A major step towards a Europe for Health

Directive on patients’ rights in cross-border healthcare

DG SANCO
Unit D2 Healthcare systems
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
Starting point: European Court of Justice jurisprudence

- Healthcare is a service within the meaning of the Treaty
- If a patient is entitled to a treatment at home he or she is entitled to reimbursement for that treatment abroad
- Reimbursement is up to cost of that treatment in home system
- For some treatments (“hospital” care), health systems may require patient to seek “prior authorisation”
Codification of the principles

- **Conditions of reimbursement**
  - National health authorities pay out ONLY for treatments that correspond to their basket of benefits;
  - They pay out NO MORE for treatments than 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 (e.g. gatekeeping).

- **Prior authorisation system**
  - Member States may introduce a system of prior authorisation.

- **General safeguard**
The path to patient empowerment

PAST

- Patient - passive receiver of care

FUTURE

- Patient – partner of health professional

TODAY
PATIENT EMPOWERMENT

- Control over her/his own care
- Sharing responsibility for health outcome
- Education of patients
- Self-managed care
- Information to patients
- Choice of provider
- Effective healthcare system
- Choice of treatment
- Patient centred care
- Patient satisfaction
1. Helping patients (1/2)

National Contact Points

To provide patients with all relevant information on cross-border healthcare to help patients make an informed choice.
1. Helping patients (2/2)

- **Rules of reimbursement**
  Patients will know:
  
  (1) need for prior authorisation;
  (2) reasons for refusal;
  (3) level of reimbursement,
  (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;
  (4) right to judicial proceedings
The System of Prior Authorisation (1/2)

- **Scope for prior authorisation (PA)**

  Healthcare that:

  - **is subject to planning requirements:**
    - one *overnight stay* in a hospital;
    - 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.**
The System of Prior Authorisation (2/2)

- **Obligation of granting PA**

  *If the healthcare in question cannot be provided within a *reasonable time limit* (undue delay).*

- **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.*
2. Quality and safety of care

**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
Cooperation between health systems (1/2)

European Reference Networks

Main goal = to facilitate improvements in the diagnosis and treatment of certain diseases of conditions across the EU by the delivery of high-quality, accessible and cost-effective healthcare.

For patients suffering of medical conditions which could require a particular concentration of expertise or resources, particularly in medical domains where expertise is rare.
Cooperation between health systems (2/2)

- **Recognition of prescriptions**
  Easier recognition of a prescription issued in another EU country

- **eHealth**
  A first step towards electronic health services at EU level for safety and quality of care, continuity of care, and health research

- **Health Technology Assessment**
  A permanent EU structure of cooperation to help decision-makers to make the right decisions on health investment and spending
The transposition process

- **Entry into force:** 24 April 2011
- **Transposition period:** 30 months (25 October 2013)
- **Report on implementation:** (2015)
Rare diseases patients

**Easier access to information:**
The National Contact Points

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**
European Reference network
Orphanet database

**No extension of basket of care but**
Decisions on prior authorisation (for diagnosis especially) should be based on an appropriate clinical evaluation by experts
Elchinov case= concept of equivalence of treatment
Thank you!

Further information: