UNIversal solutions in TELemedicine
Deployment for European HEALTH care

Deploying Telehealth in Routine Care: Regulatory Perspectives

Industry Report on Telemedicine Legal and Regulatory Framework

EHTEL Symposium – 19 Jan. 2016, Brussels

Parallel Insight Session 3 – Tackling The technology Barriers – Interoperability and Regulation

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WHY this document?

• Going deep on legal and regulatory framework of telemedicine at EU and Member State level
• Provide recommendations on establishment of an effective legal and regulatory framework
• Supplement other guidances on how to comply with EU law related to telemedicine
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   1.2 The Legal Definition of Telemedicine in Europe
   1.3 Document Methodology

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   2.1 Telemedicine legal and regulatory framework at the European level
   2.2 The Data Protection Directive
   2.3 The e-Commerce Directive
   2.4 Medical Device Directives
   2.5 Directive on Distance Contracting
   2.6 Directive on Electronic Signatures
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   5.4 Provide clear regulatory guidance
   5.5 Foster use of widely recognized standards and support mobile broadband policies

APPENDIX A: GLOBAL TELEMEDICINE LEGAL AND REGULATORY FRAMEWORK
APPENDIX B: GLOSSARY
APPENDIX C: REFERENCES AND BIBLIOGRAPHY
4 KEY Objectives

1. **Analyse** legal and regulatory environments for telemedicine implementations: pilot regions & select Member States.
2. **Identify** legal and regulatory barriers to telemedicine and to interoperable, multi-vendor integrated device connected systems.
3. **Recommend** appropriate action to address barriers.
4. **Provide** feedback towards an improved legal and regulatory environment.
Medical Practice at a DISTANCE

“Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient, or two health professionals, are not in the same location.”

Commission Staff Working Document Definition
CROSSROAD of ICT, health policy and data protection

- Under European law, Telemedicine is both a health service and an information society service.
- As a health service, citizens have the freedom to seek and receive healthcare services from another Member State regardless of how that service is delivered.
CONSTRUCTING the Document

• Literature reviews
• Peer-reviewed articles
• Articles focusing on different aspects of telemedicine policy and issues
• Rules, regulations, working documents
• Published (or not officially published) documents by the EU and/or Member States
A legal and regulatory framework needs to be established that is not only clear and simple, but also flexible and nimble, and that, as technological advances, allows for an ever-evolving variety of methods for patients, physicians, payers and regulators to interact.
KEY RECOMMENDATIONS
for an effective legal and regulatory framework

1. Integrate telemedicine into care delivery structures.
2. Enable citizens' access to their data.
3. Develop appropriate reimbursement strategies.
4. Establish a harmonised data protection regime that allows innovation.
5. Provide clear regulatory guidance.
6. Foster use of widely recognised standards and support mobile broadband policies.

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MULTIPLE Legal Instruments

- The Data Protection Directive.
- The e-Commerce Directive.
- Medical Device Directives.
- Directive on Distance Contracting.
- Directive on Electronic Signatures.
- Competition law.
- Directive on Professional Qualifications.
- Reimbursement.
Data Protection Directive

PRINCIPLES

**General Principles**
- Prohibits processing of personal data concerning health unless data is required for purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of health care services.

**ATTENTION: Pay Attention to future GDPR!**
- Will establish **one** single set of rules but implementation lies on national DPA
- Likely to come into force **by 2018!**
- Consent must be given explicitly and can be withdrawn at any time, easier access to own data and info on how data is processed, right to data portability, “right to be forgotten”

**Telemedicine Principles**
- Personal data used in telemedicine must be processed fairly and lawfully.
- Data must be collected for specified, explicit and legitimate purposes, and not undergo further processing that is not compatible with these purposes.
- Data must be adequate, relevant and not excessive in relation to the purposes for which they are collected.
- Data should be identifiable for no longer than is necessary or for as long is required for further processing.
- Data subjects should be informed regarding the processing of their personal data.
e-Commerce Directive

PRINCIPLES

General Principles

• Applies to information society services defined as any service normally provided for remuneration, at a distance, by electronic means, for the processing (including digital compression) and storage of data, and at the individual request of a recipient of a service.

• 'At a distance' means that the parties are not simultaneously present.

Telemedicine Principles

• May apply to the transmission of information via a communication network or access to a communication network.

• Depending on the legal definition of telemedicine, may apply to the use of fee-based electronic research registers by physicians.

• May apply to physicians who promote their activities via the web.

• May apply to the sending of medical information among physicians for remuneration.
Medical Device Directives

PRINCIPLES

General Principles

• A medical device is any instrument, apparatus, appliance, software, material or other article, used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception.

Telemedicine Principles

• Software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device (2007/47/EC).
Directive on Distance Contracting

**PRINCIPLES**

**General Principles**

- Applies to any contract concerning goods or services concluded between a supplier and a consumer under an organised distance sale or service by a supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication.

- Sufficient information on the identity of the supplier, the main characteristics of the services, the price of the services, the arrangements for payment, delivery and performance, and the existence of a right of withdrawal, must be provided to the consumer.

- This information must be provided to the consumer in writing or via another durable medium available and accessible to them.

**Telemedicine Principles**

- A telemedicine contract between a professional and a consumer (patient) may be subject to rules related to contracts at a distance.
Directive on Electronic Signature

PRINCIPLES

General Principles

• Member States may make use of electronic signatures in the public sector.
• Additional requirements by the Member States must be objective, transparent, proportionate and non-discriminatory, and should relate only to the specific characteristics of the application.

Telemedicine Principles

• Member State requirements may not become an obstacle to cross-border services for citizens.
Competition Law

PRINCIPLES

General Principles

• Prohibits undertakings from participating in anti-competitive activities such as agreements to set prices or abuse of dominant position.

Telemedicine Principles

• Operators of services of general economic interest are subject to the rules in so far as the application of the rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them.

• May apply to the use of electronic networks where healthcare practitioners may have a common computer servicer to exchange patient information.
  – May not be used for the exchange of competitively sensitive information (e.g., prices, turnover, etc.).
  – Cannot lead actors to no longer compete with one another.
  – Information network has to be open.
Directives on Professional Qualifications

**PRINCIPLES**

**General Principles**

- Stipulates that Member States enact uniform, transparent, and non-discriminatory rules recognising professional qualifications and experience to allow professionals to work temporarily or permanently throughout the Union.

**Telemedicine Principles**

- Health professionals licensed in one Member State may practice medicine via telemedicine in other Member States without the need to obtain a medical licence in other Member States (Directive 2011/24/EU).
- Cross-border healthcare is to be provided in accordance with the legislation of the Member State of treatment (Article 4(1) of the Directive).
- Physician is free to provide services in other Member States so long as the physician complies with his or her Member State of establishment's legislation regarding holding a valid medical licence (Directive 2000/31/EC).
Reimbursement

• The E-Commerce Directive does not regulate the reimbursement of telemedicine services, which falls under the jurisdiction of Member States.

• Patients receiving healthcare in another Member State have to be reimbursed up to the level of reimbursement applicable for the same treatment in their Member State.
## Regulatory Framework for United4Health PILOT REGIONS

<table>
<thead>
<tr>
<th>Region</th>
<th>Telemedicine legal and regulatory specific provisions</th>
<th>Practical problems with telemedicine legal and regulatory framework</th>
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<tr>
<td>Czech Republic</td>
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<td>Denmark</td>
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<td>Wales</td>
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Future Regulatory TRENDS

1. Networked Care
   - Demonstrate commitment w/funding
   - Reimbursement essential for buy-in

2. Inter-jurisdictional Practice
   - Address transfer of information
   - Complementary jurisdictional policies

3. Diffusion of Telemedicine
   - Policies to allow greater penetration
   - Universal and unlimited access to internet
Future Regulatory TRENDS

4. Integration Into Existing Systems
- Establish targets to improve effectiveness of care
- Define simple processes for payment

5. Ethical Issues
- Define policies for obtaining consent of care
- Establish complementary jurisdictional policies
Breaking down silos through **INTEROPERABILITY**

### Challenges
- Inability to exchange data with other systems
- Lack of recognised IT standards for software and devices
- Infrastructure largely insufficient

### Benefits
- Supports patient’s safety and mobility
- Facilitates work of healthcare professionals
- Removes barriers (i.e., borders) for the deployment of telemedicine

Interoperability allows different technological solutions to communicate with each other, allowing patients and doctors to exchange medical information across healthcare settings, and across borders, even if using different devices (medical software, computer, phone, medical equipment, etc.) or ICT providers.
Getting to the NEXT LEVEL

• Existing legal and regulatory framework not yet complete
• Current EU rules often remain too vague
  – Legal definition of telemedicine
  – Enactment of European criteria for reimbursement
  – Address challenges caused by new technological developments (e.g., eHealth platforms, electronic health records, health grids)
17 Specific recommendations towards the ADOPTION of telemedicine activities and services

5 THEMES

- Integrate telemedicine into care delivery structure
- Develop appropriate reimbursement strategies
- Establish a harmonised data protection regime that allows innovation
- Provide clear regulatory guidance
- Foster use of widely recognized standards and support mobile broadband policies
INTEGRATE telemedicine into care delivery structures
specific recommendations

1. Licensing, authorisation and registration of the telemedicine provider
2. Telemedicine as a medical act
3. Patients’ rights when receiving cross border telemedicine
DEVELOP appropriate reimbursement strategies

4. Patients’ rights when receiving cross border telemedicine
ESTABLISH a harmonised data protection regime that allows innovation

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<th>Number</th>
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<td>5.</td>
<td>Maintain clear and separate responsibilities between the healthcare provider and the medical technology provider (data processor)</td>
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<td>6.</td>
<td>Simplify the condition for sub-contracting between the healthcare provider and the medical technology provider</td>
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<td>7.</td>
<td>Avoid unnecessary administrative burden linked to impact assessment obligations</td>
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<td>8.</td>
<td>Allow and support the sharing of health data for health and research purposes</td>
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<td>9.</td>
<td>Enable the secondary use of data for health and research purposes by adopting a workable consent requirement</td>
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<td>10.</td>
<td>Clarify the exemption to the right to be forgotten for ‘health purposes’</td>
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<td>11.</td>
<td>Ensure only data related to a data subject are subject to the regulation by adopting a proportionate definition of personal data</td>
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<td>12.</td>
<td>Enable citizens’ access to their health data</td>
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PROVIDE clear regulatory guidance

13. Provide a harmonised regulatory framework for telemedicine across the European Union

14. Adopt a regulatory framework that allows access to health data with proportionate safeguards
PROVIDE clear regulatory guidance

15. Invest in robust networked IT infrastructures

16. Continue efforts to promote open and standardised data

17. Digitise patient records and drive interoperability to ease access to clinical data
Thank You