



## AER SUMMARY

European Commission Proposal for a Directive on  
the application of patients' right in cross-border healthcare (COM(2008)414 final)  
OG, version 18/02/2009

*This document has been prepared by the Secretariat of the AER Social Policy & PublicHealth Committee. It summarises the contents of the proposed Directive and highlights points that may have an impact on the regions' capacity to organise, manage and finance healthcare services. This document does NOT reflect the official AER position.*

### Background – Why this Directive?

It is a reality today that European Union law gives patients rights to receive treatment in another member state. The European Court of Justice (ECJ) has ruled that healthcare services also have an economic aspect and that the European internal market rules on free movement grant patients rights to receive healthcare in abroad.

There is no legal clarity regarding patients' rights to cross-border healthcare. We lack a European legislative framework that will clearly state what healthcare patients can receive abroad and under what conditions, who pays for the healthcare received abroad, who is responsible for the quality and safety of healthcare received abroad etc.

Healthcare services were excluded from the scope of the EU Services Directive adopted in December 2006 (2006/123/EC). AER had lobbied for the exclusion of healthcare from the Services Directive, arguing that healthcare was not a typical commercial commodity and should therefore be the subject of sectoral legislation based on the EU rules on health policy.

Legal clarity should be delivered in the provision of cross-border healthcare.

### Aim and Objectives of the draft Directive

The proposed Directive aims to:

- 1) clarify the conditions for exercising patients' rights to cross-border healthcare;
- 2) create a framework for increasing cooperation between Member States.

The text clearly states that it does not intend to:

- interfere with "...the responsibilities of Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness";
- nor to "endanger the financial balance of Member State's healthcare and social security systems."

### What rights and obligations will patients have under this proposed Directive?

- Right to travel abroad with the purpose of receiving healthcare, in many cases without requesting the authorisation of their home system.
- Right to equal access to healthcare abroad and equal treatment with domestic patients
- Right to clear information in their home country about the kind of healthcare available abroad, how much it costs, how much they will be reimbursed by their home system, what is the procedure for obtaining care in another country and what is the procedure for redress if something should go wrong.

### Structure of proposed Directive

- 1) reaffirm principles common to all EU health systems: universality, equity, access to good quality health care, solidarity (preamble of the draft directive)
- 2) clarify what patients are entitled to as regards cross-border healthcare and under what conditions (Articles 1-12)
- 3) create a new framework for European cooperation in key aspects of healthcare policy (Articles 13-18)

## THE DIRECTIVE AT A GLANCE

### What is the legal basis of the proposed Directive?

Article 95 EC- internal market: procedure for adopting legislation in order to implement the European internal market. The Directive “aims to establish a framework for providing safe, efficient and high-quality healthcare across Europe.”

The Directive also refers to article 152 EC – public health: European action to complement national policies in promoting a high level of health protection.

### What is the scope of the Directive? What areas does it cover?

Covered by the Directive	Outside the Directive’s scope
<p><u>Cross-border healthcare</u> irrespective of how it is organised, financed or provided and whether it is private or public.</p> <p>This means:</p> <p>1) patients receiving treatment abroad (patient mobility)</p>	<p>Long-term healthcare: assistance to families or individuals who are in a particular state of need over a long period of time (e.g. elderly homes, assistance to children and families...)</p>
<p>2) healthcare provider established in one member state provides cross-border healthcare in another member state (e.g. telemedicine, lab services..)</p>	<p>Healthcare costs incurred during a temporary stay of an insured person in another member state</p>
<p>3) healthcare provider established in another member state and providing healthcare there</p>	<p>Authorisation for treatment in another member state under the regulations of the coordination of social security schemes – this continues to be governed by the relevant EC Regulations (in particular EC Regulation 1408/71)</p>
<p>4) healthcare provider is temporarily in another member state and provides care there (mobility of health professionals)</p>	<p>Recognition of professional qualifications – continues to be covered by Directive 2005/36 on the recognition of professional qualifications + upcoming European Commission Green Paper on European Healthcare Workforce (expected to be published in December 2008)</p>

### What types of healthcare can foreign patients receive?

- ▶ Member states have to treat all patients (domestic and foreign) equally and not discriminate on any grounds.
- ▶ Member states can apply the same requirements/conditions to foreign patients as they apply to their own citizens, for example the obligation to consult a general practitioner before seeing a specialist or receiving treatment.



→ Prior authorisation schemes are effectively subject to approval by the European Commission. This means that, in the end, it is the European Commission that will judge the capacity and extent of competences of national health systems.

### How are patients reimbursed for the care they receive abroad?

- ▶ Patients can only be reimbursed for care that they are also entitled to in the country where they are insured.
- ▶ Patients pay the entire cost upfront.
- ▶ Patients are then reimbursed up to the amount they would have been reimbursed if they had received the same or similar treatment in the country they are insured.
- ▶ Patients have to carry the burden of any extra costs that may arise (costs going beyond what their home country reimburses).
- ▶ Patients cannot gain a financial advantage- they will only be reimbursed up to the level of the actual costs incurred.

### Possible areas of concern:

- What will be the financial impact of covering the costs of treatment abroad for social security systems? Without some system of prior authorisation or prior notice, how can social security systems foresee and calculate the increase in annual expenditure that may arise with patients seeking treatment abroad?
- What will be the impact on the patient of carrying the extra costs of treatment abroad? Does this proposed Directive make cross-border healthcare accessible to all European patients or only those who can cover the additional travel costs?

### Who is responsible for what?

#### Country where patient is insured

- ▶ Cannot prevent patients from seeking treatment abroad, if this treatment is also allowed in their own territory
- ▶ Provide information to patients about healthcare available in another member state and how to access it, the mechanisms and procedures for redress in case of harm resulting from the care, and the standards for quality and safety and data protection
- ▶ This information is given by the National Contact Points
- ▶ Reimburse patients within the limits of reimbursement for the same/similar treatment provided in their territory and without exceeding the actual cost of the treatment
- ▶ Must justify to the European Commission any prior authorisation schemes it puts in place for hospital care and 'special' treatments received abroad
- ▶ Must inform patients requesting prior authorisation within a time limit to be set out by the Members States (and which should consider: the specific medical condition, the patient's degree of pain, the nature of the patient's disability and the patient's ability to carry out a professional activity)
- ▶ Can impose the same conditions, eligibility criteria and formalities for reimbursement that would apply for the same/similar treatment provided in its own territory
- ▶ Implement a mechanism for calculating the costs of receiving treatment abroad that will be reimbursed.
- ▶ Guarantee patients wishing to receive treatment abroad access to their health records
- ▶ Recognise prescriptions given abroad for medicine that is also available on their territory

<b>Country where healthcare is provided</b>
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- ▶ Guarantee quality and safety of healthcare provided by creating clear standard and monitoring their implementation
- ▶ Ensure all patients (home and foreign) are treated equally
- ▶ Provide healthcare service upon request and under the same rules as for local patients
- ▶ Ensure common European principles for healthcare are respected (transparency, access to information)
- ▶ Responsible for harm that may arise for care received: has to inform patients on their entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.
- ▶ Can impose the same conditions, formalities and criteria for accessing care as those applying to domestic patients
- ▶ Cooperate with country where patient is insured to provide all necessary information for patients, via their National Contact Point.
- ▶ Guarantee data protection and ensure the continuity of healthcare by safely transmitting patient records

### The rules of which country apply?

Rules of country where patient is insured	Rules of country where care is provided
Reimbursement of treatment	Treatment received abroad
	Remedy/redress in case of harm resulting from treatment received abroad
	Healthcare provider gives treatment in another member state

### What are National Contact Points for cross-border healthcare?

- ▶ Their role is to provide information about healthcare available in another member state and how patients can receive it, as well as help them access healthcare abroad if needed.
- ▶ Each member state can decide where they will established and if they will be incorporated under existing structures (e.g. as part of existing information points for citizens).
- ▶ All national contact points should cooperate in exchanging information.

#### Possible areas of concern:

- Who will translate all the information received from the various member states? What will be the cost for translating the information and who will assume it?
- What is the financial cost of setting up the National Contact Points and how will this be covered?

### What are European Reference Networks?

- ▶ Networks of specialised healthcare providers across Europe that cooperate on a voluntary basis.
- ▶ Will act as centres for research and training, but will also provide specialised healthcare to patients.
- ▶ Their aim is to concentrate efforts, expertise and expenditure in order to provide effective and affordable specialised healthcare.

- ▶ Following the adoption of the Directive, the European Commission will produce a list of criteria and conditions for European reference networks, as well as the procedure for establishing European reference networks.

**Possible areas of concern:**

- How will these networks be financed?
- What will be the impact of this proposal on healthcare providers who are not part of a European Reference Network?

**Are medical prescriptions issued in another member state recognised?**

YES, member states have to recognise prescriptions issued in another country if they are for a product that is marketed in their own territory.

**What further measures will be adopted to ensure the effective implementation of the proposed Directive?**

- ▶ List of 'special' healthcare treatments that can also be subject to prior authorisation
- ▶ Measures to exclude certain categories of medicines from the mutual recognition of prescriptions
- ▶ List of criteria and conditions for European reference networks and procedure for establishing European reference networks
- ▶ Measures to facilitate the verification of the authenticity of prescriptions and the identification of medicinal products between countries.
- ▶ Measures for achieving interoperability of ehealth ICT systems, in particular as regards standards and terminologies.

**Decision-making procedure:** co-decision (Council following European Parliament opinion, with mandatory consultation of the European Economic and Social Committee)

**What is the timetable for adopting the proposed Directive?**

02/06/2008 proposal published by the European Commission  
 12+13/02/2009 Directive will be discussed at 78th Plenary Session of Committee of Regions  
 12/03/2009 EP: report scheduled for adoption in committee, 1st or single reading  
 23/04/2009 EP: plenary sitting (indicative date)

European Parliament Rapporteurs have been appointed and the dates for meetings have been settled:

Committee	Rapporteur / Co-rapporteurs	Political group	Appointed	Meetings
Environment, Public Health and Food Safety ( <b>responsible</b> , associated committees)	John Bowis	PPE-DE	28/08/2008	07/07/2008+ 01/12/2008
Economic and Monetary Affairs (opinion)	Harald Ettl	PSE	22/10/2008	20/01/2009
Employment and Social Affairs (opinion, associated committees)	Iles Braghetto	PPE-DE	09/09/2008	26/01/2009
Industry, Research and Energy (opinion)	Françoise Grossetête	PPE-DE	25/09/2008	02/12/2008
Internal Market and Consumer Protection (opinion, associated committees)	Bernadette Vergnaud	PSE	10/09/2008	21/01/2009
Legal Affairs (opinion)	Diana Wallis	ALDE	22/09/2008	19/01/2009

Women's Rights and Gender  
Equality (opinion)

Anna Záborská

PPE-DE

17/09/2008

19/01/2009

It is not sure that the European Parliament will be able to adopt its opinion before the end of its mandate and the European elections in June 2009.

