12 *Enabling patient mobility in the EU: between free movement and coordination*

WILLY PALM AND IRENE A. GLINOS

1. Introduction

Free movement of patients – or patient mobility, as it is commonly referred to – implies people accessing health care services outside their home state.[1] Although health care normally is delivered close to where people live, in some instances the need for medical care arises while away from home or patients decide to seek care elsewhere. Patients' readiness to travel for care, especially across borders,[2] is determined by a mix of factors linked to the specific situation of the patient, to the specific medical needs and to availability of care at home and abroad. Motivations for travelling abroad for care vary from the search for more timely, better quality or more affordable health care to treatment responding better to the patient's wants or needs – including when care is inexistent or even prohibited at home.[3]

While citizens in the EU, in principle, are free to seek health care wherever they want and from whatever provider available, in practice this freedom is limited by their ability to pay for it or by the conditions set out by public and private funding systems for health care. Traditionally, countries have confined statutory cover for health care delivered to their population to providers established in their territory.[4] Whereas initially, bilateral conventions derogated from this territoriality

[1] By 'home' state or country, we mean the country of residence, which is usually also the country where the patient is affiliated to the social security system.

[2] Patient mobility can also take place *within* countries, when, for instance, health care provision is regionalized and patients move from one region or province to another. For example, on intra-regional flows in Italy, see G. France, 'Cross-border flows of Italian patients within the European Union', *European Journal of Public Health* 7 (1997), Supp: 18–25; I. A. Glinos and R. Baeten, 'A literature review of cross-border patient mobility in the European Union', Observatoire social européen, September 2006, pp. 74–5.

[3] Glinos and Baeten, 'A literature review', above n.2, pp. 5–7.

[4] In some cases, cover is even further reduced to specific types or contracted health care professionals. See also, on the issue of access hurdles, R. Busse and E. van

principle[5] to ensure access to care for people living and working in different Member States, a more general derogation was established in the context of European integration under Article 42 EC, based on the fundamental principle of free movement of persons.[6] More recently, further steps in opening provider choice options for patients across the European Economic Area (EEA) have been made through the jurisprudence of the European Court of Justice (ECJ), based on the freedom to provide services as contained in Article 49 EC.

Although patient mobility is still a phenomenon of relatively modest scale, in terms of both overall numbers of people receiving health care in another Member State and financial impact,[7] the fact that patients are allowed to move more freely between health care systems raises a series of issues and can have consequences for the way delivery of care is organized. Certain countries and regions experience high concentrations of patient mobility, and patient flows can be considerable in some circumstances or for particular medical conditions. As numbers grow, issues relating to the quality of care, liability, responsibility and safety of care received abroad become more prominent. These developments, in combination with a decade of groundbreaking rulings by the ECJ, have placed patient mobility and cross-border health care more firmly on the political agenda in the last decade at both Member State and EU level.[8] Increasing personal mobility within the Union, its changing nature, the emerging problems and challenges occurring within national health systems, as well as the uncertainty around the impact of jurisprudence for national health care systems, have made

Ginneken, 'Access to healthcare services within and between countries of the European Union', in M. Wismar *et al.* (eds.), *Cross-border healthcare: mapping and analysing health systems diversity* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2009), pp. 12–50.

[5] R. Cornelissen, 'The principle of territoriality and the Community regulations on social security', *Common Market Law Review* 3 (1996), 439–471, at 464.

[6] See also A. P. van der Mei, *Free movement of persons within the European Community, cross-border access to public benefits* (Oxford: Hart, 2001).

[7] Although the available data on the extent of cross-border care is extremely patchy, it is commonly agreed that the current volume of patient mobility is relatively low, estimated at around 1% of overall public expenditure on healthcare. See European Commission, 'Consultation regarding Community action on health services', SEC (2006) 1195/4, 26 September 2006, p. 6. On the available data, see also Busse and van Ginneken, 'Cross-border healthcare data', in Wismar *et al.* (eds.), *Cross-border healthcare*, above n.4, pp. 219–58.

[8] See Chapter 4 in this volume for a detailed chronological analysis.

national policy-makers more wary of any developments that could weaken their policies to contain costs and strengthen actors' accountability. This has led to fierce debates about the inclusion of health services in the Directive on Services in the Internal Market[9] and about the necessity of applying a more adapted approach for health care within the European policy framework.

This chapter will analyse the state of the regulatory framework in this field as well as the relevant case-law of the ECJ. In particular, it will address the questions of who actually steers the policy on patient mobility and how the debate on free movement of patients has changed over time to anticipate the phenomenon's changing patterns, as well as the evolving behaviour and expectations of patients. It will also refer to the wider impact of the application of the Treaty-based principles of free movement, which is further developed in Chapter 11 in this volume (on free movement of health services).

The chapter will start by looking into the various governance aspects of patient mobility. It will do so by clarifying the conceptual, legal and policy fundamentals of the phenomenon, as well as the key actors and their roles (section two). The following section (section three) examines the changing legal landscape, the requirements and motivations of the patient groups concerned with mobility, as well as the range of approaches that public authorities and health care actors have taken to channel patient flows. Section four analyses the most recent policy developments in the field as national and EU-level decision-makers have tried to define the direction that patient mobility and its governance should take. In the concluding section, we present a summary of the key issues and suggest which challenges possibly lie ahead.

2. The governance of patient mobility in the European Union

A. The conceptual construct of patient mobility

Before going into the governance developments on free movement of patients, we need to clarify what concepts and values lie at the heart of the policy debate. For Member States, patient mobility is rather

[9] European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2006 No. L376/36.

an exception to the rule. Their main concerns are the loss of control and the equity implications it may have for their health care systems. For the EU institutions, the focus is rather on removing impediments to free movement and implementing the choice resulting from it. Inevitably, the fact that the political agenda on patient mobility differs widely between actors becomes a source of conflict.

The debate on free movement of patients is conceptually centred on the question of whether the right to health care extends to service providers outside the state of affiliation. This right to health care as a part of the European welfare state has been constructed on the notion of so-called 'positive' rights.[10] These rights are community-based; they involve the pooling of resources and redistributive allocation (from the wealthy and healthy to the poor and ill), promoting reciprocity and solidarity. By contrast, the ECJ in its rulings has regarded the right to health care as a 'negative' right – i.e., a right promoting the individual's liberty. Having defined medical activities as services falling within the scope of the fundamental freedom to provide services, it follows that people are free to seek medical care anywhere in the EU and that any hindrance to this freedom, including coming from statutory reimbursement rules, would need to be justified. Through the case-law of the ECJ, the scope for Member States to deny cover outside the national territory has reduced significantly. This logic, which effectively gives EU citizens the possibility (and the right) to obtain treatment outside their state of affiliation, might well be to the detriment of the community[11] and may carry important consequences in terms of equity. A key function of health care systems is to define priorities based on evaluations of what is beneficial to the community as a whole (the public interest). These priorities feed into decisions on planning and financing of the system. An individual patient choosing to go abroad for care (e.g., to obtain faster access) and who, based on EU law, can claim cover for it, could be considered to effectively

[10] The distinction between positive versus negative rights is an established one in the political philosophy literature and does not carry any value judgement. It distinguishes between rights requiring an intervention by the state (positive rights) and rights rather calling for temperance by public authority (negative rights).

[11] C. Newdick, 'Citizenship, free movement and health care: cementing individual rights by corroding social solidarity', *Common Market Law Review* 43 (2006), 1645–68.

disregard public priority-setting and divert tax-payers' money away from the national system.

What this boils down to is a tension between the four freedoms interpreted as conferring rights on the individual to health care, and the finite resources of the system, which have to be allocated in the fairest, most efficient way for the community. Moreover, free movement has equity implications because it is likely to benefit the least ill, the most literate and the wealthiest. These population groups tend to be more articulate, confident and targeted in terms of their health care needs and expectations;[12] they are likely to be more knowledgeable about their rights and more familiar with travelling abroad; and they are likely to be better able to afford the transport costs, as well as to cover medical expenses before reimbursement. Patient mobility is often sold under the banner of increased choice of provider and of treatment on a Europe-wide scale. In reality, it might well be an advantage for members of already privileged social strata.

These tensions are not just conceptual; they translate into contentious relationships between the actors involved with the free movement of patients. At the policy level, the diverging positions lead to conflicting priorities (as will be shown in this chapter). Member States are concerned with maintaining steering capacity over their systems. They inherently protect their health care systems and the principles of solidarity and collective rights they are built on. The European Commission, by its nature, promotes, and the ECJ protects, the individual rights that EU citizens derive from the Treaties. The Commission is pushing for increased choice in an integrated European market. It is supported in this by actors with a stake in the choice agenda, such as health insurers and hospitals. However, there is variation within the Commission. Different policies and different approaches are favoured by individual Directorates-General in accordance with their mission and responsibilities (see also Chapter 10). The Directorate-General for the Internal Market and Services (DG MARKT) concentrates on the effective functioning of the market for goods and services and their free circulation. The Directorate-General for Health and Consumer Protection (DG SANCO) watches over the public health and consumer issues related to free movement. The Directorate-General

[12] Z. Cooper and J. Le Grand, 'Choice, competition and the political left', *Eurohealth* 13 (2007), 18–20.

for Employment, Social Affairs and Equal Opportunities (DG Social Affairs) is committed to the unhindered mobility of workers and to ensuring their social security rights through the coordination mechanism that for decades has made it possible for persons moving within the Community to obtain health care. We deal with this mechanism in detail below.

B. Social security coordination

Since the foundation of the European Community, the policy of awarding access to health care outside the state of social security affiliation was essentially governed by secondary Community law, based upon the fundamental principle of free movement of persons enshrined in the EC Treaty. Based upon Article 42 EC, a Community framework was established to ensure the coordination of social security rights of migrant workers and their family members, including the right to statutory health care. Whereas EC Regulations 1408/71/EEC and 574/72/EEC,[13] in the first place, were intended to establish entitlements in the (new) Member State of residence for citizens moving to another Member State, or for migrant workers and their families working and living in different Member States, Article 22 and 22-*bis* (for non-active persons) specifically address the case of access to treatment outside that 'home state'. Fundamentally, these provisions provide for conditional access to care outside the state of affiliation: either people require care that has become medically necessary during a temporary stay or they receive authorization from their competent institution to obtain treatment in another Member State. These cases will be further elaborated in the next section.

Fundamentally, the social security coordination mechanism seeks to answer three key questions: where and under what conditions is an entitlement to health care benefits in kind opened in another Member

[13] Council Regulation 1408/71/EEC on the application of social security schemes to employed persons and their families moving within the Community, OJ 1971 Sp.Ed. Series I, p. 416; Council Regulation 574/72/EEC fixing the procedure for implementing Regulation 1408/71/EEC on the coordination of social security schemes for persons moving within the Community, OJ 1972 Sp.Ed. Series I, p. 159. These Regulations are regularly amended. The latest consolidated versions are available via Eur-lex, www.eur-lex.europa.eu/.

State; which legislation determines the scope and modalities of this entitlement; and who will have to cover the costs? As a general rule, people who fall under the scope of this mechanism and meet the conditions are covered as though they were insured under the statutory system of the Member State where they are treated, and this at the expense of the competent Member State – generally, the state where the person works and pays social security contributions. In practice, this means that the benefit package, tariffs and the statutory reimbursement conditions and formalities of the state in which treatment occurs apply to patients who are affiliated to another Member State.

This 'coordination route' is considered to be a sort of 'safety net',[14] a minimum guarantee to enable citizens to use their right to free movement. Through national legislation, Member States can extend the entitlements established under Community law. The European Court of Justice has stated repeatedly that Article 22 of Regulation 1408/71/EEC is in no way intended to regulate, and hence does not in any way prevent, the reimbursement by Member States, at the tariffs in force in the competent state, of costs incurred in connection with treatment provided in another Member State, even without prior authorization.[15]

Traditionally, the social security coordination policy is governed by the Directorate-General for Employment, Social Affairs and Equal Opportunities of the European Commission together with the Administrative Commission on Social Security for Migrant Workers, which is composed of Member State representatives. Their role is to deal with all administrative questions and questions of interpretation arising from the Regulation and to foster and develop cooperation between Member States in social security matters by modernizing procedures for information exchange. The actual implementation is operated by the national institutions in charge of the statutory health protection system with the help of so-called E-forms.[16]

Since 1999, the social security coordination mechanism was put under revision to better take account of societal developments, as well

[14] See European Commission, 'A Community framework on the application of patients' rights in cross-border healthcare', COM (2008) 415 final, 2 July 2008, p. 5.

[15] Case C-158/96, *Kohll* v. *Union des Caisses de Maladie* [1998] ECR I-1931, para. 27; Case C-56/01, *Inizan* [2003] ECR I-12403, para. 19; Case C-368/98, *Vanbraekel* [2001] ECR I-5363, para. 36.

[16] http://ec.europa.eu/employment_social/social_security_schemes/docs/eform_healthcare_En.pdf.

as to integrate new ECJ jurisprudence. Already, in 2003, its personal scope was extended to include non-EU nationals who are affiliated to a social security scheme within the EU.[17] In 2004, a new Social Security Regulation (Regulation 883/04/EC) was adopted to replace Regulation 1408/71/EEC.[18] However, this new Regulation will only enter into force after the adoption of a new implementing regulation replacing Regulation 574/72/EEC.[19]

Besides the complexity and rigidity often imputed to this framework of social security coordination, it also suffers from some practical and administrative problems (see also section three), which induce 'competition' with the more flexible Treaty-based access route as created by the case-law of the European Court of Justice. However, as is often repeated, the coordination mechanism also offers considerable advantages over the free choice model derived from the jurisprudence: patients using the well-defined procedures of Article 22 of Regulation 1408/71/EEC are better ensured that eventually their health care costs will be covered; they do not need to advance payment, as they can benefit from the third party payer system in place in the country of treatment; they have better guarantees that the level of coverage will match more closely the tariff charged by the treating provider and, in some cases, they can be covered for services that are not even included in the benefit basket of their country of affiliation. It is due to the fact that the social security coordination mechanism grants rights and advantages that citizens would not have otherwise that the ECJ has explicitly upheld the coordination route.[20]

C. The case-law of the European Court of Justice

Traditionally, the European Court of Justice has played an important role in defining citizens' entitlements to care outside their state of affiliation,[21] first within the context of the classical coordination route,

[17] Council Regulation 859/2003/EC extending the provisions of Regulation 1408/71/EEC and Regulation 574/72/EEC to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, OJ 2003 No. L124/1.

[18] European Parliament and Council Regulation 883/04/EC on the coordination of social security systems, OJ 2004 No. L166/1.

[19] A proposal was submitted by the Commission in early 2006. See www.secu.lu/legis/EURO-INT/reg_app_2004_883_prop/rapport%20gqs.pdf.

[20] Case C-56/01, *Inizan*, above n.15, para. 22.

[21] For example, Case 182/78, *Pierik* [1979] ECR 01977.

and, more recently, also by directly relying on the EC Treaty. As will become clear, this has had far-reaching implications.

Since 1998, through the case-law of the ECJ,[22] an alternative procedure for the assumption of health care delivered by a provider established in another Member State has been created.[23] Contrary to the social security coordination framework, this route is directly based on the fundamental principles of free movement of goods and services as enshrined in Articles 28 and 49 of the EC Treaty, respectively. It is settled case-law that medical activities fall within the scope of Article 50 EC, which defines what is to be considered a service under the EC Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment, or to have regard to the special nature of certain services.[24] Indeed, the Court made clear that a medical service provided in one Member State and paid for by the patient should not cease to fall within the scope of the freedom to provide services (Article 49 EC) merely because reimbursement of the costs of the treatment involved is applied for under another Member State's sickness insurance legislation, be it based on reimbursement, benefits in kind or national health service.[25]

Consequently, reimbursement for cross-border care cannot be unduly restricted. The actions brought before the ECJ were mainly inspired by the restrictive pre-authorization policies that Member States applied, refusing patients permission to obtain treatment outside the state of affiliation. Although the Court repeatedly confirmed that Community law does not detract from the powers of the Member States to organize their social security systems, at the same time it made clear that Member States nevertheless must comply with

[22] Case C-120/95, *Decker* v. *Caisse de Maladie des Employés Privés* [1998] ECR 1831; Case C-158/96, *Kohll*, above n.15; Case C-157/99, *Geraets-Smits and Peerbooms* [2001] ECR 5473; Case C-385/99, *Müller-Fauré* [2003] ECR 4509; Case C-372/04, *Watts* [2006] ECR I-4325; Case C-444/05, *Stamatelaki* [2007] ECR I-3185.

[23] For a detailed description of the case-law, see E. Mossialos and W. Palm, 'The European Court of Justice and the free movement of patients in the European Union', *International Social Security Review* 56 (2003), 3–29.

[24] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, paras. 53–4.

[25] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 55; Case C-385/99, *Müller-Fauré*, above n.22, para. 103; Case C-372/04, *Watts*, above n.22, para. 89.

Community law when exercising those powers.[26] Any measure that would deter or prevent citizens from seeking treatment from foreign providers is prohibited unless it can be justified by overriding reasons of general interest and proves to be necessary, proportional and non-discriminatory.[27]

Clearly, limiting the reimbursement of health care to providers established in the Member State of affiliation would be contrary to Article 49 EC. This was made clear in a case initiated by the Commission against France in which a French provision rendering impossible the reimbursement of the costs of biomedical analyses performed by a German laboratory on the basis that it did not have a place of business in France was held to be unlawful as it could not be justified by the need to maintain a high level of health protection.[28] In addition, submitting statutory cover for care provided in another Member State to the condition of prior authorization was regarded as an obstacle to the freedom to provide services, since it would deter or even prevent people from seeking care outside their home state.[29] Even if prior authorization were required to receive coverage in the state of affiliation, it would be considered, both for patients and for foreign service providers, to be a hindrance to free movement if authorization were more difficult to obtain for treatment abroad. This reasoning was followed in the *Leichtle* case, where the statutory cover for a health care service provided outside Germany was subject to the condition that it had to be established in a report drawn up by a medical officer or medical consultant that the health care was absolutely necessary

[26] In the absence of harmonization at the Community level, it is for the legislation of each Member State to determine the conditions in which social security benefits are granted. However, when exercising that power, Member States must comply with Community law, in particular the provisions on the freedom to provide services. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the health care sector. Case C-158/96, *Kohll*, above n.15, paras. 17–9; Case C-157/99, *Geraets-Smits and Peerbooms*, paras. 44–6; Case C-385/99, *Müller-Fauré*, above n.22, para. 100; Case C-56/01, *Inizan*, above n.15, para. 17.

[27] See, further, Chapter 11 in this volume.

[28] Case C-496/01, *Commission* v. *France* [2004] ECR I-02351.

[29] Case C-158/96, *Kohll*, above n.15, para. 35; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 69; Case C-56/01, *Inizan*, above n.15, para. 54; Case C-372/04, *Watts*, above n.22, para. 98.

owing to the greatly increased prospects of success outside the Federal Republic of Germany.[30]

On the other hand, citizens cannot rely on Article 49 EC in order to claim reimbursement for a service that is not included in their home state's benefit package, provided that the list is drawn up in accordance with objective criteria, without reference to the origin of the products or services. This is why, in the case of two Dutch patients who received 'experimental treatment' in another Member State, the ECJ stated that if a Member State's legislature (i.e., the Dutch) has enacted a general rule under which the costs of medical treatment will be assumed – provided that the treatment is 'normal in the (Dutch) professional circles concerned' – only an interpretation on the basis of what is 'sufficiently tried and tested by international medical science' can be regarded as satisfying these requirements.[31]

In practice, the ECJ is of the opinion that the condition of prior authorization cannot be justified for non-hospital services. Judging the case of a Dutch insured person who preferred to obtain dental treatment from a German dentist, the Court considered that its removal would not seriously undermine the financial balance of the social security system nor jeopardize the overall level of public health protection, since it was not expected that patients would be willing to travel to other countries in large numbers for this type of care, given linguistic barriers, geographic distance, the cost of staying abroad and lack of information about the kind of care provided there.[32] Furthermore, in principle, the choice of patients to receive services in another Member State would have no or only limited financial impact, as patients would only be entitled to claim reimbursement of the cost of the treatment within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation.[33] Consequently, EU citizens should be granted reimbursement for outpatient care in another Member State under the same conditions and according to the same tariffs as applicable at home. In other words, not only is the legal base of this Treaty-based procedure different from the traditional social security coordination procedure (free movement

[30] Case C-8/02, *Leichtle* [2004] ECR I-02641, para. 32.
[31] C-157/99, *Geraets-Smits and Peerbooms*, above n.22, paras. 85–9 (referring to Case 238/82, *Duphar* [1984] ECR 00523) and paras. 17–21, 91–4.
[32] Case C-385/99, *Müller-Fauré*, above n.22, para. 95. [33] *Ibid.*, para. 98.

of services and goods versus free movement of persons), it also applies a different concept of equal treatment: whereas, under social security coordination, cross-border patients are treated *as though they were insured in the country of treatment*, under the Treaty-based route they are treated *as though the treatment were provided in the country of affiliation*.

For hospital services, by contrast, the Court accepted that submitting statutory cover for services provided in another Member State to prior authorization could be justified as a necessary and reasonable measure, since its removal would jeopardize the planning of hospital services, which is considered necessary to guarantee a rationalized, stable, balanced and accessible supply of hospital services to the entire population. Also, it recognized that the hospital sector generates considerable costs and must satisfy increasing needs, while the financial resources that may be made available to health care are not unlimited, whatever the mode of funding applied. Therefore, planning, possibly through a contracting system, is also considered to be necessary in order to control costs and prevent wastage of financial, technical and human resources.[34]

Even though the ECJ accepted prior authorization for hospital services, the discretionary power of Member States to apply this condition was restricted. The ECJ underlined that prior authorization could not be used arbitrarily, as it should be based on objective, non-discriminatory criteria that are knowable in advance. Moreover, a prior administrative authorization scheme must be based on a procedural system that is easily accessible and capable of ensuring that a request for authorization will be dealt with objectively and impartially within a reasonable time, and in which refusals to grant authorization can be challenged in judicial or quasi-judicial proceedings.[35] The practical implications of this will be further elaborated in section three.

By creating a procedure for the reimbursement of health care costs generated outside the Member State of affiliation that is directly based on the EC Treaty, and concurrently maintaining the pre-authorized procedure, as included under the social security coordination regime

[34] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, paras. 76–8; Case C-385/99, *Müller-Fauré*, above n.22, paras. 77–82; Case C-372/04, *Watts*, above n.22, paras. 108–12.

[35] Case C-372/04, *Watts*, above n.22, para. 116.

(see section three), the Court has created a dual system of access to cross-border care.[36] This has added to the administrative complexity and the lack of clarity of entitlements.[37]

D. The policy response to the ECJ rulings

Concerned by the advances of the free movement principles into national health care territory and by the ECJ's expansive approach, Member States have sought to regain control over developments by moving decision-making in this area away from the juridical sphere and into the political domain. There are two sets of motivations underlying this intervention: (a) to improve legal certainty regarding the application of free movement rules to health care; and (b) to support Member States, and foster cooperation between them, in certain fields from which patient mobility would benefit (sharing resources, ensuring quality and safety and sharing information).[38] Whereas national governments initiated the discussion on patient mobility, gradually the Commission has taken the driver's seat in steering the political process.

Following several early fruitful initiatives during the Belgian and Spanish Presidencies in the second half of 2001 and first half of 2002, which mainly served to raise awareness among Member States about the potential challenges for health care systems posed by free movement, the Council of Health Ministers agreed in June 2002 to launch a 'High Level Process of Reflection'. Intended as a forum where delegates from the Member States and the European Commission, together with stakeholder representatives and the European Parliament, could examine and discuss issues related to patient mobility and health care developments in the light of European integration, the one-year process concluded in December 2003 with a series of nineteen recommendations on how to take cooperation forward to promote the better use

[36] W. Palm *et al.*, 'Implications of recent jurisprudence on the coordination of healthcare protection systems', General report produced for the Directorate-General for Employment and Social Affairs of the European Commission (2000), p. 132.

[37] T. Hervey and L. Trubek, 'Freedom to provide health care services within the EU: an opportunity for a transformative directive', *Columbia Journal of European Law* 13 (2007), 623–49.

[38] European Commission, 'Consultation', above n.7.

of resources, improve the sharing of information, accessibility and quality of care, and to reconcile national health policy goals with European internal market obligations. One of these recommendations invited the European Commission 'to consider the development of a permanent mechanism at EU level to support European cooperation in the field of health care and to monitor the impact of the EU on health systems'.[39] This materialized in July 2004 in the High Level Group on Health Services and Medical Care (HLG), which was to take forward the work initiated by the High Level Process of Reflection. In the HLG, representatives from Member States together with technical experts, organized in working groups, tackle issues related to seven main areas: cross-border health care purchasing and provision, health professionals, centres of reference, health technology assessment, information and e-health, health impact assessment and health systems, and patient safety. The work and focus of the HLG reflects the attention given to cross-border health care. One of the outcomes was the production, in late 2005, of a set of non-binding guidelines for the purchasing of treatment abroad. The guidelines aim to propose a framework to enhance both (legal and financial) clarity for contracting partners and the protection of patients and health care systems.[40] Also in 2005, the working group on centres of reference commissioned an expert report on rare diseases. The report provides an overview of Member States' different approaches to rare diseases and explores the potential for establishing European networks of reference centres.

Yet Member States' (sudden) willingness to engage in political debates on health care, an area traditionally jealously guarded from EU interference, should be seen in the context of the increasing pressure on national governments to accept the application of internal market rules in national health systems. Besides the sequence of new cases before the ECJ involving different Member States, as well as different types of health systems and of health services, the European Commission also pursued its role of guarding compliance with Community law and following its pro-market agenda. In a report on the application of internal market rules to health services

[39] http://ec.europa.eu/health/ph_overview/Documents/key01_mobility_En.pdf.
[40] http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2005_017_en.pdf.

(July 2003) issued by DG MARKT, the Commission concluded that the internal market in health services was not functioning satisfactorily and European citizens were encountering unjustified or disproportionate obstacles when applying for reimbursement or authorization.[41] Whereas reference was made to the High Level Process of Reflection, the report already clearly indicated that other tools were being considered to ensure Member States' compliance with the Court's rulings, including creating a Community legal framework. Even though, since 1998, Member States had been preparing the modernization and simplification of the existing legal framework of social security coordination, which was considered to be too complex and bureaucratic and therefore not fit to absorb the changes taking place, attempts to integrate the new Treaty-based procedure into the new Social Security Coordination Regulation 883/04/EC failed.[42]

In early 2004, the Commission put forward its proposal for a directive on services in the internal market.[43] In its draft, which envisaged the realization of the internal market for services through a horizontal non-sectoral approach, health services were included in the scope of application, while a specific article (Article 23) codified the ECJ jurisprudence on the assumption of health care costs in another Member State. This provision stipulated that Member States could not make the assumption of the costs of non-hospital care in another Member State subject to the granting of an authorization where the cost of that care would have been assumed by their social security system if provided in the national territory. This should, however, not prevent Member States from maintaining conditions

[41] European Commission, 'Report on the application of internal market rules to health services by the European Commission', Commission Staff Working Paper, SEC (2003) 900, 28 July 2003.

[42] When the new Regulation 883/04, above n.18, was adopted, the revision of the chapter on sickness and maternity benefits was already concluded under the Danish Presidency in the second half of 2002.

[43] European Commission, 'Proposal for a European Parliament and Council Directive on services in the internal market', COM (2004) 2 final, 5 March 2004. For a complete analysis, see R. Baeten, 'The potential impact of the services directive on healthcare services', in P. Nihoul and A.-C. Simon (eds.), *L'Europe et les soins de santé* (Brussels: De Boeck/Larcier, 2005), pp. 239–62; E. Van den Abeele, 'Adoption of the Service Directive: a Community big bang or a velvet revolution?', in C. Degryse and P. Pochet (eds.), *Social developments in the European Union 2006* (Brussels: Observatoire social européen, Saltsa, 2007), pp. 127–59.

and formalities, such as a referral system, to which they make the receipt of this care subject in their territory. For hospital care provided in another Member State,[44] Article 23 requested that Member States ensure that prior authorization would not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation and where such treatment cannot be given to the patient within a time frame that is medically acceptable in light of the patient's current state of health and the probable course of the illness.[45] In any case, statutory cover for care provided in another Member State should not be lower than that provided by their social security system for similar health care services provided in the national territory.

The approach set out in Article 23 of increasing legal certainty by codifying ECJ case-law in a horizontal directive aimed at establishing an internal market for services as a whole was also confirmed by the Commission's follow-up Communication on the High Level Process.[46] However, the European Parliament, in a motion in April 2005 referring to the special nature of health care, disapproved of this approach and requested a separate Commission proposal.[47] The legislature's stance was later confirmed when the European Parliament, after months of heated debate, voted on 16 February 2006 for the exclusion of health services from the Services Directive. As a consequence, the Commission announced in its amended proposal of April 2006 that it would present a separate legal initiative covering health care services.

[44] European Commission, 'Proposal', above n.43, Article 4 defined hospital care as medical care that can be provided only within a medical infrastructure and that normally requires the accommodation therein of the person receiving the care, the name, organization and financing of that infrastructure being irrelevant for the purposes of classifying such care as hospital care.

[45] Also, European Commission, 'Proposal', above n.43, required that prior authorization for treatment provided in another Member State be in conformity with the general requirement for any authorization scheme, such as the conditions of non-discrimination, necessity, proportionality, objectivity, publicity, legal certainty and openness to legal challenge (Article 23(4)).

[46] European Commission, 'Follow-up to the High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union', COM (2004) 301 final, 20 April 2004.

[47] J. Bowis, 'European Parliament report on patient mobility and healthcare developments in the European Union', A6–0129/2005, 29 April 2005.

In a new communication published in September 2006 – this time by DG SANCO – the Commission set out a broader perspective for addressing health services at EU level.[48] The new Community framework is to ensure safe, high quality and efficient health services throughout the European Union by reinforcing cooperation between Member States and resolving legal uncertainties over the application of Community law to health services and health care. In order to gain an insight into Member States' and stakeholders' views as to how to achieve this, the Commission initiated a large public consultation process between September 2006 and February 2007.[49] The consultation confirmed the need for a broad approach, not only addressing financial aspects but also issues such as clinical oversight, continuity of care, medical liability and redress.[50] Also, the need for more and clearer information was emphasized repeatedly.[51] However, given the diversity of health systems and the variable directions and levels of developing policy in different areas, it is difficult to find consensus on the appropriate measures to take. Apart from clarifying legal issues, a bottom-up approach is generally preferred for establishing the necessary context of safe, high-quality and efficient care to be guaranteed to citizens wishing to be treated outside their home state.[52]

The Commission was expected to put forward a new legislative proposal by the end of 2007. However, internal differences within the College of Commissioners,[53] as well as political factors and considerations, such as a change of Health Commissioner, the ratification process of the Lisbon Treaty and the political fear of a new flare-up of heated discussions on the role of the EU in health care, delayed the process. Finally, on 2 July 2008, the long awaited proposal for a directive on the application of patients' rights in

[48] European Commission, 'Consultation', above n.7.
[49] Baeten, 'The potential impact', above n.43.
[50] European Commission, 'Summary report of the responses to the consultation regarding "Community action on health services" ', Health and Consumer Protection Directorate-General, 20 April 2007.
[51] See also W. Palm, M. Wismar and K. Ernst, 'Assessing possible directions for the Community action on healthcare services: summary of the expert panels', in Wismar *et al.* (eds.), *Cross-border healthcare*, above n.4.
[52] *Ibid.*, p. 6.
[53] EurActive, 'Confusion surrounds EU's health services directive', *EurActiv*, 28 January 2008; Europolitics, 'Wallström raises objections to Kyprianou's directive', *Europolitics*, 17 December 2007.

cross-border health care was issued in the context of the renewed social agenda.[54] While taking a broader approach, including provisions for ensuring the quality and safety of cross-border care, as well as other flanking measures to support optimal conditions for treatment undertaken throughout the EU, at the same time the proposal stays faithful to the principles set out in the ECJ case-law. To some extent, this new proposal could be regarded as going even further than the former Article 23 in the Services Directive, which kept close to the wording and scope of the ECJ rulings – i.e., very much based on the distinction between hospital and non-hospital care. The relevant Chapter III in the new proposal, on the use of health care in another Member State, starts by first establishing the general principle that Member States should not prevent their insured citizens from receiving health care that is included in their own benefit baskets in another Member State (Article 6(1)). For that reason, it stipulates that health care provided in another Member State should be statutorily reimbursed up to the same level as 'had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received' (Article 6(2)). That reimbursement – at least for the costs of non-hospital care – shall not be made subject to prior authorization (Article 7). For hospital care,[55] the proposal accepts that Member States, under certain conditions, may uphold a system of prior authorization (Article 8(3)). This is the case when the treatment would have been assumed by the Member State's social security system had it been provided in its territory and when the purpose of the system is to address the outflow of patients if it seriously undermines (or at least is likely to undermine) the financial balance of a Member State's social security system and/or the planning and rationalization carried out in the hospital sector in order to ensure

[54] European Commission, 'Proposal for a European Parliament and Council Directive on the application of patients' rights in cross-border healthcare', COM (2008) 414 final, 2 July 2008.

[55] Hospital care in *ibid*., is defined as health care that requires overnight accommodation of the patient of at least one night (Article 8(1)(a)), while leaving the possibility to extend this to out-patient healthcare to be included on a specific list set up and regularly updated by the Commission, which either require the use of highly specialized and cost-intensive medical infrastructure or medical equipment or involve treatments that present a particular risk for the patient or the population (Article 8(1)(b)).

'the maintenance of a balanced medical and hospital service open to all or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State' by avoiding hospital overcapacity, imbalance in supply and wastage.

Clearly, the acceptance of a system of prior authorization for hospital care is no longer taken for granted but made subject to conditions that may be difficult to prove. Even though the specific wording of Article 8(3) may lead us to believe that Member States are not required to prove the actual undermining effect of a generalized implementation of the Directive, but only demonstrate that the prior authorization system is put in place with the purpose of preventing any distortion, Article 8(4) unambiguously states that the prior authorization system must be limited to what is necessary and proportionate to avoid such an impact. Along the same lines, while the proposal, in principle, accepts that the Member State of affiliation can impose on the patient using cross-border care the same conditions, criteria of eligibility and regulatory and administrative formalities as would apply at home (Article 6(3)), at the same time these conditions, criteria and formalities, as well as the reimbursement procedures and criteria for health care in another Member State, need to meet the non-discrimination test, as well as the Necessity and Proportionality Test (Article 9(1)).[56] In other words, the proposal is not likely to reassure Member States as to their control over patient flows and the financial implications, since it sheds more doubt in terms of the applicable benefit package ('same or similar health care'), the use of prior authorization for hospital treatment in another Member State, and on the conformity of conditions and formalities to which statutory reimbursement can be made subject.[57]

[56] See Chapter 10 in this volume on the justification of obstacles to free movement of health services in the EU.

[57] Whilst finalizing this book, the Council of the European Union was in the process of substantially amending the proposal and the European Parliament adopted a legislative resolution amending the proposal in first reading. See Council of the European Union, 'Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare', Progress Report, Document 16514/08, Brussels, 11 December 2008; European Parliament Legislative Resolution of 23 April 2009 on the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008)0414 – C6–0257/2008 – 2008/0142(COD)).

E. Cooperation initiatives and contractual arrangements in the field

Actors in the field and public authorities, either national or regional, have not awaited guidance or consensus from the European level to seek more adapted solutions to enable and coordinate patient mobility. Already in the early 1990s, cross-border projects emerged, especially in intra-Community border regions, with the purpose of relaxing access to health service providers across the border or stimulating exchange and cooperation between administrations and other actors. Since then, cross-border cooperation has consolidated and matured in many places.[58]

As a more tailor-made solution, patient mobility can be arranged through direct cross-border contractual agreements involving at least two cooperating partners in different Member States setting up a contract to allow for patient flows. This can be between health care providers (private or public), insurers (private or public) and/or public bodies (at the local, regional or national levels).[59] These contracts generally determine the scope of the specific arrangement (both personal and material), specify the financial conditions and address other organizational aspects, such as transportation to and from the foreign hospital, the planning of after-care, etc. While arrangements involving statutory bodies generally follow the conditions and financial rules as determined in the social security coordination mechanism (see above), contractual arrangements (with no official involvement) often deviate from the coordination mechanism, as signing parties define different procedures and rules. This means that new elements and practices may enter a health care system via the cross-border contracting route.[60]

[58] I. Glinos, 'Cross-border collaboration', in Wismar *et al.* (eds.), *Cross-border healthcare*, above n.4.

[59] I. A. Glinos, R. Baeten and N. Boffin, 'Cross-border contracted care in Belgian hospitals', in M. Rosenmöller, M. McKee and R. Baeten (eds.), *Patient mobility in the European Union: learning from experience* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2006), pp. 97–119; T. Nebling and H.-W. Schemken, 'Cross-border contracting: the German experience', in M. Rosenmöller, M. McKee and R. Baeten (eds.), *Patient mobility in the European Union: learning from experience* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2006), pp. 137–56.

[60] See below.

3. Types of patient mobility and related arrangements for access

Within the broad spectrum of possible patient movements between Member States, different patient mobility types can be distinguished.[61] The most obvious distinction is between persons *needing* medical assistance while abroad (they first move, then need care) and persons *seeking* medical care abroad (they first need care, then move). Furthermore, two special categories can be identified: people living in border regions and pensioners settling in another Member State. Although these two groups represent specific features and particularities in their own right, both in terms of needs for cross-border care, as well as in terms of arrangements through which patient mobility takes place, they will be examined in the context of the two main categories above.

By 'arrangements', we mean the financial and organizational mechanisms in place to enable cross-border consumption of care and financial cover for treatment in another Member State. These arrangements constitute patient mobility 'routes', which have different origins and legal bases. As set out above, we can distinguish between three main types: the traditional coordination route, the Treaty-based route established by the ECJ case-law and the contractual route initiated bilaterally between actors in the field. The three types of arrangements differ noticeably, not just in practical and financial terms, but also in terms of which actor leads the mobility process. While the first type is a typical statutory arrangement led by public authorities, the second type is mainly driven by individual citizens (who can afford to pay up-front, as well as to cover travel and accommodation costs). In the third type, decision-making is in the hands of contracting partners. The arrangements that are relevant for each of the different patient types will be explained in greater detail below.

A. People seeking treatment abroad

In the context of the internationalization of health care, it seems to follow that patients deliberately and increasingly go abroad to obtain treatment outside the Member State of residence. Patients can be

[61] H. Legido-Quigley *et al.*, 'Patient mobility in the European Union', *British Medical Journal* 334 (2007), 188–90. See also M. Rosenmöller *et al.*, 'Patient mobility: the context and issues', in Rosenmöller, McKee and Baeten (eds.),

motivated to do so for various reasons: because they are confronted with waiting times at home; because the specific treatment is not available or is forbidden in their country; because of the reputation of a specific provider or treatment centre in another Member State; or because care is cheaper abroad.[62] Patients compare what is available at home and abroad, and depending on their preferences, needs and abilities, might choose to travel to obtain care.

Patients can either be sent abroad by their health system or go on their own initiative, although the two situations may be interlinked and a clear distinction would be difficult to make: patients wanting to be treated abroad might first try to obtain authorization for reimbursement reasons or patients being denied authorization might ultimately choose to go anyway and possibly legally challenge the refusal afterwards before a court. In addition, treatment providers at home often play a key role in referring patients to treatment in another Member State, as reliable information on treatment options to the general public is still scarce and scattered.[63]

Hereunder we will address the situation of patients using either the Treaty-based or the coordination route to obtain cover for treatment in another Member State. Also, special attention will be given to people living in border regions, as well as to patients getting treatment abroad in the context of pre-arranged – mostly bilateral – schemes. Finally, we will also mention purely private patients.

The remaining scope of prior authorization

As set out above, citizens in the EU fall under the principle of free movement of goods and services and are free to take up medical treatment or buy medical goods throughout the European Union.[64] Any measure that would hinder the free delivery of services and supply of goods – and its corollary of free reception of services and goods – needs to be justified on grounds of public policy, public security or public health or by overriding reasons of general interest. This also applies to the field of statutory health cover.[65] As already outlined, the

Patient mobility, above n.59, pp. 6–7; and Glinos and Baeten, 'A literature review', above n.2, pp. 18–21.

[62] Glinos and Baeten, 'A literature review', above n.2, pp. 18–21.

[63] Palm, Wismar and Ernst, 'Assessing possible directions', above n.51, p. 19.

[64] Joined Cases 286/82 and 26/83, *Luisi and Carbone* [1984] ECR 00377; and Case C-159/90, *SPUC* v. *Grogan* [1991] ECR I-04685.

[65] See above.

ECJ has defined the ambit of access to statutorily covered treatment not requiring prior authorization outside the state of affiliation.

Patients are free to take up non-hospital care in any Member State and claim for reimbursement with their social security system according to the tariffs and modalities applied there. In other words, treatment is covered as though it were provided in the Member State of affiliation – which also means that the treatment must be covered by the statutory system of the patient's home state. Member States have only gradually modified their administrative practices accordingly. Luxembourg and Belgium were among the first to apply 'open borders' for outpatient care.[66] Austria already applied a system of partial reimbursement of non-pre-authorized care abroad before the first rulings of the Court.[67] Germany introduced reforms in 2004 stipulating that non-hospital care is exempt from the prior authorization requirement,[68] while France and the Netherlands changed their respective legislation along similar lines in 2005.[69] With the new cross-border health care patients' rights proposal, it is expected that non-hospital care received in another Member State will be reimbursed without any additional condition up to the level of costs that would have been assumed had the same or similar health care been provided in the Member State of affiliation, without exceeding the actual costs of health care received (Articles 6(2) and 7). In cases where Member States do not have an existing set of defined reimbursement levels, they are required to put in place a mechanism for calculation based on objective, non-discriminatory criteria known in advance (Article 6(4)).

For hospital services – or, more precisely, services requiring planning in order *to guarantee a rationalized, stable, balanced and accessible*

[66] Initially, Belgium limited reimbursement for non-hospital care provided in another Member State without prior authorization to a ceiling of coverage up to €500 (later extended to €1000). This limitation was abolished in 2005. Also, the arrangement was, subject to certain conditions, further extended to day hospitalization, clinical laboratory analyses and pharmaceuticals purchased abroad.

[67] Palm *et al.*, 'Implications of recent jurisprudence', above n.36, p. 47.

[68] D. S. Martinsen, *EU for the patients: developments, impacts, challenges*, Report 6 (Stockholm: Swedish Institute for European Policy Studies, 2007), p. 37.

[69] M. Coucheir and Y. Jorens, 'Patient mobility in the European Union – the European framework in relation to patient mobility', Report written for the European 6th Framework Project 'Europe for Patients', European Commission, DG Research (2007).

supply of hospital services[70] – the ECJ accepted that reimbursement could be made subject to prior authorization for as long as it could be considered to be necessary, proportionate and based on objective, non-discriminatory criteria that are knowable in advance.[71] The ECJ argued that a large outflow of patients to be treated in other Member States would be liable to put at risk the very principle of having contractual arrangements with hospitals and, consequently, undermine all the planning and rationalization carried out in this vital sector to avoid the phenomena of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage.[72] In the *Stamatelaki* case, the absolute exclusion of any treatment in private hospitals abroad from statutory cover under the Greek legislation was considered by the ECJ to be a disproportionate measure, especially since restrictions on access to care in private Greek institutions were less severe.[73] As mentioned earlier, the European Commission in its new proposal for a directive has limited the use of prior authorization systems for statutory reimbursement along the same lines (Article 8(3–4)). It also obliges Member States to specify in advance and in a transparent way the criteria for refusal of prior authorization (Article 9(3)).

Although it is up to Member States to further define the scope of their authorization policies within these limits,[74] the ECJ has made clear that authorization cannot be refused for health care that is part of the statutory benefit package in the state of affiliation and that cannot be obtained there within medically justifiable time limits.[75] To properly assess the latter concept of 'undue delay' – the lack of timely access to the treatment at home – the competent institution is required to take account of all the circumstances of each individual case, including the patient's medical condition. In the cases of Mrs Van Riet and Mrs Watts, the ECJ made clear that, although Member States are entitled to institute a system of waiting lists to manage the supply

[70] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 81.
[71] See above.
[72] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 106.
[73] Case C-444/05, *Stamatelaki*, above n.22, paras. 27, 38.
[74] On the national practices in terms of prior authorization, see Y. Jorens, 'Cross-border health care: the use of E112 form', Training and Reporting on European Social Security (2007), p. 14; Coucheir and Jorens, 'Patient mobility', above n.69.
[75] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 103.

of treatments and to set priorities on the basis of available resources and capacities, the existence of waiting lists in itself could not justify a refusal to authorize hospital treatment in another Member State.[76] Only if the waiting time does not exceed the period that is acceptable in light of an objective medical assessment of the clinical needs of the person concerned, taking into consideration the medical condition, the history and probable course of the illness, the degree of pain and/or the nature of the disability at the time when the authorization is sought, can authorization for treatment in another Member State be refused.[77] This reasoning has effectively opened up new opportunities for patients in the EU – rights that they might not have in their home system. When Mrs Watts brought her case in front of the High Court, the English judge in charge examined domestic legislation and human rights law to conclude that they did not constitute a basis for providing National Health Service (NHS) patients with a right to treatment. Yet, turning to EU law, the judge conceded that the freedom to seek and provide services in the EU entitles English patients to look for treatment abroad. As the Department of Health appealed against this decision, the *Watts* case reached the ECJ in early 2004.[78]

In order to establish more certainty around the concept of undue delay, some countries have started to introduce so-called 'time-dependent' guarantees, giving patients the right to be treated outside the national system and to go abroad for care if treatment is not available in the home system within specified time periods. Such treatment guarantees were introduced in 2002 in Denmark[79] and in 2004 in Norway.[80] The Irish National Treatment Purchase Fund (NTPF) has a similar effect of guaranteeing NHS patients timely access by commissioning services from the private sector, and there appears to be a shift in the approach among the English judiciary too (see above). Denmark has

[76] Case C-385/99, *Müller-Fauré*, above n.22, para. 92; Case C-372/04, *Watts*, above n.22, para. 75.

[77] Case C-157/99, *Geraets-Smits and Peerbooms*, above n.22, para. 104; Case C-372/04, *Watts*, above n.22, paras. 67–70, 119.

[78] J. Montgomery, 'Impact of EU law on English healthcare law', in E. Spaventa and M. Dougan (eds.), *Social welfare and EU law* (Oxford: Hart, 2003), pp. 145–56.

[79] Indenrigs- og Sundhedsministeriet, *Resultater paa sundhedsomraadet* (Copenhagen: Ministry of the Interior and Health, 2004).

[80] Trygdeetaten, *Bidrag til behandling i utlandet etter paragraf 5–22* (Oslo: Trygdeetaten/National Insurance Administration, 2004).

been one of the few Member States to adapt a revised national health policy following the *Kohll* and *Decker* rulings and later to implement a health reform to address waiting lists.[81] The 2002 reform guaranteeing Danish patients the right to be treated by a non-contracted (foreign) hospital if treatment is not available from a contracted provider within two months can be seen as a reaction to the *Geraets-Smits and Peerbooms* ruling.[82] Indeed, the preparatory documents on the reform make an explicit link between the ruling and the opening up of the Danish public system to allow access to publicly paid treatments outside the statutory system independently of whether care is provided in Denmark or another Member State. Since 1 October 2007, the waiting time criterion has been further reduced to one month.[83]

Other countries have also softened their policies by incorporating new rights into national law. In France, reforms in 2004–5 on the reimbursement of costs replaced the term 'abroad' with 'outside a Member State of the European Union or party to the agreement on the European Economic Area', thus signalling that restitution of health care consumed in EU/EEA Member States is not considered to be an exemption to the territoriality principle but rather to be a *right* of insured persons (subject to certain conditions allowed by the ECJ).[84] In Sweden, a series of cases brought before the Supreme Administrative Court regarding reimbursement by the national health insurance system for non-emergency care provided in Germany and France[85] also led to the Swedish authorities revising their policy towards treatment abroad after the national court recognized the right to compensation for care – even hospital care – that would have been reimbursed by the Swedish health care system if the care had been delivered in Sweden.[86]

[81] D. S. Martinsen, 'Towards an internal health markets with the European court', *West European Politics* 28 (2005), 1035–56.

[82] D. S. Martinsen, 'The Europeanization of welfare – the domestic impact of intra-European social security', *Journal of Common Market Studies* 43 (2005), 1027–54.

[83] Martinsen, *EU for the patients*, above n.68.

[84] Coucheir and Jorens, 'Patient mobility', above n.69.

[85] Case No. 6790–01, *Stigell* v. *The National Social Insurance Board*, Swedish Supreme Administrative Court; Case No. 6396–01, *Wistrand* v. *National Social Insurance Board*, Swedish Supreme Administrative Court; Case No. 5595–99, *Jelinek* v. *National Social Insurance Board*, Swedish Supreme Administrative Court.

[86] T. Palmqvist, 'Answers to questionnaire on the impact of EU law on national health care systems', Swedish Ministry of Health and Social

The increased choice options for patient via the access routes to care abroad sometimes also has implications for the way access to care is regulated nationally. Following the *Müller-Fauré* ruling of the ECJ, the Netherlands reviewed the principle that patients seeking care with non-contracted providers would not be covered at all. Recent French legislation is also illustrative in this respect. In mid-2004, a system of mild gatekeeping was adopted in France as part of the reorganization of the sickness insurance scheme. The new system foresees that people can register with an attending doctor of their choice (GP or specialist) who will be responsible for coordinating the patient's treatment pathway. If a patient chooses not to register or to see another doctor without prior referral, the amount of restitution from the sickness fund will be reduced. Yet a circular from May 2005 exempts insured French people from following the treatment pathway when in another Member State, and recognizes the right to choose an attending doctor in another Member State on the condition that the foreign health professional exercises the profession lawfully in the country of establishment and accepts the responsibility of being attending doctor according to French practices.[87]

Adjustments to the coordination route

Even if, in light of Articles 49 and 50 EC, the scope for denying cover of deliberate treatment in another Member State was seriously reduced, the general requirement of a prior authorization, which traditionally had also been provided for under Article 22(1)(c) of Regulation 1408/71/EEC and which is formalized through the granting of an E112 form, was upheld by the ECJ.

Given that insured persons under the coordination route are granted rights that they would not otherwise have, as they may claim reimbursement in accordance with the legislation of the place of stay, the ECJ in its *Inizan* judgement explicitly confirmed the consistency of the coordination route with Articles 49 and 50 EC on the freedom to provide services. Indeed, the Community legislator is free to accord

Affairs, 1 December 2006; questionnaire organized and sent to Member States by Observatoire social européen; U. Bernitz, 'Everyone's right to health care in Europe: the way forward', Paper prepared for the European Parliament Committee Meeting on Cross-Border Aspects of Health Services, 24 January 2007, pp. 3–4.

[87] Coucheir and Jorens, 'Patient mobility', above n.69.

rights and advantages in order to ensure freedom of movement for workers and also to attach conditions to or determine the limits thereof.[88] Nevertheless, the ECJ reinterpreted the provision of Article 22 in light of Articles 49 and 50 on two points.

First, the scope for denying prior authorization was aligned to the conditions set out above. From the *Inizan* ruling, it became clear that Member States could not take into account normal waiting times in order to assess whether they should authorize treatment abroad under the Social Security Regulation.[89] Whereas Article 22(2) initially stated that prior authorization may not be refused if the treatment in question is covered by the home state but cannot be given within the time normally necessary, the ECJ clarified that this should be understood in such a way that the request for authorization could not be turned down whenever treatment that is the same or equally effective for the patient – and that is part of the statutory benefit package – cannot be obtained without undue delay in the Member State of residence.[90] Since then, this change has been incorporated into Article 20(2) of the new Regulation 883/04/EC. It should be noted in this respect that Member States may grant authorizations for treatment in another Member State on a much wider basis even when the treatment is available without undue delay. Article 22(2) of the Regulation merely indicates when such authorizations may not be refused, but it does not set any limits as to when they may be granted.[91]

Since the conditions according to which prior authorization cannot be refused under Article 22(2) of Regulation 1408/71/EEC were completely aligned with the terms defined by the ECJ in the *Geraets-Smits and Peerbooms* ruling (see above), the 'coordination route' would be given priority in cases of undue delay. In its proposal on cross-border patient rights, the Commission stipulated that, whenever the conditions of Articles 22(1)(c) and 22(2) of Regulation 1408/71/EEC are met, the insured person shall always be granted an authorization pursuant to the Social Security Regulation (Article 9(2) *in fine*). The alternative mechanism put in place by the Directive is more specifically designed to provide a solution for citizens who may have

[88] Case C-56/01, *Inizan*, above n.15, paras. 22–3.
[89] Jorens, 'Cross-border health care', above n.74, p. 4.
[90] Case C-56/01, *Inizan*, above n.15, para. 45.
[91] Case C-368/98, *Vanbraekel*, above n.15, para. 31.

other reasons to travel to another country to receive treatment.[92] The Commission acknowledges that there are downsides to this procedure, as people would 'bear the financial risk of any additional costs arising'.[93] For that reason, the social security coordination procedure is given priority over the Directive, since '[t]he patient should not be deprived of the more beneficial rights guaranteed by Regulation 1408/71/EEC and 883/04/EC when the conditions are met'.[94]

If the level of payment in accordance with Article 22(1)(c) of Regulation 1408/71/EEC turns out to be lower than that to which the person would have been entitled if he/she had received (hospital) treatment in the competent Member State, an additional reimbursement covering the difference must be granted to the insured person by the competent institution.[95] This is the second improvement the ECJ has introduced on the basis of Articles 49 and 50 EC. This additional financial guarantee applies to the socially insured who were – or should have been – authorized to seek treatment in another Member State under the Social Security Regulation. Otherwise, this lower level of cover may deter or even prevent persons from accessing providers of medical services established in other Member States and therefore constitute an unjustified restriction of the freedom to provide services within the meaning of Article 49 EC.[96]

In addition, where hospital treatment is provided free of charge by a national health service and no tariff for reimbursement therefore exists in the legislation of the competent Member State, the ECJ specified that any possible user charge the patient would be required to bear in accordance with the legislation of the Member State of treatment should be additionally covered by the competent state up to the difference between the cost, objectively quantified, of the equivalent treatment in the home state and the amount reimbursed pursuant to the legislation of the treatment state, if the latter would be lower – with the total amount invoiced for the treatment received in the host

[92] European Commission, 'Proposal', above n.54, Consideration No. 21. See, further, European Commission, 'Patients' rights in cross-border care', Citizen's Summary, 2 July 2008, http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/citizens_summary_En.pdf.

[93] European Commission, 'Proposal', above n.54, Explanatory Memorandum, p. 5.

[94] *Ibid*., Consideration No. 22.

[95] Case C-368/98, *Vanbraekel*, above n.15, para. 53.

[96] *Ibid*., paras. 43–52.

Member State as a maximum.[97] In this context, it should also be noted that Article 22 only grants a right to reclaim the costs of medical services received by the insured person in the host Member State. There is no right to reimbursement by the competent institution for the costs of travel, accommodation and subsistence that the insured person and any accompanying person incurred in the territory of the latter Member State, with the exception of the costs of accommodation and meals in hospital for the insured person him/herself.[98]

Whereas these additional financial guarantees were established in cases where prior authorization under Article 22(1)(c) of Regulation 1408/71/EEC are wrongly denied, this principle could also be extended to the more frequent case of occasional care delivered to a tourist, student or any other person requiring treatment while temporarily residing in the territory of another Member State (see below). Recently, the Commission has referred Spain to the ECJ over the refusal to grant additional reimbursement of the costs incurred for hospital care required during a temporary stay in another Member State.[99] Such an extension would not be without financial consequences for national security institutions, and, more significantly, would impose on them a heavy administrative burden.[100]

Improving access to care for people living in border regions

While at the periphery of Member States, border regions deserve particular attention as poles of often intense mobility. Due to short distances, the relative scarcity of facilities in peripheral areas and strong bonds among the populations (common languages, shared culture and a certain natural propensity to move across borders), border regions have more potential for patient mobility, which can reach relatively significant levels in concentrated areas. From a patient perspective, it is mainly proximity and familiarity that make people seek health care across the border. There appears to be a link between motivations and distance: the stronger the linguistic and cultural affinity and the shorter the distance to the border, the more likely it is that incentives

[97] Case C-372/04, *Watts*, above n.22, para. 131.
[98] Case C-466/04, *Acereda-Herrera* [2006] ECR I-05341.
[99] European Commission, 'Spain: reimbursement of the cost of hospital care required during a temporary stay in another Member State', Press Release No. IP/08/328, 28 February 2008.
[100] Coucheir and Jorens, 'Patient mobility', above n.69.

such as reputation of providers, ease of travel and familiarity with going abroad will encourage people to travel. Vice versa, longer distances to the foreign provider require stronger push factors to make patients travel for treatment (e.g., long waiting times, dissatisfaction or lack of specific services in the home system).[101]

As European integration has traditionally focused on the movement of workers, the particular situation of border region populations was translated into specific health care rights for frontier workers.[102] This category of workers, living and working on either side of the border, benefited from an unconditional double access to the health systems in both the working and residence state. Some Member States decided to extend these entitlements to the family members of frontier workers. In the context of the modernization of the social security coordination instrument, this extension has now been integrated into the new Regulation 883/04/EC.[103] Furthermore, the benefit of double access is also extended to retired frontier workers. After retirement, a frontier worker can continue a treatment that was already started in the Member State where he/she last pursued his/her activity as an employed or self-employed person.[104] Beyond the case of continuation of treatment, Member States can also decide to maintain retired frontier workers' unconditional right to treatment in their former working state. This would only apply to persons who have worked for at least two years as frontier workers in the five years preceding the effective date of old age or invalidity pension. Furthermore, both the former working state as well as the competent Member State that is to cover the medical expenses of the retired frontier worker in his/her state of residence have to have opted for this possibility and have to be listed

[101] R. G. Frost, 'Follow-up treatment of breast cancer patients in Flensburg of citizens from Southern Jutland County', Southern Jutland County (2000), p. 13; N. Boffin and R. Baeten, 'Dutch patients evaluate contracted care in Belgian hospitals: results of a mail survey', Observatoire social européen (2005); Glinos and Baeten, 'A literature review', above n.2, pp. 59–75.

[102] 'Frontier worker' is defined as any person pursuing an activity as an employed or self-employed person in a Member State and who resides in another Member State to which he/she returns as a rule daily or at least once a week. Article 1(f), Regulation 883/04/EC, above n.18.

[103] Article 18(2), Regulation 883/04/EC, above n.18. It should be noted that Member States have been given the possibility of opting out of this extension to family members, through their inclusion in Annex III.

[104] Article 28(1), Regulation 883/04/EC, above n.18. 'Continuation of treatment' means the continued investigation, diagnosis and treatment of an illness.

in Annex V. This will also apply to family members of retired frontier workers for as long as they already benefit from the extension under Article 18(2) in the period prior to retirement of the frontier worker or his/her death.[105]

Despite these extensions, which still mainly depend on Member States' discretion, the notion of 'frontier worker' was not replaced by 'frontier resident' in the new Social Security Regulation. To respond to local needs, specific arrangements have therefore been set up to allow patient mobility in border regions.[106] Local stakeholders have long been active in setting up these kinds of arrangements, with the aim of achieving cross-border complementarity between facilities and improving services available to the local populations. The function of these arrangements is generally to simplify access procedures for cross-border care, mainly through developing a relaxed version of the E112 procedure, which automatically grants prior authorization for cross-border care for people living in a border region. A series of regional projects involving local hospitals, statutory health insurers and health authorities along the borders between France and Belgium and between the Netherlands, Germany and Belgium have taken this approach to facilitating patient flows. Another approach is that of cross-border contracting between a funding body (statutory health insurer or health authority) and a hospital, between two statutory health insurers or between two hospitals. There is a concentration of contractual agreements on the borders between the Netherlands and its two neighbours, Germany and Belgium, but contracts also exist on the border between Denmark and Germany, and between Scandinavian regions. It should be noted that border region arrangements of either type can cover selected treatments, such as elective care, and can cover the entire border region population or just segments of it.

Contractual arrangements for planned care

In recent years, a growing number of health care funding bodies have started to explore the third patient mobility route by contracting with

[105] Article 28(3), Regulation 883/04/EC, above n.18.

[106] Besides the extension of the double access to family members of frontier workers, Belgium also abolished the requirement of prior authorization for any hospital care and renal dialysis performed in an institution situated less than 25 km from the Belgian border for any Belgian insured person residing less than 15 km from the border.

foreign providers. This has partly been a result of Member States adapting to the ECJ rulings by changing national legislation.

As a structural arrangement that controls patient flows while allowing mobility, contracting offers a way for purchasers to combine the concerns of sustainability and cost controls with those of satisfying a population's needs and expectations.[107] Cross-border contracts can either follow the rules of the social security coordination instrument or apply their own rules and tariffs established through negotiation between the contracting partners. These new practices and mechanisms, establishing parallel sub-systems of tariffs, quality standards and legal conditions can lead to new pressures. As public authorities are not necessarily aware of or involved in contractual processes, it may challenge the functioning of national health systems and change relations between stakeholders and actors.[108]

Patients who are given the opportunity to go abroad by their home funding body may do so in a pre-arranged setting. In several countries, long waiting lists have prompted public authorities to offer patients faster access abroad, or authorities have chosen not to deliver specific services within the country, for example, when population numbers do not justify it. In both cases, patients are 'sent abroad' to receive care that is part of the domestic benefit package. This implies that the practical aspects of the cross-border route, including medical appointments and travelling, are organized by the purchasing body, and that expenses are covered by the competent body.

Examples of countries that have set up structures for sending patients abroad include England, Ireland, Norway and the Netherlands. In December 2004, a paragraph was inserted into the Dutch law on contractual agreements between insurers and hospitals in order to provide a legal basis for Dutch insurers to contract with foreign hospitals that are part of the social security system of the state of establishment.[109] Yet, as early as 2002, at a time when the Netherlands was referred to the ECJ, the Dutch authorities had advised health insurers to conclude contracts with foreign providers if they planned to systematically offer their affiliated members access to cross-border care. The English NHS

[107] Glinos, Baeten and Boffin, 'Cross-border contracted care', above n.59, pp. 97–118.
[108] *Ibid*.
[109] Coucheir and Jorens, 'Patient mobility', above n.69.

set up two short-lived schemes in 2001–3 to send waiting list patients to Germany, France and Belgium; in the same period, the Norwegian health service created a 'patient bridge', which, for three years, channelled patients to Scandinavian and other countries; in Ireland, the National Treatment Purchase Fund, in place since 2002, allows waiting list patients access to private hospitals in Ireland and the United Kingdom. All these initiatives have emerged after the early landmark ECJ rulings, and it could be suggested that the (pending) court cases, together with domestic factors, such as highly unpopular waiting lists and mounting political pressure from public dissatisfaction, might have led Member States to look abroad to tackle shortages.[110] It is probably no coincidence that all the countries that have made overseas arrangements are based on benefit-in-kind and, with the notable exception of the Netherlands, are NHS-based systems, considered to be more prone to capacity problems. Another characteristic is that arrangements are based on cross-border contracting between the NHS (health insurers in the Dutch case) and foreign providers.

The contracts make it possible for the sending country to define all aspects of the cross-border care route, including medical and quality standards, procedures used, services given, prices, length of stays, numbers of patients going abroad, etc., and thereby control patient movements and costs while ensuring that patients receive care that fulfils national criteria and expectations.[111] On the other hand, however, contracting can present challenges to the receiving country, depending on the approach taken by the contracting parties.

A different approach is to embed contracts in bilateral framework agreements signed between the competent authorities of the states involved. In early 2003, such an agreement was signed between Belgium and England.[112] Belgian health authorities were concerned

[110] College voor zorgverzekeringen, 'Grensoverschrijdende zorg', Circulaire 02/021, 2 May 2002; K. Lowson, P. West, S. Chaplin and J. O'Reilly, 'Evaluation of treating patients overseas', York Health Economics Consortium, Department of Health (England), July 2002, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005742.

[111] For an inventory of the elements that cross-border contracts might include, see High Level Group on Health Services and Medical Care, 'Guidelines on purchase of treatment abroad', 9 November 2005, http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2005_017_en.pdf.

[112] UK Department of Health and Belgium, 'A framework for cross-border patient mobility and exchange of experience in the field of health care

that cross-border contracts would put the integrity of the national system at risk and therefore sought an accord that clearly stated that foreign patients could not be given priority over Belgian patients and that official Belgian tariffs would be adhered to in the contracts.[113] Yet, in most cases, such bilateral agreements do not exist and stakeholders are not bound to follow national requirements regarding tariffs, medical procedures, quality standards, etc. Instead, contracting parties negotiate on these aspects, which generally results in the purchasers imposing the requirements in force in their system on the foreign providers receiving the patients. New elements might thus be introduced into the receiving system that can have adverse effects if parallel circuits are created in which it becomes lucrative to treat foreign (commercial) patients compared to domestic patients.[114] This is potentially a problem when contracts are made with hospitals that serve patients from the publicly financed system in their country. In this respect, the issue of applying different pricing for foreign patients was also mentioned as a concern in the public consultation undertaken by the Commission.[115]

It should be mentioned that Member States can take a different approach to sending patients abroad for care that is not available at home. Since the 1970s, Malta has had a bilateral agreement with the United Kingdom for sending Maltese patients requiring highly specialized treatments to United Kingdom hospitals (mainly in London). The scheme is rooted in a waiver agreement that assumes that the cost of treating large numbers of United Kingdom tourists in Malta is equivalent to the cost of treating far smaller numbers of Maltese patients with diseases requiring highly specialized equipment and facilities in the United Kingdom.[116] Luxembourg, being a small country surrounded by larger neighbours, has taken the approach of granting prior authorizations for planned care (based on Regulation 1408/71/EEC) more liberally than most other Member States.

between Belgium and England', Common Framework between the UK Department of Health and Belgium, 3 February 2003.

[113] I.A. Glinos, N. Boffin and R. Baeten, 'Contracting Cross-border Care in Belgian Hospitals: An Analysis of Belgian, Dutch and English Stakeholder Perspectives', Observatoire social européen, August 2005, pp. 29–30.

[114] Glinos, Baeten and Boffin, 'Cross-border contracted care', above n.59.

[115] European Commission, 'Consultation', above n.7.

[116] N. A. Muscat *et al.*, 'Sharing capacities – Malta and the United Kingdom', in Rosenmöller, McKee and Baeten (eds.), *Patient mobility in the EU*, above

Private patients

As noted above, citizens in the EU are, in principle, free to seek any health care, where they want and from whatever provider available – the only limitation being their ability to pay for it or the conditions set out by public and private funding systems for health care. When patient mobility occurs because the desired care is not part of the national benefit package and patients have to pay out-of-pocket or through private insurance cover, a series of particular issues may arise as patients seek treatment on their own initiative. Although the data are far from complete, there are clear indications of 'private' patients travelling within the EU for cheaper treatments[117] (dental care, aesthetic surgery, etc.) or for care that is outlawed or non-existent at home (e.g., abortion and late term abortion, fertility treatments, genetic screening, as well as (unapproved) alternative treatment methods for various serious diseases). As these mobile patients go abroad on their own initiative, often based on information found through Internet sources, they are not necessarily supported in their selection of foreign providers and may face issues related to quality and safety of care, as well as obtaining appropriate after-care when returning home. This patient group might be in an altogether more delicate situation due to the ethical controversies surrounding the care they seek abroad.

B. People in need of care while temporarily abroad

Apart from patients moving across borders, Europeans in general increasingly travel across the European Union for work, study or leisure. Consequently, situations where people need to receive medical attention while temporarily staying in another Member State have become ever more frequent. As their length of stay and their familiarity with the country of stay vary, the needs of these groups in terms of access to and

n.59, pp. 119–36; J. M. Cachia, 'Cross-border care: provision of highly specialized hospital services to island populations – a case study of the Maltese Islands', Ministry of Health (2004).

[117] T. Albreht, R. P. Brinovec and J. Stalc, 'Cross-border care in the south: Slovenia, Austria and Italy', in Rosenmöller, McKee and Baeten (eds.), *Patient mobility in the EU*, above n.59, pp. 9–21; J. Cienski, 'Polish health services quick to cash in on eager EU patients', *Financial Times*, 20 June 2005, p. 4; A. Cojean, 'Tourisme dentaire en Hongrie: beaux sourires de … Budapest!', *Le Monde*, 20 August 2005, pp. 18–21; Glinos and Baeten, 'A literature review', above n.2.

use of health care facilities will differ considerably. While tourists will mainly need emergency care, people staying longer in another Member State might need access to the full range of health care services.

Extending the right to occasional care abroad

To accommodate this situation, the scope of the coordination route has been progressively extended. Where, initially, Article 22(1)(a) of Regulation 1408/71/EEC only granted access to treatment during a temporary stay[118] in another Member State for 'immediately necessary care', this was widened towards 'benefits in kind which become necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay'.[119] This change was also motivated by the introduction of the European Health Insurance Card (EHIC) as of 1 May 2004, to replace the E111 form,[120] which was part of the EU Action Plan on Skills and Mobility,[121] aimed at promoting the mobility of citizens and particularly that of workers in the context of the Lisbon strategy. To enable a more easy and uniform access to health care for EU citizens while temporarily staying outside their state of affiliation, an alignment of rights was required with the categories of pensioners and their family members, who on the basis of Article 31 of the Regulation were exempted from the condition of urgency. The ECJ had already indicated that the right of a (Greek) pensioner to benefits in kind during a temporary stay in another Member State could not be made subject to the condition that the illness he suffered from had manifested itself suddenly and was not linked to a

[118] In the context of this Regulation, the difference between temporary stay and (more) permanent stay (residence) is important for the definition of entitlements.

[119] European Parliament and Council Regulation 631/2004/EC amending Council Regulation 1408/71/EEC on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, and Council Regulation 574/72/EEC laying down the procedure for implementing Regulation 1408/71/EEC, in respect of the alignment of rights and the simplification of procedures, OJ 2004 No. L100/1.

[120] European Commission, 'Communication concerning the introduction of the European health insurance card', COM (2003) 73 final, 17 February 2003.

[121] European Commission, 'Action plan of the Commission on skills and mobility', COM (2002) 72 final, 13 February 2002.

pre-existent pathology of which he was aware.[122] Clearly, the ECJ wanted to prevent the situation that citizens suffering from a chronic condition would be excluded from their right to mobility.

Although the EHIC was promoted as a sort of European passport for citizens, it was not intended to create any new entitlements or to establish an unconditional right to medical care across the EU. Since, by the abolition of the emergency requirement, it became difficult to distinguish occasional (E111 form) from planned cross-border care (E112 form), two additional criteria were introduced to assess the medical need for care while abroad: the nature of the benefits and the expected length of stay. As a method to implement these elements in practice, the Administrative Commission on Social Security for Migrant Workers suggested that it should be determined whether the medical treatment was aimed at enabling the insured person to continue his/her stay under medically safe conditions pending treatment by his/her usual doctor so as to prevent him/her from being obliged to return home for treatment.[123] To clarify certain aspects, the Administrative Commission recognized the applicability of Article 22(1)(a) for benefits in kind provided in conjunction with pregnancy and childbirth.[124] Furthermore, in line with Article 22(1)(a), it included kidney dialysis and oxygen therapy in a non-exhaustive list of benefits in kind that, in order to be provided during a stay in another Member State, require, for practical reasons, a prior agreement between the person concerned and the institution providing the care.[125]

Although the Administrative Commission clearly mentions that the European Health Insurance Card is not meant to cover situations

[122] Case C-326/00, *IKA* v. *Ioannidis* [2003] ECR I-01703.

[123] Administrative Commission on Social Security for Migrant Workers, 'Guidelines for uniform application of Article 22(1)(a)(i) by the social security institutions of the Member States', CASSTM Note 376/03, Annexe 1a; Decision No. 194 of the Administrative Commission on Social Security for Migrant Workers concerning the uniform application of Article 22(1)(a)(i) of Council Regulation 1408/71/EEC in the Member State of stay, OJ 2004 No. L104/127.

[124] Decision No. 195 of the Administrative Commission on Social Security for Migrant Workers on the uniform application of Article 22(1)(a)(i) of Regulation 1408/71/EEC as regards health care in conjunction with pregnancy and childbirth, OJ 2004 No. L160/133.

[125] Decision No. 196 of the Administrative Commission on Social Security for Migrant Workers of 23 March 2004 pursuant to Article 22(1a), OJ 2004 No. L160/135.

where the aim of the temporary stay is to receive medical treatment, it cannot be excluded that it would be used to bypass prior authorization for planned care, especially since under the coordination route the benefit basket of the host country applies, and patients could be motivated to seek care that would not be reimbursed – or reimbursed to a lesser extent – in the state of affiliation. The assessment of whether the conditions are met lies in the hands of the treating care provider. To prevent any abuse, it is recommended that social security institutions should instruct these providers[126] and cooperate with each other. The fear of abuse should not lead to the duplication of medical examinations by the competent institution in the home state[127] nor to any penalization of the insured persons. In the context of urgent vitally necessary treatment, the Court considered that a person covered by an E111 or E112 form cannot be required to return to the competent Member State to undergo a medical examination there. It highlights that the competent institution, once it has consented, by issuing the E111 or E112 form, to one of its insured persons receiving medical treatment in a Member State other than the competent Member State, is bound by the findings of the doctors authorized by the institution of the Member State of stay, acting within the scope of their office, during the period of validity of the form. They are clearly best placed to assess the state of health of the person concerned and the immediate treatment required by that state. This would even extend to the decision of transferring the patient to a hospital establishment in another state, even if that state is not a Member State.[128]

[126] Administrative Commission on Social Security for Migrant Workers, 'Practical information for health care providers receiving European health insurance card holders', CASSTM Note 376/03, Annexe 1b.

[127] Reference is made to Case C-344/89, *Martinez Vidal* [1991] ECR I-3245, in which the ECJ ruled that, in the case of recognition of invalidity, the competent institution is required to take into account any documents and reports drawn up by institutions of any other Member State in order to avoid repetition of examinations.

[128] Case C-145/03, *Keller* [2005] ECR I-2529, paras. 50–63. The reasoning of the Court is based on a sharing of responsibilities between the competent institution and the institution of the Member State of stay, in correlation with the Community framework on the mutual recognition of professional qualifications. However, some have pointed to some inconsistencies in the ruling as regards respecting the logic of Article 22 and the division of responsibilities upon which it relies. Coucheir and Jorens, 'Patient mobility', above n.69.

Whereas the main reason for introducing the European Health Insurance Card was to modernize and simplify the administrative practice for receiving occasional care across the European Union,[129] practical problems still may handicap the coordination route. Firstly, since Article 22 obliges holders of European Health Insurance Cards to comply with local rules in regard to accessing care, reimbursement might be refused if they seek care with providers who are working outside the statutory health care system in the host state. The situation may be exacerbated given that patients often do not know the foreign health care system or the language of the country. Furthermore, it is reported that, in certain Member States, some providers would not accept the card, with patients ending up having to pay for the care themselves and then to claim reimbursement back home.[130] In principle, the coordination route provides for the possibility of reimbursement by the competent institution back home according to the applicable tariffs in the state of treatment in the case that formalities could not be completed during the stay.[131] However, given all these practical stumbling blocks and the

[129] The different paper forms used (E110, E111, E119, E128) were replaced by one card, which, at a later stage, should also allow for electronic communication between competent institutions in different Member States. Also, citizens can no longer be required to first contact the social security institution before seeing a health care provider.

[130] M. Rosenmöller and M. Lluch, 'Meeting the needs of long-term residents in Spain', in Rosenmöller, McKee and Baeten (eds.), *Patient mobility in the EU*, above n.59, pp. 59–78.

[131] Article 34(1), Regulation 574/72/EC, above n.13, provides for the possibility to reimburse costs at the request of the person involved on his return home. In principle, reimbursement is adjudged according to the applicable tariffs in the state of stay. When necessary, this state will be called on to provide the relevant information on these tariffs. On the other hand, the institution of the place of residence may reimburse at its own tariffs, with the consent of the person involved, if these tariffs allow for reimbursement and if the total costs do not exceed the amount set by the Administrative Commission (see Decision No. 176 concerning reimbursement by the competent institution in a Member State of the costs incurred during a stay in another Member State by means of the procedure referred to in Article 34(4) of Regulation 574/72/EEC, OJ 2000 No. L243/42) and without the consent of the person involved, if the state of stay does not dispose of any reimbursement rates (Article 34(5)). Also, the proposal for the Regulation laying down the procedure for implementing Regulation 883/2004/EC, which is supposed to replace Regulation 574, provides for similar provisions under Article 25(6–7). See European Commission, 'Proposal for a Regulation of the

complexity of the coordination route, patients in some cases could use the Treaty-based route to directly claim reimbursement according to home state tariffs. This would be clearly the case for outpatient care services purchased in another Member State that are part of the home state benefit package. Member States remain in charge of fixing the reimbursement levels to which patients are entitled, although these have to be based on objective, non-discriminatory and transparent criteria. Also, the systematic refusal of the EHIC by providers in some countries and the need to respond to certain demands for better and more adapted treatment (in the individual's own language) has pushed some national health insurers to directly contract foreign providers in certain foreign regions popular with holidaymakers. This has become possible as Member States have adapted national legislation to the ECJ rulings. In 2004, German health care reforms were implemented to allow cross-border contracts provided that the services covered are included in the German benefit basket; that the foreign providers are part of the statutory system of the country of establishment; and that the requirements of German law are incorporated into the contracts.[132] Indeed, several German sickness funds have opened up contractual routes for affiliated members travelling in the EU.[133]

European Parliament and of the Council laying down the procedure for implementing Regulation 883/2004/EC on the coordination of social security systems', COM (2006) 16 final, 31 January 2006.

[132] A. Schneider, 'Grenzüberschreitende Inanspruchnahme von Krankenhausleistungen aus der Sicht des BMGS', *Zeitschrift fur europaishes Sozial- und Arbeitsrecht* 10 (2004), 413–5.

[133] The German sickness funds AOK Rheinland and Techniker Krankenkasse (TK) have had contracts with Dutch and Belgian hospitals on the Northern Sea coast line since 2003 as a result of German tourists having difficulties in getting their E111 forms accepted or even recognized by providers. Due to the same problems with accessing Austrian emergency facilities following ski injuries, TK has been in contract negotiations with University Hospital of Innsbruck. Nebling and Schemken, 'Cross-border contracting', above n.59. Some German insurers (such as Taunus BKK) have started making direct contracts with individual German doctors who have settled down on the Spanish coast where there is an important concentration of German tourists (for example, in Majorca). Rosenmöller and Lluch, 'Meeting the needs', above n.130. This not only creates an entire German health care network in another country, but also breaks with German practices, as direct contracts between purchasers and individual providers are not allowed on German territory but have to be concluded with the *Krankenversicherung*, the doctors association. Glinos, 'Cross-border collaboration', above n.58.

Taking into account the changing health care needs of people retiring to other countries

Pensioners retiring to a different Member State than their home country justify special attention because of their particular features. This 'high risk' population group presents specific age-related health care needs and raises related financial questions about who is to cover their health care costs.[134]

According to official figures, in July 2006 more than 300 000 United Kingdom citizens were receiving their pension in another Member State, with top destination countries being Ireland (103 667), followed by Spain (76 357) and France, Italy and Germany (with more than 30 000 United Kingdom pensioners each).[135] In December 2004, more than 50 000 German citizens were receiving their pension from the German statutory pension insurance in another Member State: 16 375 in Austria, followed by some 12 000 both in France and in Spain.[136] These data should be treated with caution due to likely underreporting, as not all residents actually submit an E121 form[137] or register with authorities in the new Member State, even though they reside there for more than three months per year. These so-called 'false tourists' are likely to regularly travel between their country of origin and the new country where they use the European Health Insurance Card or private insurance to access health services.

The 'false tourism' phenomenon could even be stimulated by the fact that pensioners, when registering in the new Member State, lose their right to directly access care in their former home country. The ECJ confirmed that Article 22(1)(c) and (i) of Regulation 1408/71/EEC also applies to a pensioner and members of his/her family who officially reside in a Member State other than the one that is liable for

[134] Rosenmöller and Lluch, 'Meeting the needs', above n.130.

[135] H. Legido-Quigley and D. La Parra, 'The health care needs of UK pensioners living in Spain: an agenda for research', *Eurohealth* 13 (2007), 14–8.

[136] Verband Deutscher Rentenversicherungsträger, *VDR Statistik*, Vol. 152 – Rentenbestand (Frankfurt am Main: VDR, 2004), Table 18, p. 23.

[137] Under the Social Security Regulation, form E121 constitutes the certified statement required for the purposes of registering a pensioner and members of his/her family with the institution of their place of residence in accordance with Article 28 of Regulation No. 1408/71, above n.13, and Article 29 of Regulation 574/72/EC, above n.13. This form is provided by the competent institution in the Member State granting the pension and in charge of covering the health care costs, following the rules established in Articles 27–8, Regulation 1408/71/EC, above n.13.

payment of that pension, and who wishes to get medical treatment in another Member State, even if that would be the state paying for his/her pension, as laid down by Article 28 of that same Regulation.[138] Furthermore, the prior authorization and the related E112 form need to be issued by the institution of the place of residence.[139] This also follows from the fact that all health care costs for this particular group are systematically covered on the basis of a yearly lump sum to be paid by the competent institution in the Member State liable for paying the pension to the new Member State of residence.[140] As a compensation for this lump sum payment, the financial liability for this group is integrally transferred to the institution in the state of residence, which has to be considered as competent to grant authorization for care abroad. As explained, in so far as treatment can be provided within medically acceptable time-limits, the residence state can refuse to cover for the pensioner wishing to return for medical reasons to his/her country of origin. To ease this situation, it is explicitly provided for under the new Social Security Regulation that, similar to the double access right for frontier workers, Member States can opt for the possibility of granting their pensioners residing in another Member State a permanent right to return for care in their territory at the expense of the competent institution.[141] Furthermore, in an attempt to rebalance the financial costs for pensioners between Member States, the rule of lump sum coverage between states for the category of pensioners has been abolished,[142] thus shifting responsibility for granting prior authorization back to the competent Member State – i.e., the state paying for the pension. This not only disrupts the logic behind the entire lump sum system but also increases administrative complexity.

4. Towards a community framework for safe, high-quality and efficient care?

Although consecutive rulings of the ECJ, as well as legislative proposals and decisions of the Administrative Commission on Social Security

[138] Case C-156/01, *van der Duin* v. *Wegberg/ANOZ* [2003] ECR I-7045, para. 51.
[139] *Ibid*., para. 56.
[140] Article 36, Regulation 1408/71/EC, above n.13; Article 95, Regulation 574/72/EC, above n.13.
[141] Articles 2, 27, Regulation 883/04/EC, above n.18, which requires these Member States to be listed in its Annexe IV.
[142] Articles 4, 5, 27, Regulation 883/04/EC, above n.18.

for Migrant Workers, have further clarified different issues regarding the rules applicable to treatment received outside the state of affiliation, still more clarity is called for.[143] However, as was expressed throughout the public consultation that the European Commission's Directorate-General for Health and Consumer Protection organized between September 2006 and January 2007, this demand for clarity is not limited to the sole question of entitlements to reimbursement, nor is it limited to legal clarity. Indeed, it was increasingly understood that, if medical treatment throughout the European Union was to become a more common option for patients, it did not suffice to remove obstacles to the reimbursement of that care, but the establishment of a clear and transparent framework for ensuring the safety, quality and efficiency of those health services was also required. This acknowledgment of the need for so-called 'flanking measures',[144] next to clarification on the entitlement to statutory coverage for cross-border care, basically constitute the more adaptive approach announced by the European Commission after the exclusion of health care from the Services Directive.

In general, the observed diversity of quality and safety policies throughout the EU[145] were considered by many respondents to the consultation to be a major stumbling block to promoting the increased use of cross-border care. Given the lack of commonly agreed standards and of data to assess quality, the need to guarantee safe, high-quality and efficient cross-border care is, in the first place, addressed by clarifying what Member States need to do to ensure the clinical oversight of medical treatment. In its proposal, the Commission confirmed that the Member State of treatment should be entrusted with the task of ensuring that the common principles for health care – as set out in the Council Conclusions on 'common values and principles in the EU

[143] European Commission, 'Summary report of responses to the consultation regarding "Community action on health services" ', Health and Consumer Protection Directorate-General, http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_rep_En.pdf.

[144] See Y. Jorens, 'General regulatory framework: competition and regulation in the internal market – what mixture is best for Europe?', in Federal Ministry of Health, *The social dimension in the internal market, perspectives of health care in Europe, conference documentation* (Berlin: Federal Ministry of Health, 2007), p. 19.

[145] H. Legido-Quigley *et al.*, 'Quality and safety', in Wismar *et al.* (eds.), *Cross-border healthcare*, above n.4.

health systems'[146] – are also met in the case of cross-border treatment. In particular, this implies that every Member State must ensure that treatment given to patients from other Member States is provided according to clear quality and safety standards of health care defined by that Member State, taking into account international medical science and generally recognized good medical practice, and that mechanisms are in place to both ensure that providers are able to meet these standards and that they are monitored and, where necessary, sanctioned (Article 5(a-b)). This minimum core set of obligations is meant to establish confidence in the quality and safety of health care provision throughout the EU. It is commonly agreed that, given the diversity of strategies and of levels of development in this field, only a non-regulatory and process-oriented approach would be feasible from an EU perspective.[147] While Member States remain responsible for setting the standards in their country, the Commission is allowed to develop guidelines or standards in order to facilitate the implementation of the above-mentioned provisions (Article 5(3)).[148]

Linked to this, the fear of harm arising from treatment in other countries is another aspect that calls for additional guarantees. While research indicates that in 10% of cases harm arises directly from medical intervention, the risk could be even greater for cross-border treatment due to insufficient information, inadequate assessment prior to surgery or lack of follow-up afterwards.[149] In this respect, lack of clarity and distrust centres on patient rights and liability issues. Although the Commission's proposal was renamed 'Directive on the application of patients' rights in cross-border health care', it only addresses individual patient rights to a limited extent. The Member State of treatment is also held responsible for ensuring that

[146] 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, www.eu2006.at/en/News/Council_Conclusions/0106HealthSystems.pdf.

[147] Palm, Wismar and Ernst, 'Assessing possible directions', above n.51.

[148] In December 2008, the Commission adopted a Communication and a Proposal for a Council Recommendation on patient safety, including the prevention and control of health care associated infections: http://ec.europa.eu/health/ph_systems/patient_eu_en.htm.

[149] A survey conducted in the UK suggested that 18% of respondents reported complications following treatment abroad, including infections. BBC, 'Overseas ops "harm one in five"', *BBC News*, 20 March 2008.

appropriate remedies and compensation mechanisms are in place when patients suffer harm from health care and that they can make complaints (Article 5(d)). Member States are also required to impose professional liability insurance or similar arrangements upon health care professionals (Article 5(e)). However, this does not rule out the possibility of Member States extending domestic liability coverage to patients seeking health care abroad, especially when this is deemed necessary (Recital 15).[150] Moreover, the fundamental right to privacy in the context of data processing is also mentioned as a responsibility of Member States (Article 5(f)). In this context, the consultation has drawn attention to the importance of ensuring continuity of care between different treating professionals and institutions when addressing cross-border care and the need to ensure timely exchange of personal patient data. Although the proposal also lists continuity of care as one of the areas of uncertainty to be addressed, it only reaffirms that this data transfer needs to take place in respect of the relevant provisions of the Data Protection Directive and, more specifically, in respect of patients' rights to have access to personal data concerning their health. The proposal explicitly reaffirms this right in the context of patients receiving care outside their home state (Article 6(5)). Experts have supported the idea of improving legal guarantees with respect to the use of and access to medical files.[151]

Another important component of a framework for ensuring optimal care throughout the EU is informed choice. In the first place, patients should know what the applicable rules are. This is why the new proposals reaffirm that, in cases where a patient or a provider temporarily move, the actual provision of health care is governed by the rules of the Member State of treatment (Article 11). Entitlements to statutory reimbursement are governed by the Member State of affiliation (Article 6(2–3)). Apart from the applicable legislation, there is a clear consensus that insufficient information is available on cross-border treatment. This not only refers to the availability of understandable information

[150] As a way of ensuring fair treatment, some countries, such as Denmark and Sweden, extend liability coverage provided by their national public no-fault insurance – which normally only applies to medical errors occurring on the national territory – when referring patients to providers abroad.

[151] Palm, Wismar and Ernst, 'Assessing possible directions', above n.51, p. 53. See Chapter 13 in this volume on the protection provided by Article 8 of the Data Protection Directive in the context of electronic health records.

regarding entitlements to statutory coverage or to the legal position with respect to liability and patient rights, but also links to the availability of treatment options throughout the Union and related information on quality and clinical outcomes. Obscurity surrounding the medical, financial and practical implications of seeking health care abroad is considered an obstacle to free movement and another source of distrust for patients. However, as experts also have pointed out, there is an opportunity and equity cost related to increasing the level of information on cross-border options, while, at the same time, information on domestic options also is not optimal.[152] While the European Commission proposes to entrust the Member State of treatment with the basic and general responsibility of providing all relevant information to enable patients to make informed choices, including information on availability, prices, cover, outcomes and professional liability (Article 5(c)), the Member State of affiliation is obliged to inform its citizens on entitlements and related administrative procedures, including mechanisms for appeal and redress, as well as terms and conditions that would apply whenever harm is caused following treatment abroad (Article 10(1–2)). In addition, patients should be informed about prior authorization systems (Article 8(5)).[153] The proposal also seeks to ensure that decisions about reimbursement of health care incurred in another Member State are taken in a timely manner. Where a period of fifteen calendar days is considered normal, this should be shorter if urgency requires.[154] The elements that were listed by the ECJ to define 'undue delay' in an individual case are here used to assess the time limits within which Member States should deal with individual requests (Article 9(4)). To combine all efforts in terms of improving information, the Commission proposes to establish national contact points for cross-border care in all Member States, which should provide and disseminate available information, as well as assist patients in protecting their rights, seeking appropriate redress and facilitating the out-of-court settlement of disputes arising from cross-border health care (Article 12).

[152] Palm, Wismar and Ernst, 'Assessing possible directions', above n.51, p. 17.

[153] Minimal requirements for these information obligations, especially when Member States need to address citizens coming from abroad, are not specified in the proposal. Only the case of information about entitlements is left to the Commission, which is assisted by a special Committee of Member States representatives, under Article 19, in developing a standard Community format, Article 10(3).

[154] European Commission, 'Proposal', above n.54, Consideration No. 33.

Finally, it is also increasingly understood that patient mobility is not just a matter of enabling patients to seek treatment elsewhere but also requires cooperation and mutual assistance among Member States, ranging from specific collaboration in border regions to overall coordination and monitoring. European cooperation is considered to add value to the individual actions of Member States because of the scale or nature of the health care concerned.[155] The Commission's proposal establishes a general duty of cooperation (Article 13) necessary for the implementation of all provisions contained in the Directive. More specific areas of cooperation are defined in recognizing medicines prescriptions throughout the Union (Article 14), developing European reference networks (Article 15), achieving interoperability for e-health applications (Article 16), collecting statistical and other complementary data for monitoring cross-border care (Article 17), and in assessing new health technologies (Article 18). The actual implementation of cooperation in these fields, however, depends greatly on the willingness of Member States to invest in it.

5. Conclusions

After more than ten years of public attention to the relatively modest phenomenon of patient mobility in the European Union, the much advocated need for legal clarity and certainty has still not been achieved. With the jurisprudence of the ECJ, an alternative, less restrictive and less cumbersome procedure was created on the basis of the principle of free movement of services and goods for the statutory cover of health care delivered outside the state of affiliation. The new procedure not only has a different legal base than the traditional social security coordination mechanism, but also applies a different concept of equal treatment: whereas under the latter cross-border patients are treated as though they were insured in the country of treatment, under the Treaty-based route they are treated as though the treatment were provided in the country of affiliation. As a consequence, different legislation applies in terms of benefit packages, applicable tariffs and conditions, as well as formalities that need to be observed. Despite consecutive rulings of the ECJ and attempts to align and codify procedures, the situation is still confused. Member

[155] European Commission, 'A Community framework', above n.14, p. 6.

States have only reluctantly started to review their administrative practices in terms of relaxing conditions for treatment outside their territory. Moreover, the review and modernization of the social security coordination framework could not integrate both routes, nor has it led to the simplification of administrative procedures and the resolution of practical problems, such as the acceptance of the European Health Insurance Card. Despite all this, the coordination route still applies and was not ruled out by the ECJ; in many respects, it remains preferable to the free choice route established through case-law, as it provides better social protection and certainty for patients.

Through the ECJ's rulings, and also through developments in the field enacted by health care actors (sickness funds, providers, local and regional authorities, etc.), options for patients to obtain cover for treatment outside their home state have increased, thereby challenging the territoriality foundations of health care systems.[156] Even where prior authorization is upheld, the discretionary power of Member States to apply it has been restricted. In fact, authorization can only be refused if the same treatment or a treatment that is equally effective for the patient can be obtained without undue delay in the Member State of residence. Prior authorization is only one of the instruments policymakers use to control costs and ensure safe, high quality and efficient health services within their statutory health system. Its curtailment by the ECJ, therefore, had a significant symbolic meaning, announcing potentially even more far-reaching clashes between the objectives pursued within national health policy and obligations under EU law.[157] Some argue that the freedom of services approach puts too great an emphasis on patient choice at the expense of the fundamental values of European health care systems, particularly efficiency, solidarity and equality of access.[158] This is probably also why Member States initially reacted so vigorously to the ECJ jurisprudence and became more willing afterwards to engage in a political debate on the issue. The exclusion of health care from the Services Directive in 2006 was perhaps less related to the inclusion of Article 23 codifying ECJ case-law on patient mobility than to other provisions and obligations extending the internal market approach to new regulatory

[156] Martinsen, *EU for the patients*, above n.68.
[157] See Chapters 7, 8 and 9 in this volume on health services and competition.
[158] Hervey and Trubek, 'Freedom to provide health care', above n.37.

instruments or areas that were not even directly linked with the issue of mobility or that did not contain any cross-border elements. This is probably why, despite its limited scope and impact, patient mobility has attracted so much political attention over the years. It has opened the door towards aligning health systems overall with market logic and entrepreneurialism, which had become apparent in the systems or were introduced by reforms in the late 1980s and early 1990s.[159]

The need for more governance on patient mobility is not only motivated by the need for more legal certainty as to the application of internal market rules on health care. The uncertainties go beyond legal questions. As patient mobility types and patterns have diversified and motivations for patients to seek treatment outside their home state have changed, so too has the debate on patient mobility moved from being merely a matter of entitlements towards other issues, including quality of care, liability, responsibility, safety of care received abroad, etc. As indicated by the process enacted by the 2003 High Level Process of Reflection on Patient Mobility and Health Care Developments in the EU, there is an increasingly felt need to directly coordinate health care systems through closer cooperation between actors across borders and the creation of a common framework for ensuring safe, high-quality and efficient health care provision throughout the Union. However, some kind of legal framework is needed to embed these 'flanking measures' and steer the processes. This is what the European Commission has been aiming to do by developing a 'more adapted' legislative proposal after health services were excluded from the Services Directive.

The proposal for a new framework will still need to make it through the legislative process. In addition, it remains to be seen whether it will be able to effectively change the context for organizing and regulating health care provision throughout the EU. Considering the wide diversity in how health systems are structured, financed and regulated, the proposal developed by the Commission remains relatively vague and minimal. Since no minimal standards are provided for many of the obligations to be taken on by Member States and no concrete measures are being proposed

[159] R. B. Saltman, R. Busse and E. Mossialos, *Regulating entrepreneurial behaviour in European health care systems* (Buckingham: Open University Press, 2002).

for cross-border cooperation, much will depend on the willingness of Member States. As to the question of entitlements to cover for health care provided in another Member State, the new proposal by the Commission seems to go even further than the previous Article 23 in the Services Directive. It sheds more doubts in terms of the applicable benefit package, the use of prior authorization for hospital treatment in another Member State, as well as the conformity of conditions and formalities to which statutory reimbursement can be made subject. In this way, the proposal may not sufficiently reassure Member States as to their control over patient flows and its financial implications. On the other hand, the final proposal, to some extent, reinstates the traditional social security coordination mechanism as the preferred route, whenever the conditions for its application apply. It recognizes that this procedure provides more financial certainty for patients.

Meanwhile, developments of a different nature are taking place that are likely to change the outlook and patterns of patient mobility and cross-border care, creating new challenges for health systems. Besides a growing commercial drive in health care combined with increased access to information about treatment options, developments in e-health are likely to raise new legal questions as to what legislation applies in a specific case.[160] Furthermore, other legal and ethical problems could arise from more controversial interventions that may be entirely or partially outlawed at home due to bioethical concerns.[161] Although no systematic research has been carried out yet on these patient flows, anecdotal evidence from across Europe provides examples of couples travelling to other countries for fertility treatments and pre-implantation genetic diagnosis, women seeking to have an abortion or to give birth under anonymity when giving up the child for adoption, cases of people going abroad for euthanasia, stem cell therapy, gene treatments against cancer or to carry out genital mutilation. Considering these developments, any legal framework to be developed for cross-border care should be sufficiently flexible to progressively incorporate novel aspects.

For all these reasons, the question of who is actually steering the policy of increased mobility in health care has become more pressing than ever. While national governments initiated the discussion

[160] See Chapter 13 in this volume. [161] See Chapter 6 in this volume.

on patient mobility, the Commission has gradually put itself in the driving seat of the political process. But, here also, we can observe divergent actions from different Directorates-General, with different approaches and objectives. Stakeholders and the European Parliament have played a significant role in taking health services and the reimbursement of cross-border care out of the 'horizontal' Services Directive. High level processes and groups have, until now, been unable to reach a consensus over this issue, or to design a desirable framework. With the proposed new Community framework on the application of patients' rights in cross-border health care, we are entering a new phase, which, it is hoped, will lead to clearer guidance for patients, administrations and actors in the field as to what the future might bring. If not, the European Court of Justice cannot but continue its work of interpreting primary and secondary Community legislation and playing the role of policy-maker.