



AER SUMMARY
European Commission Proposal for a Directive on
the application of patients' right in cross-border healthcare (COM(2008)414 final)
OG, version 21/11/2008

This document has been prepared by the Secretariat of the AER Social Policy & Public Health 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.

We need a piece of legislation to clarify the rules that apply to 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 care 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 and to ensure the free movement of health services and a high level of health protection.”

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> <ol style="list-style-type: none"> 1) patients receiving treatment abroad (patient mobility) 	<p>Long-term care: 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>
<ol style="list-style-type: none"> 2) healthcare provider established in one member state provides cross-border healthcare in another member state (e.g. telemedicine, lab services..) 	<p>Healthcare costs incurred during a temporary stay of an insured person in another member state</p>
<ol style="list-style-type: none"> 3) healthcare provider established in another member state and providing healthcare there 	<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>
<ol style="list-style-type: none"> 4) healthcare provider is temporarily in another member state and provides care there (mobility of health professionals) 	<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.

- ▶ The Directive does not create new/additional entitlements for foreign patients. A regional authority does not need to grant a treatment to a foreign patient if this treatment is not available for domestic patients also. Patients abroad are entitled to the same treatment as is provided to domestic patients.

Possible areas of concern:

- What support will be provided to patients who do not speak the language of the country where they are treated? Who will cover the extra costs for interpretation/translation?

Do patients need prior authorisation before receiving treatment abroad?

Non-hospital care: patients can receive this treatment abroad without prior authorisation from their own system

Hospital care: treatment abroad can be subject to prior authorisation from the patients' own system BUT only if the member state can prove to the European Commission that:

- if the treatment had been provided on its territory, the social security system would have carried the costs
- the outflow of patients, after the draft Directive is implemented, undermines or may undermine the financial balance of the social security system or the planning and rationalisation of the hospital sector
- the application of a prior authorisation scheme is proportionate and justified by imperative reasons

Possible areas of concern:

- What will be the impact of treating foreign patients on the planning, management and delivery of healthcare services? Will there be an influx of foreign patients and what will be the impact on healthcare waiting lists?
- How can healthcare providers estimate the number of patients they are expected to treat and the implications in terms of their infrastructure and staff?

What is 'hospital care'?

Article 8 (1) of the proposed Directive: healthcare that requires the patient to take overnight accommodation for at least one night and special kinds of healthcare that does not require overnight accommodation.

This special healthcare will be outlined in a special list that the European Commission will develop (in cooperation with representatives of the Member States) after the adoption of the draft Directive. The list will be limited to treatments that are highly specialised and need expensive equipment or infrastructure and treatment that presents a particular risk to the patient or the wider public.

Possible areas of concern:

- No clear definition of 'hospital care' - the requirement for overnight accommodation varies across the different healthcare systems and the list of 'special' healthcare has not been defined yet
- No direct role is foreseen for regional health authorities to identify what should be considered as 'special' healthcare, and thereby subject to prior authorisation. The European Commission will work with a Committee of national experts created for this purpose.

Country where care is provided

- ▶ 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 implement procedures and mechanisms for redress and compensation of the patient
- ▶ 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 be 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.

What is the timetable for adopting the proposed Directive?

2 June 2008 : proposal published by the European Commission

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

European Parliament Rapporteurs have been appointed:

Committee	Rapporteur / Co-rapporteurs	Political group	Appointed
Environment, Public Health and Food Safety (responsible , associated committees)	John Bowis	PPE-DE	28/08/2008
Economic and Monetary Affairs (opinion)			
Employment and Social Affairs (opinion, associated committees)	Iles Braghetto	PPE-DE	09/09/2008
Industry, Research and Energy (opinion)	Françoise Grossetête	PPE-DE	25/09/2008
Internal Market and Consumer Protection (opinion, associated committees)	Bernadette Vergnaud	PSE	10/09/2008
Legal Affairs (opinion)			
Women's Rights and Gender Equality (opinion)	Anna Záborská	PPE-DE	17/09/2008

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.