Directorate-General for Health & Consumers

A major step towards a Europe for Health

Directive on Patients' rights in cross-border healthcare

European Health Care Conference – 20 May 2011

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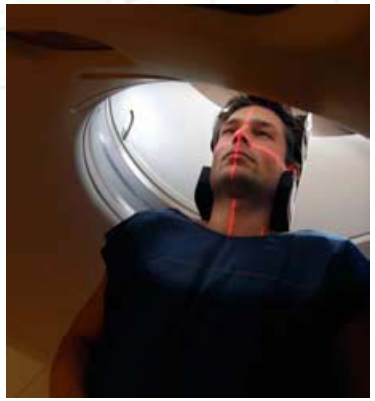
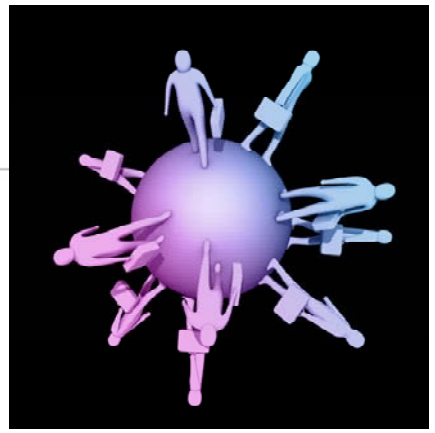
The 3 Aims of this Directive

1. **Help patients to exercise their rights to reimbursement for healthcare received in another EU country**

2. **Provide assurance about safety and quality of cross-border healthcare**



3. **Establish formal cooperation between health systems**



1. Helping patients

Information to patients

Patients will have access to all relevant information via their National Contact Points.

Rules of reimbursement

Clarification of rules - patients will know:

(1) need for prior authorisation; (2) reasons for refusal; (3) level of reimbursement, and (4) need for up-front payment

Procedural guarantees

Patients will benefit from:

(1) clarification of responsibilities; (2) clear rules if something goes wrong; (3) right to review of administrative decisions; and (4) right to judicial proceedings

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Information to patients

National contact points

- Rights and entitlements to cross-border healthcare in general
- Terms and conditions for reimbursement of costs (mechanism for calculation of costs)
- Procedures for assessing entitlements, including prior authorisation
- Appeal and redress procedures to challenge administrative decisions
- Standards and guidelines on safety and quality in the MS of treatment
- Healthcare providers subject to these quality and safety standards
- Healthcare providers' right to provide services and any restrictions on its practise
- Complaint procedures and mechanism for seeking remedies

Social Security Authorities (or health insurers)

- Their entitlements ("basket of benefits")
- Their level of reimbursement
- Application of prior authorisation in their case

Healthcare providers

- Options and types of treatments
- Prices and invoices
- Quality and safety of the healthcare they provide
- Their authorisation or registration status
- Insurance cover or other means of protection against professional liability

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Safeguards for health systems

Conditions of reimbursement

- National health authorities pay out NO MORE than for treatments that correspond to the benefits provided for in its territory;
- They pay out ONLY for treatments they would pay for at home.

Maintaining of national rules

- Member States define the rules applicable on their territory.
- Conditions and formalities for treatments required in Member States can also be imposed for treatments abroad.

General safeguard

In case of serious risks for health systems, Member States can introduce a system of prior authorisation.

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The System of Prior Authorisation

Scope for prior authorisation (PA)

Healthcare that:

- is subject to planning requirements: (a) one overnight stay in a hospital; (b) use of highly specialised or cost-intensive medical infrastructures or equipments;
- involves a particular risk to patients or population;
- is provided by a healthcare provider who raises concerns over quality and safety of care.

Patients affected by rare diseases

Recommendation to carry out a clinical evaluation by an expert in this field

Obligation of granting PA

If the healthcare in question cannot be provided within a reasonable time limit.

Reasons to refuse a PA

- Safety risk for patient or for population;
- Healthcare is provided by a healthcare provider that raises concerns over quality and safety of care;
- Healthcare can be provided within a reasonable time limit.

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2. Quality and safety

- **Transparency and accountability**

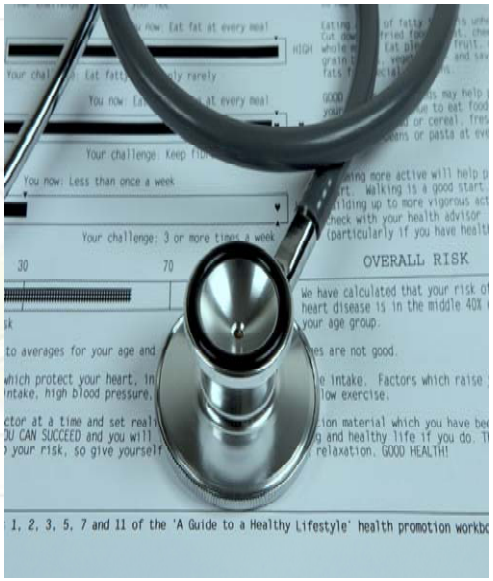
  Information on healthcare providers and on standards applied

- **Member States responsibility**

  Refusal of prior authorisation if doubts over quality and safety of a healthcare provider

- **Cooperation of Member States**

  On standards and guidelines on quality and safety



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3. Cooperation between health systems

- **Recognition of prescriptions**
  A prescription issued in another EU country will be recognised in a patient's country of residence and vice versa
- **European Reference Networks**
  It will bring together specialised centres accross Europe helping health experts to disseminate information and expertise
- **Health Technology Assessment**
  A permanent EU structure of cooperation to help decision-makers to make the right decisions on health investment and spending
- **eHealth**
  A first step towards "interoperability" of ICT for health at EU level for safety and quality of care, continuity of care, and health research

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The legislative process

- **Adoption** of the Commission proposal: 2 July 2008
- **First reading:** July 2008 - September 2010
- **Second reading:**
  - Sept. – Dec. 2010: Negotiations
  - 19 January 2011: Vote in Parliament
  - 28 February 2011: Formal adoption of the Council
  - 4 April 2011: Publication in the Official Journal
  - 24 April 2011: Entry into force
- **Transposition time:** 30 months (25 October 2013)

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THANK YOU!

Further information:
http://ec.europa.eu/health/cross_border_care/policy/index_en.htm