

Social developments in the European Union 2008

Tenth annual report

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edited by
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The proposal for a directive on patients' rights in cross-border healthcare¹

Rita Baeten

Introduction

On 2 July 2008, the European Commission adopted a 'proposal for a directive on the application of patients' rights in cross-border healthcare' (CEC, 2008a). The adoption of this proposal marks the provisional end of a laborious policy process aimed at finding adequate responses to the rulings of the European Court of Justice (ECJ) with regard to patient mobility and health services in the internal market.

In a series of judgments over the last decade, the ECJ has made clear that healthcare provided against remuneration is an economic activity in the meaning of the EC Treaty, irrespective of how and by whom it is funded. As a consequence, the Treaty provisions on the freedom to provide services apply². The Court ruled that making the reimbursement for care received abroad subject to the requirement that the patient must first receive authorisation from his domestic social protection system is an obstacle to freedom of movement, which can be justified for hospital care but not for ambulatory care.

Since then, policy makers have been considering how to cope with this situation and how to strike a balance between the internal market

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1. I would like to thank Marleen Steenbrugghe, Philippe Pochet, Stefan Clauwaert and Anna Safuta for their much-appreciated feedback on this chapter.
 2. Case C-158/96, *Raymond Kohll v. Union des caisses de maladie*, Judgment of 28 April 1998; Case C-120/95, *Nicolas Decker v. Caisse de maladie des employés privés*, Judgment of 28 April 1998; Case C-157/99, *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen*, Judgment of 12 July 2001; Case C-385/99, *V.G. Müller-Fauré c/ Onderlinge Waarborgmaatschappij O.Z. Zorgverzekeringen UA and E.E.M. Van Riet c/ Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*, Judgment of 13 May 2003. Case C-372/04 *Watts*, [2006] ECR I-4325; Case C-444/05 *Stamatelaki* [2007] ECR I-3185.

principle of free movement and the social characteristics of their national healthcare systems. They fear losing control over areas such as healthcare priority setting and capacity planning.

This chapter begins by outlining the developments that led up to this proposal. We will then put the different sections of the proposal under the spotlight and weigh them against the stated objectives and the concerns that led to the proposal. Next we assess whether or not the proposal provides adequate responses to concerns about preserving the social character of healthcare systems. Then the ongoing policy process for the adoption of the proposal is commented on, and finally we will draw some conclusions.

1. The laborious path towards a proposal

Several policy initiatives have been taken at EU level in an attempt to put forward policy responses to the legal uncertainty and the pressure on the regulatory powers of health authorities (see Baeten, 2005 and 2007). A High Level Group on Health Services and Medical Care (HLG), consisting of senior officials of EU Member States and chaired by the European Commission, was set up in 2004 with the aim of supporting European cooperation in the field of healthcare and to monitor the impact of the EU on healthcare systems³.

The setting-up of the HLG did not prevent the European Commission from including healthcare services in its proposal for a services directive (CEC, 2004). After two years of heated policy debate, healthcare services were finally excluded from the scope of the directive (European Parliament and Council of the European Union, 2006). This exclusion did not however eliminate the applicability of free movement rules to health services.

The European Commission therefore announced in 2006 that it would put forward a specific legal initiative on the health sector (CEC, 2006a). In order to seek input from stakeholders on a potential legal initiative, the Commission initiated a wide public consultation process (CEC, 2006b).

3. http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm.

The European Commission's adoption of the proposal for a directive was the result of a lengthy and painful policy process. It was initially scheduled for the autumn of 2007 but was delayed several times, due to major disagreements within the Commission and severe criticism from Member States and the European Parliament. Systematic leaks from the interdepartmental consultation meant that from early October 2007 onwards, several versions of the proposal have been circulating. The Commissioner for health, Markos Kyprianou, was thus bogged down in an unmanageable communication process which provoked a lot of criticism.

In December 2007 the proposal was withdrawn from the agenda of the college of Commissioners right at the very last minute, due to a 'full agenda'. Nothing was heard of the Directive in early 2008. The Commission had shelved the issue due to a lack of support from several Commissioners. Mindful of their experiences with the services directive, some Commissioners wanted to avoid a painful controversy prior to the ratification of the Lisbon Treaty which could jeopardise – yet again – the EU's institutional reform.

However, with the appointment of the new Commissioner for health, Androulla Vassiliou, the Commission ultimately adopted the proposal for a directive in July 2008 as part of the Renewed Social Agenda (CEC, 2008a and b). The proposal was reworked and reworded, without however changing it fundamentally compared with its earlier versions. The basic structure of the text remained intact. Nevertheless, a general 'clean-up' had been carried out in order to eliminate any notion of 'health services' from the text. Instead, the provisions were presented under the heading of 'patients' rights'. This general tidying up did however not concern the legal basis of the proposal, which remained Art. 95 of the EC Treaty, concerning the internal market.

It is striking that these almost symbolic changes in the text enabled it to be adopted by the Commission. The Irish (no) vote on the Lisbon Treaty in June neutralised the fears that the proposal might affect the approval of the Lisbon Treaty. The removal of all references to 'services' dispelled the concerns that it could be considered as a resurgence of the Bolkestein Directive. By including the text in the social package, the Commission's DG Employment was officially involved, assuaging the disagreements between this DG and the responsible DG, DG Sanco, as

to whether the implementation of the Court's rulings should be incorporated into the existing legal framework on the co-ordination of social security systems (Regulation 1408/71) (Council of the European Communities, 1971) or whether a specific legal instrument was needed. The Swedish Commissioner, Ms Wallström, has perhaps come under pressure from her national government (in which her political group no longer participates) to take a more favourable stance towards the proposal, since Sweden is one of the sole countries backing the Commission's approach.

Furthermore, by presenting the proposal as patients' rights – instead of the right to free movement of services – the Commission certainly hoped to find an objective ally in the European Parliament, defending the rights of European citizens.

Quite surprisingly, even though no radical changes had been made compared with the draft versions, the launch of the proposal did not provoke strong reactions. The timing was of course favourable, at the beginning of the summer holidays. Furthermore, and probably more importantly, there was general relief that a phantom proposal that had been around for so long and was the subject of so many debates and discussions, but did formally not exist, was finally officially on the table and could be the subject of formal negotiations. After many years of policy debates on what political response to give to the Court's rulings, there was at last a legal proposal with which one could agree or disagree, but that at least had the merit of existing. It was generally felt that there was no other way forward than to open political negotiations. Stopping debate on the issue was not an option, as it would re-emerge time and again. Resuscitating soft mechanisms such as the High Level Group, knowing full well that the Commission has a legislative proposal in reserve, was not an option either.

2. Analysis of the proposal

The proposed directive aims to clarify the right of patients to seek healthcare in another EU country, thus implementing and clarifying the rulings by the European Court of Justice.

The proposal is structured around three main areas. It provides a specific framework for reimbursement of care received abroad; it addresses the question as to which Member State, in the case of cross-border care, should be responsible for ensuring quality and safety standards, information, redress and liability as well as privacy protection; and finally it aims to encourage European cooperation on healthcare in specific areas. The creation of an executive committee to implement the proposal is suggested.

In what follows we will assess the most important and sensitive issues in each of the areas of the proposed directive, taking into account the line taken by the Court's rulings. We will not analyse or comment on the ECJ rulings themselves, since this would go too far and has been the subject of many other publications⁴.

2.1. Reimbursement of treatment received abroad

The first objective of the proposed framework is to provide clarity about the right to be reimbursed for healthcare provided in another Member State. The proposal aims to codify the ECJ judgments. However, as will be substantiated below, several key aspects of the proposal are seriously debatable in this respect.

Under the proposal, EU citizens have the right to seek care abroad and be reimbursed up to the level of costs that would have been assumed, had the same or similar healthcare been provided in their Member State of affiliation to a social protection scheme. For non-hospital care patients can do so without prior authorisation from their domestic social security system. For hospital care, Member States may put in place a system of prior authorisation for reimbursement for care abroad, if they can provide evidence that the outflow of patients would be such that it puts at risk either the finances of the national social security system or the planning of hospital capacity. If that is the case, authorisation must be limited to what is necessary and proportionate and must not constitute an arbitrary method of discrimination. The criteria according to which

4. See e.g. Palm *et al.* (2000); Mossialos *et al.* (2002); McKee *et al.* (2002); Jorens *et al.* (2005); Hervey and McHale (2004) and Newdick (2006).

the decision will be made must be set in advance, transparently, and take into account the patient's specific medical condition. Hospital care is defined as care requiring overnight accommodation of the patient for at least one night. Other forms of care that either require highly specialised cost-intensive medical infrastructure and equipment or healthcare involving treatments presenting a particular risk for the patient or the population can however be equated with hospital care, provided that they figure on a list to be drawn up in the executive committee.

The funding authorities may impose on care abroad the same conditions that apply domestically, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, in so far as they are neither discriminatory nor an obstacle to freedom of movement.

In what follows we will argue with regard to four key aspects of the proposal that, in several major ways, the proposal does not follow the lines set out by the Court, with potentially important consequences.

2.1.1. Prior authorisation for hospital care

The limitations placed on the possibilities for requiring prior authorisation for hospital care are among the most controversial issues of the proposal for a directive. The Court has indeed consistently held that a system of prior authorisation for the assumption of the costs of hospital care provided in another Member State is justified by the need to preserve the financial balance of the social security system and the need for hospital planning⁵. This has never been seriously contested so far, not even by the Commission itself. Even Article 23 of the controversial initial proposal for a services directive in 2004 did not require any justification for maintaining a system of prior authorisation for hospital care, and the Commission communication, launching the consultation process in preparation for the proposed directive in 2006, confirmed that the Court had developed principles according to which 'Any hospital care to which they are entitled in their own Member State they

5. Case C-157/99, *Geraets-Smits and Peerbooms*; Case C-385/99, *Müller-Fauré*; Case C-372/04, *Watts*.

may also seek in any other Member State provided they first have the authorisation of their own system' (CEC, 2006b: 4).

In the current proposal however – as in all the unofficial versions that preceded it – the threshold for introducing a prior authorisation system for hospital care is very high. In spite of the fact that Commissioner Vassiliou had announced that a 'safeguard clause' would be introduced in the proposal, allowing Member States to maintain a system for prior authorisation, the final version of the proposal did not change fundamentally in this respect and the burden of proof for health authorities to justify a system of prior authorisation is very high. The explanatory memorandum of the proposed directive even states that 'there is no evidence that cross-border hospital care will undermine the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services' (CEC, 2008a: 16), suggesting that it will be almost impossible to justify a prior authorisation system.

We may wonder why the Commission persists in limiting the possibilities for a Member State to require prior authorisation for hospital care, although well aware of the thrust of the Court's rulings and the fact that this provision is unacceptable to the Member States⁶. Could it be that the Commission intends to use this provision in due course as a bargaining chip during the negotiations, by ceding ground on this point and thus preventing other aspects of the proposal from being watered down?

2.1.2. The link with Regulation 1408/71

Alongside the proposed directive, the existing framework for coordination of social security schemes remains in place. This regulation includes provisions on reimbursement of healthcare which becomes necessary on medical grounds during a temporary stay abroad by the insured person, e.g. based on the European Health Insurance Card. For patients seeking planned cross-border healthcare, this regulation ensures that if the appropriate care for the patient's condition cannot be provided in their own country within medically justifiable time-limits (undue delay), they will be authorised to go abroad.

6. See e.g. section 4 on the policy process.

This procedure puts the patient receiving healthcare in another Member State on an equal footing with the residents of that Member State, and the treatment costs are covered by public funds based on the social security arrangements applicable in the Member State of treatment. According to the proposed directive, whenever the conditions set out in Regulation (EC) No.1408/71 are fulfilled, the authorisation shall be granted and the benefits provided in accordance with that regulation.

Contrary to what is suggested in the proposal, the relationship between the regulation and the proposed directive is not altogether straightforward. *Firstly*, it is not clear whether the patient may choose which of the two mechanisms he prefers⁷ or whether the directive does not apply to healthcare becoming necessary during a temporary stay abroad or when the conditions for planned care provided for under the regulation are met⁸. *Secondly*, the proposal does not take into account the Vanbraekel ruling in which it is stated that patients having the right to receive planned hospital treatment in another Member State, based on the regulation, have to be granted reimbursement at least identical to that which they would have been granted if they had been hospitalised in the Member State in which they are socially insured. The Court pointed out that this could result in the payment of additional reimbursement if the rate of reimbursement in the Member State in which the patient is insured is more beneficial than that in the Member State in which the hospital treatment was provided⁹.

The Commission recently decided to bring actions before the Court of Justice against several Member States for not implementing this judgment (CEC, 2007a and 2008c). The Commission even takes the view in these procedures that European citizens must enjoy the same rights whether they are authorised to undergo hospital treatment in another Member State or are hospitalised during a temporary stay in another Member State.

We may thus wonder why the Commission did not include this view in the proposed directive. One explanation might be that it opted not to

7. Recital 23.

8. Article 3(2) and Recital 20.

9. Case C-368/98, *Vanbraekel*, Judgment of 12 July 2001.

overload its project, well aware that there is still the legal track through which compliance with the Court rulings can be exacted. Furthermore, the Commission possibly wanted to shift part of the task to DG Empl, to integrate it in Regulation 1408/71 on the co-ordination of social security systems. There has indeed been an ongoing struggle for many years between the Commission's DG Sanco, taking the lead on this proposal on the one hand and DG Empl, responsible for the regulation on the coordination of social security systems on the other hand, as to whether the Court rulings should be implemented in a specific directive or in a modification of the regulation. The Commission is however well aware that changing the regulation is much more difficult, since it has to be approved by unanimity within the Council.

Many other questions have been raised with regard to the relationship between the regulation and the proposed directive, e.g. on the differences in the definition of the Member State which should provide the prior authorisation and the Member State of affiliation, as well as the differences in scope of the two legal instruments, which could lead to three methods of assumption of costs existing side by side, based respectively on the Treaty, the directive and the regulation (see e.g. Council of the European Union, 2008).

2.1.3. Conditions for reimbursement of care abroad

The European Commission stresses in its communications that Member States may in any event impose the same conditions on patients seeking cross-border care as they apply domestically, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care (CEC, 2008d). This would indeed be in line with the Court's rulings that make allowance for imposing requirements upon the reimbursement of care provided abroad on condition that the requirements are necessary to protect a general interest objective and proportional to this objective¹⁰. However, the proposed directive limits these conditions to 'in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons'¹¹. No mention is made here of the possibilities of justifying requirements that could form an

10. Case C-385/99, *Müller-Fauré*.

11. Article 6.3.

obstacle¹². In the recitals it is added that these conditions should be 'based primarily on medical considerations' and that they do 'not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation'¹³. Given that almost any condition or requirement can be considered as a potential obstacle to free movement, it will become extremely difficult for Member States to justify requirements for the reimbursement of treatments provided abroad. The criteria and conditions for funding healthcare are however key elements of healthcare policies in all EU countries, aiming to guarantee the most cost-effective use of limited financial resources. The ECJ rulings did challenge national requirements, since it was not clear which domestic conditions could be justified for care provided abroad. This led to considerable legal uncertainty. The current formulation of the proposal, however, does not provide any more clarity as to which requirements can be justified. On the contrary, it becomes questionable whether the directive allows any criteria at all to be imposed on patients going abroad for treatment. However, defining the threshold for treatment is as much a part of the system of controlling access to insured healthcare as the decisions on what treatments to offer (OHE, 2008). As a consequence, patients could circumvent or challenge national rules by going abroad, thus putting pressure on the domestic legal framework.

2.1.4. Reimbursement of 'similar' healthcare

According to the proposal, the care costs that should be reimbursed are those which would have been paid 'had the same or similar healthcare been provided in its territory'¹⁴. However, the notion introduced by the Court was 'equally effective treatment'¹⁵, which could invite the authorities to assess, measure and compare the effectiveness of treatments. The notion 'similar healthcare', does not refer to such a potentially scientific objectifiable criterion, which might lead to even more legal uncertainty.

12. Article 9(1) imposes *additionally* that the requirements should be necessary and proportional, but does not allow for justification of criteria that might be an obstacle to free movement, as does the Court. Given the odd relationship between Art. 6(3) and 9(1), it might be that the Commission did not intentionally formulate Art. 6(3) so stringently.

13. Recital 28.

14. Article 6(1).

15. See e.g. Case C-157/99, *Geraets-Smits and Peerbooms* and Case C-385/99, *Müller-Fauré and Van Riet*.

2.2. Quality assurance for cross-border care

The second stated objective of the proposal is to ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

Here the Commission was required to do a very sensitive balancing exercise. The Court held that Member States should rely upon quality controls for healthcare providers and institutions supervised by the Member State of treatment, and thus cannot refuse reimbursement of care provided abroad on the grounds that they are unable to verify the quality of this care¹⁶. Yet mutual trust is not self-evident, in the absence of minimum rules at EU level. The proposal therefore aims to establish certain minimum guarantees for patients receiving treatment abroad. In fact this is the counterpart of the removal of obstacles to free movement: when nationally set guarantees are removed (negative integration), they are supposed to be replaced by EU level minimum guarantees on important aspects, so as to facilitate free trade and protect citizens (positive integration). However, with regard to healthcare EU level harmonisation is explicitly excluded in the EC Treaty.

According to the proposal, the Member State of treatment is responsible for ensuring that healthcare is provided according to clear standards of quality and safety; that healthcare providers make available relevant information to enable informed choices by patients; that patients have a means of making complaints and obtaining redress if they suffer harm from the healthcare they receive; and that both access to and privacy of medical records is guaranteed. The Commission, in cooperation with the Member States, shall develop guidelines to facilitate the implementation of these provisions. Strikingly, the drafting of these guidelines is not assigned to the executive committee, and it is not clear how they should be set.

The Member States of affiliation in turn will have to establish national contact points to provide information on applicable processes for cross-border healthcare.

16. C-444/05, *Stamatelaki*, judgment of 19 April 2007, par 36-7.

The provisions with regard to quality guidelines proposed in this section are among the most sensitive for Member States, since they imply EU interference in national health policies. The proposed guidelines on quality and safety standards would indeed apply not only to patients coming from another Member State, but to all care provision.

One final remark concerning the quality of cross-border care is that the proposal pays ample lip service to the importance of continuity of care, but does not provide the necessary tools to ensure the patient's smooth passage throughout the care chain. As shown by several studies on patient mobility, continuity of care and cooperation between the treatment providers domestically and abroad is often weak (Baeten, 2009). Since the proposal is based on the principle of free movement of (individual health) *services*, as opposed to the organisation of integrated health *systems*, the concept of continuity does not really fit into this approach.

2.3. Cooperation among Member States

The third section of the proposal obliges Member States to facilitate cooperation in cross-border healthcare provision, without however further specifying what this would entail or how it should be implemented.

Additionally, the proposal makes provision for developing future practical cooperation at European level in some specific areas such as mutual recognition of prescriptions issued in another Member State; the establishment of European reference networks for highly specialised care; the adoption of measures to make healthcare ICT systems interoperable and the pooling of efforts regarding the management of new health technologies (HTA).

2.3.1. European reference networks (ERN)

The Commission proposes that Member States should cooperate in the establishment of European networks, bringing together centres for specialised healthcare requiring a particular concentration of resources or expertise. Such networks could enable the relevant expertise to be brought to the patient, and could serve as focal points for medical training and research. In some instances patients would need to go to centres in other countries.

This proposal builds on the work of the High Level Group on Health Services and Medical Care (HLG) (*cf. supra*) (CEC, 2005a). It was interesting to see how Member States, traditionally watching jealously lest the EU should interfere in matters pertaining to the quality of care, agreed rather readily in the HLG on a series of criteria with which such reference networks should comply. These criteria could easily be considered as embryonic EU level quality norms for healthcare institutions. The criteria have been largely reproduced in the proposed directive.

The stimulus for establishing these centres seems to come from highly specialised domestic healthcare centres, pushing their national authorities to put this issue on the EU agenda (see e.g. Kostera, 2008). They hope to benefit from it, by gaining an international reputation and attracting patients from abroad. There seems however to be less demand to send patients abroad to centres in another Member State. And where such a need exists, such as in smaller EU countries, procedures guaranteeing patients access to specialised care abroad are already long since in place.

The proposal does not clarify how the care provided to patients coming from another Member State in centres integrated in European reference networks should be funded. According to the explanatory memorandum patients would be funded through the framework provided for by Regulation (EC) No.1408/71, based on the granting of prior authorisation¹⁷.

Patients will thus in principle either need prior authorisation from their national competent authority to have access to these centres and/or only be reimbursed at the level applicable in their home state. The latter might be very costly for patients, especially for patients from a 'newer' Member State needing care in an 'older' Member State. For these same patients, it might be beneficial if reimbursement levels are set according to the applicable tariffs in the EU 15 Member State of treatment, but this may conversely be very expensive for the funding health authority of the EU 10 Member State concerned; this could put pressure on the financial viability of the funding health system.

17. Recital 21.

Moreover, there is no intention to establish any kind of EU level planning, nor an EU level agreement for the payment of the centres' investment costs, which is logical since this would considerably encroach on Member States' competencies. As a consequence, it is difficult to see how these centres could acquire a concentration of resources and expertise.

One might therefore question whether these networks will really bring the added value for patients that is claimed and how they will achieve their objective of helping to promote access to high quality and cost-effective healthcare.

2.3.2. Data collection

Member States should also collect and transmit to the Commission statistical data on the provision of cross-border care to enable long-term assessment and management thereof. This implies that Member States will have to set up systems for data collection on the care provided, its providers and patients, the cost and outcomes. This might seem a logical request, yet its implementation could have important consequences. It would mean that authorities have to collect data not only on publicly funded care, but on all care provided on their territory. These data collection systems will apply to all care provided on their territory, since it will not be reasonably practicable to limit this to patients coming from abroad. Furthermore, the European Commission will be able to standardise the national data collection systems and it is not clear what the Commission might do with these data. For instance, publishing treatment outcomes per care institution could have perverse effects in the sense that providers might be encouraged to accept for treatment only low-risk patients. It remains to be seen to what extent Member States will be willing to cooperate in implementing this provision.

2.4. The executive committee

Many unsolved questions in the proposal will be dealt with by a committee set up according to the 'comitology' procedure¹⁸. This committee, chaired

18. Such committees are forums for discussion, consisting of representatives from Member States and chaired by the Commission. They enable the Commission to establish dialogue with national administrations before adopting implementing measures. A Council Decision sets out the decision-making procedures for these committees. Parliament can object to

by the Commission and made up of representatives from Member States will be responsible for deciding, for example, on the list of costly healthcare to be equated with hospital care; the application of rules on recognition of prescriptions and the criteria; the type of information to be provided to patients; the data collection for monitoring purposes and the conditions to be met by European reference networks.

The Commission is in the driving seat in this committee. By delegating decisions on key issues to this committee, the Commission *de facto* reduces them to technical questions, depoliticises them and keeps better control over the debates; interference from the European Parliament is avoided. The committee may potentially decide on issues that seriously impinge on Member States' health policies, as illustrated above with regard to the networks of centres of reference.

3. The social objectives and steering instruments of healthcare systems and the proposal

Health authorities are concerned about the potential deregulating effect of the internal market principles, obliging them to remove unjustified obstacles to free movement. Member States pleaded for more clarity on the possibilities for justifying regulations forming an obstacle to free movement, in the general interest. Therefore, in 2006, they asked in Council Conclusions on the common values and principles of EU health systems that the overarching social values of universality, access to good quality care, equity and solidarity be protected when drafting an EU level legal proposal (Council of the European Union, 2006).

The proposed directive suggests implementing these overarching social values of healthcare systems and refers to the 2006 Council Conclusions. However, based on Article 95 of the Treaty, with regard to the internal market, the directive ensures the fundamental *freedom* of movement of health services (and patients as consumers of these services) and guarantees minimum levels of quality throughout the EU. These are market based principles. National healthcare systems, on the other

measures proposed by the Commission or, as the case may be, by the Council if it considers them to be beyond its remit (http://europa.eu/scadplus/glossary/comitology_en.htm).

hand, aim to ensure the fundamental (social) *right* of access to care. For this reason, healthcare systems are mainly publicly funded and highly regulated to redress the market imperfections from which healthcare markets are suffering. Here we encounter the fundamental internal contradictions on which the proposal is built. In spite of the lip service it pays to these social objectives, the proposal can only start from the perspective of the *individual patient*/provider and lacks the legal and financial tools to contemplate coherent health *systems* and their social obligations. Furthermore, where there is potential to address the general interest mission of health services or to confirm the importance of the tools to manage the systems, such as planning, the proposal falls down. We will substantiate these assertions in the paragraphs below.

3.1. Mission of general interest

Apart from a very general reference in the recitals recalling that ‘health systems are part of the wider framework of services of general interest¹⁹, the proposal makes no mention of the general interest mission of health services, which could serve as a basic premise for health authorities to justify regulations. This contrasts with the earliest unofficial version of the proposal in autumn 2007, in which the general interest mission of health services was referred to clearly and explicitly. This initial version did indeed precede the publication of the Commission Communication on Services of General Interest (SGI) in which the Commission tried to conclude the debate on a specific legislative framework for SGI and social SGI, arguing that the Lisbon Treaty includes a protocol on services of general interest (CEC, 2007b).

It is also noteworthy that in this 2007 Communication on SGI, the Commission states that ‘Where an EU sector specific rule is based on the concept of universal service, it should establish the right of everyone to access certain services considered as essential and impose obligations on service providers to offer defined services according to specified conditions, including complete territorial coverage and at an affordable price.’ These principles are however not reproduced in the proposed directive. The directive is thus not based on the concept of universal service obligation.

19. Recital 4.

3.2. Overarching social values and equal treatment

The proposed directive states that it is up to the Member States to respect the shared overarching values of universality, access to good quality care, equity and solidarity²⁰. Member States have furthermore to ensure 'that these values are respected with regard to patients from other Member States, and that all patients are treated equitably on the basis of their healthcare needs'²¹. Furthermore, 'patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment'²². However 'Nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment'²³.

It is rather ironic to require Member States to ensure universal access to care for patients whose care is funded by a social security body from another Member State and for whom the possibility of interfering in the price setting for the care has been removed, since these patients receive care as private patients, as opposed to patients integrated in the statutory healthcare systems.

How can the Member State of care provision ensure 'equal treatment' when in the case of foreign patients the care providers act as private – as opposed to statutory – providers who cannot be obliged to accept patients from abroad for planned treatment? Furthermore, how should 'equal treatment' apply to patients from abroad if for instance domestic patients have to register with a GP or if they are not free to choose their hospital of treatment?

The explanatory memorandum explains that patients from within and outside domestic systems have to be treated in a non-discriminatory manner because 'this avoids either perverse incentives to prioritise patients from abroad ahead of domestic patients, or long-term under-

20. Recital 12 and Article 5.

21. Recital 12.

22. Article 5(1g).

23. Recital 12.

mining of capital investment in health. From a health perspective, treating patients equitably is essential to ensure that the health impact of cross-border healthcare on health consequences such as waiting times remains reasonable and manageable' (CEC, 2008a: 12). It is difficult to understand how the non-discrimination clause could provide these guarantees. Nothing in the directive prevents providers from prioritising better paying patients from abroad or selecting the most lucrative pathologies. Whether treatment of foreign patients undermines capital investment depends on whether these costs are incorporated into the treatment tariffs and not on whether foreign patients are treated in a non-discriminatory manner. These assertions of the directive aim to reassure those stakeholders worried about the effects the proposal could have on the social dimension of healthcare systems, but with unfounded arguments. Here the proposal becomes a political document, trying to convince, rather than a legal document.

3.3. Controlling the influx of patients and cross-border contracting

The directive does not provide any tools for health authorities to limit the influx of patients when substantial patient flows would put pressure on waiting times, planning policies or investment costs. This could for instance be the case when (semi-)public health purchasers conclude contracts with health providers in another Member State without consulting the health authorities of the receiving Member State. The proposal does not deal with such cross-border contracting practices. This contrasts with the fact that the first document agreed on by the HLG, in 2005, consisted of guidelines on the purchase of treatment abroad, thus illustrating the importance attached to this issue by the members of the HLG (CEC, 2005b). These guidelines were aimed at closer cooperation between the authorities of the Member States responsible for the purchasing and provision of healthcare respectively, and set out guidance for instance on the applicable legislation with regard to price setting and liability.

3.4. Freedom of establishment for providers

The implications of the ECJ rulings go far beyond issues related to patient mobility. Regulations limiting access to healthcare services or restricting

the exercise of these activities can form a barrier to the single market²⁴. This became particularly clear with the initial proposal of the much debated directive on services in the internal market, which obliged Member States to assess whether their healthcare regulation – e.g. the planning of healthcare services and tariff setting – was necessary and proportionate and, if not, it should be changed or abolished (CEC, 2004). Even though healthcare was finally withdrawn from the scope of the Services Directive, the EC Treaty rules on freedom of establishment still remain applicable to healthcare and this is likely to put even more pressure on the regulatory capacity of Member States than the patient mobility rulings have so far done. This is why the Member States urged the Commission in May 2007 to put forward a broad framework, not just on patient mobility (Council of the European Union, 2007).

Although the proposed directive claims to cover situations in which a patient moves to a healthcare provider in another Member State for treatment, the delivery of services from the territory of one Member State into the territory of another, such as telemedicine services, the permanent establishment of a healthcare provider in another Member State and temporary mobility of health professionals to provide services²⁵, in practice the directive only deals with patient mobility.

4. The decision-making process

At the time of writing, the proposal is being discussed in parallel in the European Parliament and the Council. It is to be adopted through the co-decision procedure with qualified majority voting in the Council of Ministers.

Stakeholders involved in statutory healthcare systems (purchasers and providers) support the overall objectives of the proposal but do express serious concerns (ESIP, 2008; HOPE, 2008). On some important aspects their positions correspond with the views taken by the organisations representing both the European employees and employers in the health sector (HOSPEEM, 2008; ETUC, 2008; EPSU, 2008). They stress that

24. For a complete discussion on this point see Gekiere *et al.* (2009).

25. Recital 10.

the majority of people wish to be treated as close to home as possible and warn of unintended long-term consequences for the health sector. Their concerns include the risk of creating health inequalities since only mobile, well informed, well-off patients will be able to pay up front and receive treatment abroad; the proportionality of the proposal, generating a heavy bureaucratic burden compared to the limited scale of patient mobility; the need to establish a prior authorisation system for certain types of care and the importance for Member States of retaining the ability to prioritise and manage resources and plan services. The ETUC and EPSU furthermore point to the potential impact on healthcare professionals and the risk that providers could give preference to the more profitable branches, thus accentuating the privatisation and commercialisation of healthcare. These positions contrast with the position of the Standing Committee of European Doctors which welcomes the proposal and congratulates the Commission (CPME, 2004). The European Consumers' Organisation for its part particularly welcomes the establishment of national contact points to provide patients with information on essential aspects of cross-border healthcare, but does also urge further discussion on the system for prior authorisation for hospital care (BEUC, 2008).

In the *Council*, Member States recognise the importance of having a Community legal framework governing patients' rights for 'cross-border care' to codify case law from the European Court of Justice.(Council of the European Union, 2008a). However, the majority of Member States emphasise that their competence over social security and healthcare must be maintained.

In December 2008 the French presidency of the Council drafted a remarkably detailed publicly available progress report on the debates in the Council (Council of the European Union, 2008b). This makes clear that nearly all Member States want to see significant changes to key provisions of the proposed directive. Furthermore, some Member States have substantive reservations on the whole Commission proposal.

Despite the diversity of their healthcare systems, the Member States are reaching a surprising degree of consensus on key aspects of the proposal. They all supported the following principles as formulated by the French presidency:

- Member States should be able to establish a prior authorisation system for hospital and specialised care. (One Member State preferred the Commission proposal). The definition of hospital and specialised care should refer to nationally listed types of care, based on EU criteria;
- Cooperation between Member States (intergovernmental) on quality of care, complemented by a system of information to patients.

Thus, among Member States there is not (any more) an east-west divide, nor a divide based on the different health systems, nor based on the political composition of the respective governments (with the possible exception of Sweden). Initially, some – mainly new – Member States hoped to make money out of incoming patients. But this divide has faded out, ending up in a shared concern to keep control over their healthcare systems.

The *Commission* expressed a general reservation on the compromise text put forward by the French presidency and had major concerns on all the issues on which there is a broad consensus among Member States.

The *European Parliament* takes the perspective of the individual patient/citizen, rather than that of the health system, responsible for ensuring equal access to care for the whole population. The draft report by J. Bowis, tabled in the Environment Committee, mainly focuses on issues related to the costs of care for mobile patients and on the possibilities for patients on waiting lists to receive treatment abroad. The Court's rulings and the proposed directive do indeed only create the right to reimbursement of costs incurred, implying that patients have to pre-finance their treatment and all the additional costs such as travel and translation. The Bowis report moreover further fleshes out the provisions concerning information. It does not question the provisions with regard to (removal of the) prior authorisation system for hospital care. With the elections approaching, MEPs will probably increasingly be inclined to take the perspective of the individual patient/citizen. Therefore it might well be that the European Commission will find an ally in the European Parliament in its confrontation with the Council and is awaiting the vote in Parliament before making concessions to the Member States.

Conclusion

The proposal for a directive on the application of patients' rights in cross-border healthcare marks the provisional end of a lengthy and laborious policy process aiming to find adequate responses to the rulings of the ECJ with regard to patient mobility and health services in the internal market. It aims to provide legal certainty concerning the implementation of the Court's rulings and to provide flanking measures, more specifically with regard to quality of care. It has been packaged as a document on patients' rights in an attempt to garner support from stakeholders and policy-makers.

However, in many respects the proposal – as it stands now – does not provide the necessary legal clarity on the ECJ rulings or with regard to the steering instruments that health authorities can use to manage their healthcare systems. On the contrary, the proposal removes several important possibilities for justifying obstacles to the free movement of health services which the Court had allowed for.

However, the stakes are high in respect of a legislative initiative in this domain. Indeed, where secondary legislation exists to clarify the application of the free movement rules in a certain field, the European Court of Justice will in principle apply a stricter test to verify the proportionality of the rules and obstacles to the free movement of services than where there is no such piece of secondary legislation²⁶. Furthermore, the Court itself is unlikely to search for grounds to justify obstacles in the general interest other than those included in the secondary legislation where such a document exists. As a result, a directive can only have added value on condition that it provides clear guidance, otherwise it risks eroding even further the regulatory capacity of health authorities.

With regard to quality of care an extremely sensitive balancing act was required between respecting the autonomy of Member States to organise their health systems on the one hand and the need to provide

26. See Sauter Wolf (2007): 'In the absence of a Community standard, the applicable proportionality test is whether the infringements of the Treaty rules were 'manifestly disproportionate' or not. Where secondary Community law applies (i.e. pre-emption of national norms by Community norms) a stricter 'least restrictive means' test may be applied'.

some EU level minimum guarantees, when EU law has removed the national guarantees, on the other. It looks as though the result will be that the proposed provisions will be weakened, but that for the first time Member States will accept some EU level soft procedure to discuss quality standards.

The proposal is replete with fine social principles on universal access and non-discrimination. However, these principles, as included in the proposal, do not pass muster in practice. The proposal, based on internal market logic, lacks the means – financial and legal – to pursue a social policy and to take into account the responsibilities and duties of health systems as opposed to the rights/freedoms of individual patients/citizens. As a consequence, concepts such as equity and access are detached from their social policy context. In this respect the document becomes a political declaration of intent rather than a piece of enforceable legislation.

The directive suffers from the contradictions between its stated aims – ensuring patients' rights – on the one hand and its real motivation – the establishment of an internal market for healthcare services – on the other. For instance, the proposal implicitly admits that the established procedures are not suitable for those patients who really need to go abroad for care, such as those requiring highly specialised treatment or on unduly long waiting lists. According to the proposal, such patients should go abroad through the 'classic' procedure, set out in the regulation on the coordination of social security systems, which does indeed provide the necessary guarantees of affordable care that the directive is unable to provide. Also, national contact points have to help protect patients' rights and enable them to seek appropriate redress in the event of harm caused by the use of healthcare in another Member State. Health authorities do provide such guarantees to their domestic patients. For patients going abroad, however, burdensome and costly mechanisms and procedures need to be put in place to guarantee only a fraction of what Member States (can) do at home.

Finally, in an attempt to avoid tough questions, the proposal often remains vague as to its implementation. It refers many key issues to a committee functioning according to the comitology procedure, where political accountability and democratic control are low. Many of the

decisions to be taken by this committee may however have a considerable impact on health systems.

It remains to be seen what the proposal will look like once finally approved. There is certainly potential for positively amending the proposal, and some of the positions set out by the French presidency and many of the amendments tabled in the European Parliament could contribute to that end.

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