' entitlement to freedom of movement.