



**COUNCIL OF EUROPEAN MUNICIPALITIES AND REGIONS  
CONSEIL DES COMMUNES ET REGIONS D'EUROPE**

## **CEMR position**

**Proposal for a Directive on the  
application of patients' rights in cross-  
border healthcare**

**Brussels, January 2009**

## **CEMR position on the proposal for a Directive on the application of patients' rights in cross-border healthcare**

### **Background of the Commission's proposal**

On 2 July 2008, the European Commission published its *proposal for a Directive on the application of patients' rights in cross-border healthcare* as one of the initiatives of the "Renewed Social Agenda".

Even though most Europeans prefer to receive healthcare in their own countries, there are situations when patients may seek healthcare abroad. In recent years a number of cases have been brought to the European Court of Justice (ECJ) that assert patients' rights to reimbursement for healthcare provided in other Member States. Since 1998, the ECJ has consistently ruled that patients have the right to have their healthcare costs reimbursed in cases where it has been received abroad.

According to the European Commission, the directive should clarify patients' rights in cross-border healthcare and the limits Member States can place on such healthcare abroad and the level of financial coverage that is provided for cross-border healthcare. It should also prepare future practical European cooperation on healthcare.

### **Key Points of CEMR's position**

1. In many EU Member States local and regional authorities act as healthcare providers and are responsible for the organisation and financing of hospitals. They are therefore concerned by a directive on the application of patients' rights in cross-border healthcare.
2. CEMR questions the legal basis, article 95 of the EC Treaty, of the directive and thus applying the internal market concept to the provision of healthcare. We believe that the directive should be based on article 152 of the EC Treaty, public health.
3. We would like to underline the responsibility of Member States for the well functioning of healthcare systems as described by article 152.
4. Patients should in general be treated in their Member State of affiliation, according to the principle of proximity. Under certain conditions they might seek treatment abroad.
5. The organisation and delivery of cross-border healthcare should be provided according to the legislation of the Member State of treatment, including liability and aftercare in case of problems.
6. The Member State of treatment should be reimbursed the costs incurred as a result of the treatment. In cases where the costs are higher than in the Member State of affiliation, a provision should clarify the compensation of the extra costs, whilst not imposing an unfair burden on the Member State of affiliation.
7. The Member State of affiliation should have the possibility to establish a general system of prior authorisation for hospital and specialised care.
8. Hospital and specialised care include a broad range of treatments, and different from one Member State to the other. Therefore, hospital and specialised care should be defined by the Member State of affiliation.
9. Member States have to facilitate the cooperation in cross-border healthcare at all levels concerned; hence local and regional authorities should be consulted on the transposition and participate in the implementation of the directive.
10. CEMR recommends that detailed information concerning the organisation or administration should not be included in the text of the directive, but in form of guidelines or as an annex.

## **Introduction**

1. In a number of Member States local and regional authorities are responsible for the organisation and / or financing of hospitals and are therefore concerned by a directive on the application of patients' rights in cross-border healthcare.
2. We understand that the European Commission bases its initiative on the fact that several rulings of the European Court of Justice on individual cases necessitate clarification and a common legal framework.
3. Since the Commission's first intention to include provisions on the "application of freedoms to receive and provide health services" in the directive on services in the internal market in 2004, was not accepted by the European Parliament and the Council, the Commission prepared this specific directive for a Community framework for cross-border healthcare.
4. The proposal especially concerns cross-border healthcare for planned treatment and hospital and specialised care.
5. The draft directive does not address healthcare, which becomes necessary on medical grounds during a temporary stay of insured persons in another Member State. This is covered by Regulation (EC) 1408/71 on the application of social security schemes to employed persons and their families moving within the European Union.
6. CEMR welcomes a European framework on cross-border healthcare and the clarification of patients' rights whose main objective is to provide legal certainty for those patients that receive treatment in another Member State, provided that certain conditions, which we express in this position paper, are met.
7. Organising and financing health infrastructure, especially hospital and special care as targeted with the directive, includes long-term planning and investment and therefore these services cannot be considered as ordinary market services.
8. We believe that the main objective of a European framework should not be the unconditioned free movement of patients to seek treatment in another country than their own and their free choice of a healthcare provider. This could have a negative impact on the health infrastructure of the countries concerned.
9. The Commission aims with this proposal at providing a general framework for the provision of safe, high quality and efficient cross-border healthcare. However, we believe that the draft directive goes beyond this target and implicitly follows the idea of creating a market for hospital and special care.
10. CEMR does not agree with this approach, which could be an incentive for Member States to reduce their investment in healthcare services, including hospital and specialised care for their citizens on their territory.
11. We wish to stress that the directive must respect the principle of subsidiarity and the repartition of the competencies between the European Union and the Member States in the field of healthcare.

## **CEMR comments on specific provisions**

### **Legal basis (recital 2; article 1)**

12. The European Commission bases the draft directive on article 95 of the EC Treaty and thus chooses the establishment and functioning of the internal market as its main objective (recital 2).
13. The directive aims at establishing a general framework for the provision of safe, high quality and efficient cross-border healthcare (article 1).
14. CEMR questions article 95 of the EC Treaty being the right legal basis and would prefer the public health article (article 152 of the EC Treaty), which retains the Member States' responsibility for a well functioning public healthcare system. A legal framework based on this article would better serve the objective of accessible, available and sustainable cross-border health services.
15. Article 152(2) of the EC Treaty states that the Member States should coordinate among themselves their policies concerning public health. The role of the European Union is to encourage and promote this coordination. Article 152(5) refers to the responsibility of the Member States: *“Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care (...).”*
16. In line with the Treaty we want to stress that while a European directive should provide the legal framework, it has to respect the Member States' competencies in this area.
17. CEMR would like to refer to the European Commission's Communication “Services of general interest including social services of general interest: a new European commitment” from 2007, which also includes healthcare. It points at article 152 EC Treaty and states the importance to respect the responsibility of the Member States: *“Health Services are also part of the wider framework of services of general interest. Article 152 of the Treaty makes clear that Community action in the field of health services must respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.”*

### **Responsibilities of the Member State of treatment (article 5)**

18. CEMR agrees with the Commission that in the case of cross-border healthcare the Member State of treatment should be responsible for the organisation and delivery of healthcare. However, we advocate for clearly indicating in the directive that healthcare is provided according to the legislation of the Member State of treatment.
19. The Commission's proposal also calls for Member States to assure the existence of systems of professional liability insurance. CEMR would be in favour of clearer provisions on liability and aftercare in the case of problems, with special regard to the responsibilities of the Member State of treatment. <sup>\*1</sup>

⇒ *CEMR proposes to amend article 5(1) to clarify responsibilities of the Member State of treatment.*

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<sup>1</sup> Paragraphs marked by \* correspond to an amendment in the annex.

## **Reimbursement and prior authorisation for hospital and specialised care (articles 6 and 8)**

20. The proposal of the European Commission signifies an unconditioned free movement of patients to seek treatment. CEMR believes that patients should in general be treated in the Member State of affiliation in proximity of their home and with timely treatment. However, there might be conditions under which patients seek treatment abroad.
21. The Commission's proposal states that the Member State of treatment will be reimbursed by the Member State of affiliation up to the level of costs in the Member State of affiliation, without exceeding the actual costs. However, there is no provision for cases where the costs of treatment would be higher than in the Member State of affiliation. This raises difficult problems of how to balance the budgetary interests of the Member State of affiliation with the financial interests of the provider in the Member State of treatment.
22. CEMR seeks clarification on this issue, aiming that the Member State of treatment gets compensation for the costs incurred, without imposing an unfair burden on the Member State of affiliation. An agreement could for example in many cases be made as a compulsory part of the prior authorisation, ensuring that the patient would cover the extra cost.
23. The Commission would allow Member States to establish a system of prior authorisation under certain conditions (e.g. where the application of the directive would be likely to undermine the financial balance of the social security system or the planning and organisation of hospital capacities). Member States would only be allowed to establish a system of prior authorisation that is proven necessary and proportionate, and only if their situation meets the conditions laid down in the directive.
24. CEMR advocates that Member States should be able to establish a general prior authorisation system for hospital and specialised care. This system would enable Member States and hospitals, to better plan and finance their services according to the needs of the patients respecting the sustainability of healthcare systems. It would also ensure patients and healthcare providers with a guarantee of reimbursement. \*
25. Hospital and specialised care comprise a broad range of treatments and the definition of hospital and specialised care differ very much from one Member State to the other. Therefore, Member States should be able to establish a prior authorisation system for hospital and specialised care as defined by the Member State of affiliation.
  - ⇒ *CEMR proposes to amend article 6(1) with regard to timely treatment,*
  - ⇒ *to amend article 8(3) to allow Member States to introduce a general system of prior authorisation for the reimbursement of the cost of hospital and specialised care provided in another Member State.*

## **Subsidiarity in the cooperation on healthcare (articles 12, 15,17)**

26. CEMR supports the provision laid down in the proposed directive that Member States shall facilitate the cooperation in providing cross-border healthcare at regional and local levels. In line with this provision, we would like to stress the importance of consulting these levels during the transposition of the directive.
27. According to our understanding and with reference to the European Union's objective for better regulation, we advocate for a less prescriptive directive with less detailed provisions. This would help to reduce bureaucracy and respect the responsibility of the Member States to organise healthcare, in line with article 152 of the EC Treaty.

28. The European Commission proposes that Member States designate national contact points to better inform patients. We wish to underline the importance for patients to obtain necessary information on their rights related to cross-border healthcare, but we would prefer fewer details on the content of the information that should be provided by the national contact points. In this context the role of the Commission should also be limited in the management of the national contact points leaving any necessary measures to the Member States. \*
29. The draft directive defines objectives for European reference networks of healthcare providers such as sharing knowledge and providing quality and safety benchmarks. We believe that these networks might be very useful, but their objectives and the Commission's role should not be laid down in detail in the directive, but be provided as an annex or in the form of guidelines. \*
30. CEMR agrees with the principle of cooperation on management of new health technologies, but we consider it unnecessary to lay down in detail the objective of a network. Again, we advocate for a provision of the objectives in an annex or as guidelines. \*
- ⇒ *CEMR proposes to amend the following articles in order to have a less detailed directive respecting the principle of subsidiarity:*
- ⇒ *article 12(2) on national contact points,*
- ⇒ *article 12(3) on the European Commission's role regarding national contact points,*
- ⇒ *article 15 on European reference networks*
- ⇒ *article 17(2-4) on a health technology assessment network.*

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## Annex

### CEMR proposal for amendments

Document of reference: COM(2008) 414/3

#### Recital 10\*<sup>2</sup>

<i>Text proposed by the Commission</i>	<i>Amendment</i>
(10) For the purpose of this Directive, the concept of “cross-border healthcare” covers the following modes of supply of healthcare: <ul style="list-style-type: none"><li>- Use of healthcare abroad (i.e. a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as ‘patient mobility’;</li><li>- Cross-border provision of healthcare (i.e. delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;</li><li>- <b>Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,</b></li><li>- <b>Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).</b></li></ul>	(10) For the purpose of this Directive, the concept of “cross-border healthcare” covers the following modes of supply of healthcare: <ul style="list-style-type: none"><li>- Use of healthcare abroad (i.e. a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as ‘patient mobility’;</li><li>- Cross-border provision of healthcare (i.e. delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;</li></ul>

#### Article 5 – paragraph 1

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In <b>such a</b> context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards <b>for healthcare provided on their territory</b> , and ensure that:	1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare <b>on their territory</b> . In <b>this</b> context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards and ensure that:
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#### *Justification:*

Article 152 of the EC Treaty, the article for public health; paragraph 5 states that it is the competence of the Member States to organise and deliver the health services and medical care.

#### Article 5 – paragraph 1a–d\*

(a) mechanisms are in place for ensuring that healthcare providers are able to meet such	(a) <b>when healthcare is provided in a Member State other than that where the patient is an</b>
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<sup>2</sup> Amendments marked by \* are taken from the report of the leading parliamentary committee ENVI (environment, public health and food safety), drafted by MEP John Bowis; CEMR supports these amendments.



standards, taking into account international medical science and generally recognised good medical practices;	<b><i>insured person, or in a Member State other than where the healthcare provider resides, is registered or established, such healthcare is provided according to the legislation of the Member State of treatment.</i></b>
(b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;	<b><i>(b) healthcare referred to in paragraph 1 (a) is provided according to standards and guidelines on quality and safety defined by the Member State of treatment ensuring that:</i></b>
	<b><i>(i) patients and healthcare providers from other Member States can be provided with information on such standards and guidelines, including provisions on supervision, inter alia by electronic means;</i></b>
c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;	<b><i>(ii) patients and healthcare providers from other Member States can be provided with information on availability, prices and outcomes of the healthcare provided and details of the healthcare provider's insurance cover or other means of personal or collective protection with regard to professional liability;</i></b>
(d) patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;	<b><i>(d) patients have the means of making complaints when they suffer harm arising from the healthcare they receive and are guaranteed remedies and the right to seek compensation;</i></b>

#### Article 5 - Paragraph 3\*

3. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, shall develop guidelines to facilitate the implementation of paragraph 1.	3. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, <b><i>may</i></b> develop guidelines to facilitate the implementation of paragraph 1.
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**Article 6 – paragraph 1**

<p>1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State <b>where</b> the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled.</p> <p>The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.</p>	<p>1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State.</p> <p>The treatment in question <b>must be</b> among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. <b>Finally, treatment should be conditional on the Member State of affiliation not being able to provide it in time.</b></p> <p>The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.</p>
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**Article 8 – paragraph 3**

<p>3. The Member State of affiliation <b>may</b> provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State <b>where the following conditions are met:</b></p>	<p>3. The Member State of affiliation <b>has the possibility to</b> provide for a <b>general</b> system of prior authorisation for reimbursement by its social security system of the cost of hospital <b>and specialised</b> care provided in another Member State.</p>
<p>(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and</p>	<p><b>deleted</b></p>
<p>(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:</p>	<p><b>deleted</b></p>
<p>(i) the financial balance of the Member State's social security system; and/or</p>	<p><b>deleted</b></p>
<p>(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, 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.</p>	<p><b>deleted</b></p>

*Justification:*

The provision on prior authorisation (paragraph 3) goes beyond the Commission's competence as referred to in Article 152 EC Treaty. At present, patient mobility across Member States accounts for only a tiny proportion of all patients in the healthcare system. Under the directive however, one would

expect patient mobility to increase, especially in border regions and for certain types of treatment such as elective surgery.

We therefore recommend that a general system of prior authorisation for hospital treatment be set up giving Member States the possibility to control and plan their entire healthcare systems. Member States of treatment would thus be more likely to receive payment for the services they provided, since patients would have received prior authorisation for the treatment from the Member State of affiliation.

#### Article 12 – paragraph 2

2. The national contact point in the Member State affiliation shall, in close cooperation with other competent national authorities, <b>and with national contact points in other Member States, in particular in the Member State of treatment, and with the Commission:</b>	2. The national contact point in the Member State affiliation shall, in close cooperation with other competent national authorities,
(a) provide and disseminate information to patients <b>in particular</b> on their rights related to cross-border healthcare <b>and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;</b>	(a) provide and disseminate information to patients; on their rights related to cross-border healthcare

#### Justification:

It is important for patients to be able to obtain the necessary information on treatment options in other EU countries. The requirement for Member States to provide information, however, is very sweeping and would prove extremely difficult to implement in practice. Moreover, it is not clear what the Commission means with "legally binding as regards dispute settlement". The role and competences of national contact points should be more clearly defined.

#### Article 15 – paragraph 1–4

1. Member States shall facilitate the development of the European reference networks of healthcare providers. <b>Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfill all the required conditions and criteria.</b>	1. <b>The European Commission may support</b> Member States <b>in facilitating</b> the development of the European reference networks of healthcare providers.
2. The objective of European reference networks shall be:	<b>deleted</b>
(a) to help to realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems from innovations in medical science and health technologies	<b>deleted</b>
(b) to help to promote access to high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of resources or expertise.	<b>deleted</b>
(c) to maximise cost-effective use of resources by concentrating them where appropriate;	<b>deleted</b>
(d) to help to share knowledge and provide training for health professionals;	<b>deleted</b>
(e) to provide quality and safety benchmarks and to help develop and spread best practice within and outside the network;	<b>deleted</b>

(f) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide a full range of highly specialised services of the highest quality.	<i>deleted</i>
3. The Commission shall adopt:	<i>deleted</i>
(a) a list of specific criteria and conditions that the European reference networks must fulfil, including the conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks: (i) have appropriate capacities to diagnose, to follow-up and manage patients with evidence of good outcomes so far as applicable; (ii) have sufficient capacity and activity to provide relevant services and maintain quality of the services provided; (iii) have capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control; (iv) can demonstrate a multi-disciplinary approach; (v) provide high level of expertise and experience documented through publications, grants or honorific positions, teaching and training activities; (vi) provide strong contribution to research; (vii) are involved in epidemiological surveillance, such as registries; (viii) have close links and collaboration with other expert centres and networks at national and international level and capacity to network; (ix) have close links and collaboration with patients associations where such associations exist.	<i>deleted</i>
(b) the procedure for establishing European reference networks.	<i>deleted</i>
4. The measures referred to in paragraph 3, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).	<i>deleted</i>

*Justification:*

European reference networks may be useful and might be further developed, but they should not be dealt with in a directive, but for example in guidelines or in an annex.

**Article 17 – paragraph 2–4**

2. The objective of the health technology assessment network shall be:	<i>deleted</i>
(a) to support cooperation between national authorities or bodies;	<i>deleted</i>
(b) to support provision of objective, reliable, timely, transparent and transferable information	<i>deleted</i>

on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.	
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.	<i>deleted</i>
4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment and the management of this network and specifying the nature and type of the information to be exchanged.	<i>deleted</i>

*Justification:*

We support cross-border cooperation and the cooperation with regard to health technology assessment, since this will create added value for Member States. However, it is not necessary to use a directive to regulate cooperation on highly specialised treatment and on the management of new health technology via a directive; this would create a legal obligation for Member States to cooperate. The provision is thus not considered to be amongst the objectives set out in Article 1.