



**PWG_10_84_O_Proposal for a Directive on the
application of patients' rights in cross-border
healthcare_2010Jun**

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Type	Others
Date	2010Jun28
Comments	



Proposal for a Directive on the application of patients' rights in cross-border healthcare - the debate is moving forward

1. Background

On [2 July 2008](#), the European Commission presented a proposal for a directive on patients' rights in cross-border healthcare, which aims to facilitate the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between member states, in full respect of national competencies in organising and delivering healthcare.

The proposed directive is part of the social agenda package of 2 July 2008, focusing on a triple objective:

- To guarantee that all patients have care that is safe and of good quality;
- To promote cooperation between health systems.
- To support patients in the exercise of their rights to cross-border healthcare;

The aim of the last objective is in particular to codify the case law of the Court of Justice relating to the reimbursement of cross-border healthcare, avoiding a "third method" of reimbursement (in addition to *regulation 883/2004* and the draft directive). Health systems are primarily the responsibility of the member states, but in some cases, as confirmed by several European Court of Justice (ECJ) rulings since 1998, EU citizens may seek health care in other member states, with the cost covered by their own health systems.

In the European Parliament (EP), the committee on Environment, Public Health and Food Safety (ENVI) was responsible for that proposal, with MEP Rapporteur at that time, Mr John BOWIS (EPP/ED, UK). On [23 April 2009](#) the EP adopted in plenary session its first reading opinion, approving 122 amendments to the original Commission's proposal. However, the report of Mr BOWIS was considered controversial and was the subject of criticism from political groups and the Committee of the Regions (CoR).

Despite the substantial progress made by the French, Czech and Swedish EU Presidencies, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) was unable to reach a political agreement on the proposal on [1 December 2009](#). The discussions in the Council focused mainly on the **reimbursement of costs with regard to non-contractual healthcare providers and on pensioners living abroad.**

2. Relaunch of the legislative procedure



After years of political wrangling, EU Health Ministers finally managed to reach a deal during the Spanish Presidency of the EU. This was done at the occasion of the EPSCO Council meeting that took place on [7-8 June 2010](#), where Health Ministers agreed on a draft directive concerning the application of patients' rights in cross-border healthcare, on the basis of a compromise text proposed by the Spanish Presidency.

During the Council meeting the discussions focused on four issues:

- The definition of **the member state of affiliation** with regard to pensioners living abroad;
- **Reimbursement and prior authorisation** with regard to non-contractual healthcare providers;
- The legal basis;
- The provisions on e-health.

The two first issues remained open at the EPSCO Council meeting of 1 December 2009 and the compromise text contains new solutions for these issues.

With regard to the **member state of affiliation** (which concerned in particular the reimbursement of healthcare costs of pensioners living in the EU outside their home country and receiving healthcare in a third member state), the Council agreed that as a general rule the member state competent to grant a prior authorisation according to regulation 883/2004 (i.e. the member state of residence) should reimburse the cost of cross-border healthcare for pensioners. If a pensioner is treated in his country of origin, this country would have to provide healthcare at its own expenses.

Concerning **healthcare providers**, the compromise seeks to ensure that patients looking for healthcare in another member state will enjoy the quality and safety standards applicable in that country, independently of the type of provider. Furthermore, the Council agreed that member states may adopt provisions aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the member state of affiliation.

Concerning the **legal basis**, the Council agreed on a double legal basis, striking a balance between the case law of the European Court of Justice on the application of Article 114 (approximation of laws) to health services and the member states' competencies recognized by the Treaty as regards the organisation and provision of health services (according to Article 168 on public health policy).

As regards **e-health**, the Ministers agreed on a close collaboration between the member states and the Commission in this field for the elaboration of guidelines on list of data to be included in patient summaries and for the development of



common identification and authentication measures to ensure the transferability of data in cross-border healthcare.

The draft directive also contains the following key elements:

- As a general rule, patients will be allowed to receive healthcare in another member state and be reimbursed up to the level of **reimbursement** applicable for the same or similar treatment in their national health system if the patients are entitled to this treatment in their country of affiliation;
- In case of overriding reasons of general interest (such as the risk of seriously undermining the financial balance of a social security system) a member state of affiliation may limit the application of the rules on reimbursement for cross-border healthcare; member states may **manage the outgoing flows of patients** by requiring prior authorisation for certain healthcare (those which involve overnight hospital accommodation, require a highly specialised and cost intensive medical infrastructure or which raise concerns with regard to the quality or safety of the care) or via the application of the "gate-keeping principle" (meaning that that general practitioners will act as "gatekeepers" who decide whether their patients should be considered for treatment overseas);
- In order to **manage ingoing flows of patients** and ensure sufficient and permanent access to healthcare within its territory, a member state of treatment may adopt measures concerning the access to treatment where this is justified by overriding reasons;
- Member states of treatment will have to ensure, via **national contact points**, that patients from other EU countries receive on request information on safety and quality standards on their territory in order to enable patients to make an informed choice;
- **Cooperation** between member states in the field of healthcare is **strengthened**, for example in the field of e-health and through the development of European reference networks which will bring together, on a voluntary basis, specialised centres in different member states;
- The **recognition of prescriptions** issued in another member state is improved; as a general rule, if a product is authorised to be marketed on its territory, a member state must ensure that prescriptions issued for such a product in another member state can be dispensed within its territory in compliance with its national legislation;
- Sales of medicinal products and medical devices via the **Internet, long-term care services** provided in residential homes and access to and allocation of organs for the purpose of **transplantation** fall outside the scope of the draft directive;

To sum up, the draft directive aims to facilitate access to safe and high-quality cross-border healthcare and to promote cooperation on healthcare between member states. It also provides clarity about the rights of patients who seek healthcare in another member state and supplements the rights that patients already have at the EU level through the legislation on the coordination of social security schemes (*regulation 883/04*).



3. Next steps

The Council's compromise text aimed at reaching a political agreement on a common position in the Council. The formal adoption of this first-reading position is scheduled for [September 2010](#). The adoption should then allow for the second reading in the EP which may be expected by [the end of 2010](#). If a majority of MEPs vote in favour of the revised text, the new rules will finally become EU law and will have to be transposed into national law.

The Belgian Presidency (which will take over the Spanish Presidency as from 1 July 2010) is expected to begin negotiations with MEPs with a view to producing a final agreement before Belgium hands over the rotating EU Presidency to Hungary in 2011.

The EP should debate the reformed proposal before the end of the year.

4. Challenges

There have been substantial differences between the Parliament and member states on the issue about **patients' rights in cross-border healthcare**. In principle, the EP has a more liberal view of how far the directive should go in facilitating patient mobility, and according to some MEPs the Council's compromise attaches too many conditions to patients' rights.

The new rapporteur on the proposed directive in the EP is **MEP Françoise Grossetête** (EPP, France) of the ENVI committee. Ms Grossetête welcomed the finally agreed deal by member states. However, Ms Grossetête sees some of the commitments as "fragile" and wants more equity and justice for all patients, depending on their medical needs and not on their financial means. Hence, there is still a lot of work to do in the EP given the shortcomings of the text that the rapporteur wants to address.

In the view of the **European Patients' Forum (EPF)**, the compromise deal clears the way for the next phase of negotiations, although 'more still needs to be done to make it really work for patients. The EPF is concerned, among others, that patients will have to pay for treatment upfront and seek reimbursement later under the rules. Patients' groups want accordingly mechanisms in place for alternative means of payment that would not leave patients to bear the whole cost of cross-border health care up-front.

As far as the European Commission is concerned, the ministers' agreement is not what the Commission initially wanted (the Commission doubts that the agreement will add layers of costly bureaucracy). For instances under the revised directive, patients must seek prior authorisation from healthcare authorities if their treatment involves a hospital stay of more than one night, high-tech



equipment or raises safety and quality concerns. National governments argue that these safeguards will allow them to manage health budgets, but in the view of the Commission they will frustrate the original intention of the law to help patients assert their rights.

The Spanish Presidency's compromise text can be found at:

<http://register.consilium.europa.eu/pdf/en/10/st09/st09948.en10.pdf>

Employment, Social Policy, Health and Consumer Affairs Council meeting of 7-8 June 2010:

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/115003.pdf

First reading in the European Parliament on 23 April 2009:

<http://register.consilium.europa.eu/pdf/en/09/st08/st08903.en09.pdf>

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