mHealth and the need to reconcile patient interests and the interests of the industry

Stefaan Callens

Professor of health law KU Leuven (Belgium)

Lawyer at the Brussels bar

www.callens-law.be

CALLENS

Content

- Introduction: e-Health, mhealth, telemonitoring and health-apps
- Existing legal framework
- Challenges for Healthcare Practitioners, for Hospitals and for Health law

e-Health, mhealth, telemonitoring and health-apps

- International health care actors
- Different health care systems although differences are diminishing
  - Justice and cost-efficiency in all health care systems
  - Impact of e-health, mhealth, …

Existing legal framework

- TFEU
- Directive 95/46
- Directive 98/34
- Directive 2002/58
- Directive 2000/31
- Directive 200747
- Directive 1997/7
- Directive 2011/24
- Rome I and Rome II regulations
- …

Potential issues and barriers to mHealth

1. The way health institutions are organized

- Networks of hospitals: European-wide reference centers

- Shift from inpatient to oupatient treatment

- Cross-border healthcare: beyond national boundaries

2. The on call services of healthcare providers

-Increasing shortage of physicians

-Patients are not present physically in hopitals but want to be monitored at a distance

3. Towards reimbursement of telemonitoring services

- Applicable law in crossborder telemonitoring

  Art. 3, d Directive patient rights and cross-border care

  '*Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established.*

- Reimbursement and Telemonitoring/mHealth

  Art. 7. 1 Directive patient rights and cross-border care:

  "The Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation."

- Art. 7.7:

*"The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, **including healthcare received through means of telemedicine,** the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources."*

4. The way the industry is involved in the delivery of health care

- Who is responsible for the data center?
  - who pays for it?
  - Can it be offered for free?
    - legitimate benefit?
    - impact on competition?

- Data center need to comply with ‘privacy rules’
- ‘Providing information’ versus ‘promoting medical devices’:
  - illegal advantage?
  - violation competition rules?
  - distinction between providing information - advertising

- Distribution of medical devices

- Direct contact between industry and patients:

  - health care settings apply telemonitoring/mobile health apps;
  - device manufacturers own data center
  - industry installs/follows up the device

5. New healthcare actors

-Role of data center?

-Legal qualifications of persons working at a data center?

Conclusions

- Need for a clear European legal framework
  - Towards European reimbursement principles
    - Criteria, delay etc.
  - Need for European rules on the
    - role of data centers and qualification of personnel
    - Distribution/promotion of medical devices/impact of industry in distributing devices/guiding patients