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Directorate-General for Health & Consumers

A major step towards a Europe for Health

Directive on patients' rights in cross-border healthcare

DG SANCO D2
Healthcare Systems

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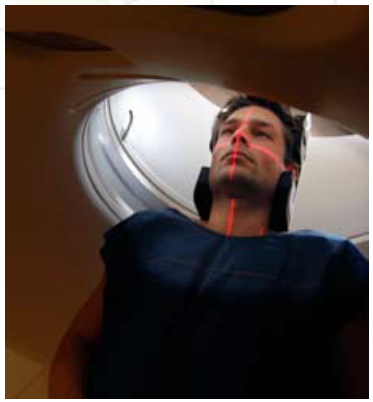
The 3 aims of this Directive

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



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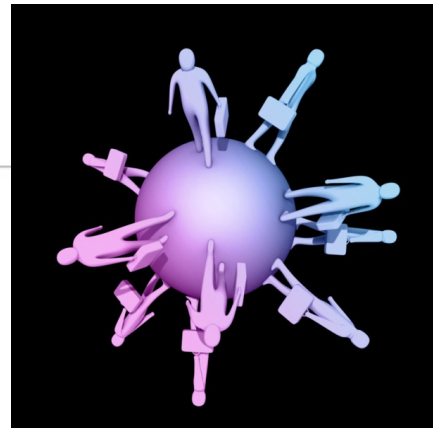

1. Helping patients

Information to patients

Patients will have access to all relevant information via 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

Member States will set up their National Contact Point(s) to help patients make informed decisions

Information provided will cover:

Rights; entitlements; reimbursement; quality and safety standards; healthcare providers and restrictions on their right to practise; appeal and complaint procedures and mechanisms for seeking remedies, etc.

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Safeguards for health systems

Conditions of reimbursement

- National health authorities pay out ONLY for healthcare that correspond to the benefits provided for in its territory;
- They pay out NO MORE 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.

Prior authorisation system

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.

Obligation of granting PA

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

Reasons to refuse 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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Rare disease patients

Easier access to information

Dissemination of information through the National Contact Points (created by the Directive) should benefit all rare disease patients in Europe who need a specialised treatment

Making patients, health professionals and payers of healthcare aware of the possibilities for referral of patients with rare diseases to other Member States

Dissemination of expertise

Better identification of appropriate health experts and dissemination of expertise by means of eHealth tools and networking of Centers of Expertise

Making health professionals aware of the tools available to them at Union level (Orphanet database, etc..)

Fostering appropriate clinical assesment

Decisions about prior authorisation *(for diagnosis especially)* should be based on appropriated clinical evaluation by experts in that field

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2. Quality and safety

- **Transparency and accountability**

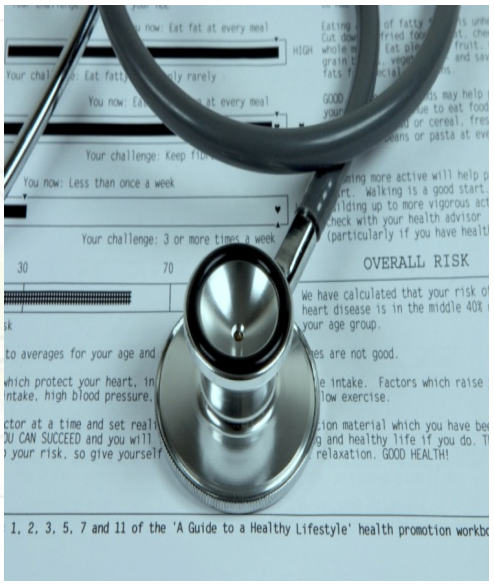
  Information on healthcare providers and on standards applied

- **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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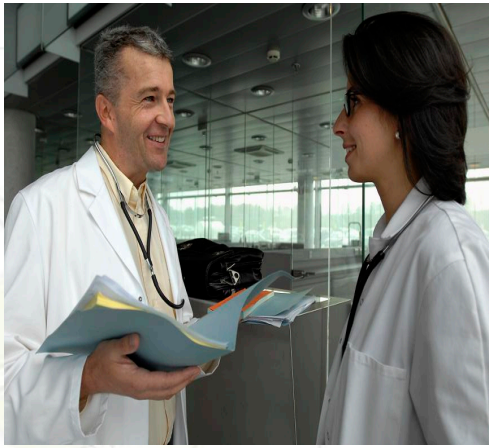
3. Cooperation between health systems



- **Recognition of prescriptions**
  A prescription issued in another EU country will be more effectively recognised
- **European Reference Networks**
  They 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:**
  - 19 January 2011: Vote in Parliament
  - 28 February 2011: Formal adoption of the Council
- **Publication in the Official Journal:** 4 April 2011
- **Entry into force:** 24 April 2011

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The transposition process

- **Transposition period:** 30 months **(25 October 2013)**
- **Bilateral discussions** with 27 Member States (MS):
  - COM **questionnaire** on the transposition of the measures provided for in the Directive (May – October 2011)
  - COM bilateral **visits** in all 27 MS (2011 – 2012) to discuss particular issues related to transposition
- **Committee on Cross-Border Healthcare**
  - Formal forum created by the Directive where all 27 MS will meet regularly to vote on implementing acts and discuss general issues linked with the transposition of the Directive.

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Thank you!

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