

**International Scientific Conference:
EU eHealth Law and Public Health
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**LIABILITY IN MEDICINE – AN OVERVIEW OF MACEDONIAN LEGAL SYSTEM
AND PRACTICE**

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Legal aspects of eHealth

- Since the start of the development process of eHealth in EU it is considered that legal and regulatory issues are among the most challenging aspects of eHealth. This aspect of eHealth includes questions regarding privacy, confidentiality, data protection, and liability and they all present challenges that need to be addressed to enable a sustainable implementation and use of eHealth applications.
- In most EU countries the use of eHealth is regulated only by the general legal framework, by laws on patient rights and data protection, and by regulations on professional conduct and any new legislation is often still in the process of being drafted. The number of countries that have coherent set of laws especially designed to address these aspects of health law is very small and refers only on certain legal matters

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EU countries status on eHealth law

Amongst the forerunners in designing a legal framework adapted to the use of eHealth are Denmark, England, Estonia, Finland, France, Norway, Scotland, Slovak Republic and Sweden. Almost all countries which do not (yet) have specific regulations with regards to one or more fields of eHealth, such as Austria, Cyprus, Latvia, Malta or Portugal, do have some regulation on health data

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Vicarious liability

- the plaintiffs often claim damage from the healthcare institution (claims filed against healthcare provider) because the success of receiving compensation is more likely to be achieved on institutional than on individual level. On the other hand, in cases when the employer has compensated the damage caused by the employee with intention or gross negligence, the employer is entitled to regress

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Regress rules

- 6 months from the day the damages were compensated on behalf the Healthcare institution
 - Only in cases of intention or gross negligence
 - In cases of ordinary negligence (when the standard of good professional is breached this possibility is not provided)

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PRINCIPLE OF PRESUMPTION OF FAULT

- The hospital is liable for medical malpractice according to the principle of presumed fault, which means that the hospital must prove that it acted in a manner prescribed by the rules of the medical profession and that the damage was not caused by ordinary negligence on the part of the doctor who performed the task.
- The burden of proving that the rules of the medical profession were followed falls on the doctor/medical institution
- Also accepted in comparative law (Croatian)

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Court practice 2011-2021 based on research – official request for information

| Basic Court | Number of criminal verdicts | Number of civil court decisions |
|-----------------------|-----------------------------|---------------------------------|
| Shtip | 1 valid 1 in procedure | 0 |
| Strumica | 0 | 0 |
| Civil court in Skopje | / | 6 |
| Prilep | 1 valid 1 in procedure | 0 |
| Veles | 1 | 1 |

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Increasing number of claims

The general public is becoming more aware of the fact that adverse developments after medical treatment are not necessarily governed by fate and that there are ways to pursue claims for compensation against healthcare professionals and institutions which are not predetermined to fail

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In case of criminal proceeding

- The civil procedure is interrupted till the end of the criminal procedure
- The existence of guilt needs to be proved in the criminal procedure
- If the criminal procedure is negative or stopped, according to the Supreme Court:” the fact that Dr. T.V., employee of the defendant, was acquitted (declared innocent) by a final verdict regarding the accusation that he committed a crime "Serious crimes against human health", does not exempt the court from determining the civil liability of the defendant's health workers, which is a broader liability than the criminal legal liability, so in that sense the court should decide within on the set claim, i.e. whether the employee acted with the standard of care required according to the rules of practicing the profession.”

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Criminal offences related to medical care

Criminal Code

- - criminal offense from Article 207 "Negligent treatment of the patient",
- - criminal offense from Article 208 "Failure to provide medical aid" and
- - criminal offense from Article 217 "Serious crimes against human health"

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Plaintiffs

- The plaintiff in the cases of healthcare liability is the patient himself. But in cases of patient's death or severe disability, the plaintiff can also be a member or members of the family (the spouse, the children and the parents of the patient). According to the Macedonian tort law, certain family members have the right to fair monetary compensation and the court can determine the right of these persons to monetary compensation (under Article 190 od ZOO).
- The scope of these family members is determined by the law and includes the **spouse, the children and the parents of the patient**.
- **Brothers and sisters of the patient, the grandparents and the grandchildren of the patient, as well as the partner of the patient (for unmarried couples that live in community)**, but only under condition that between these persons and the deceased/ injured person there was a permanent life-long community.

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Rule in favor of wider scope for plaintiffs

- Although the close relatives of the injured/deceased have this right in a large part of the comparative legal systems, there are also legislations that do not recognize the right of the relatives to claim compensation for damages due to the death of a close person.
- Thus, in Germany, the Netherlands and Sweden, relatives do not have the right to claim compensation in the event of death, unless they themselves experience a nervous breakdown and thus develop a certain medical condition.

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Pecuniary damage

- General regime on pecuniary damage applies together with
- Special rules on pecuniary damage compensation in case of death, bodily injury and damage to health

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Types of pecuniary damage

Loss profits

Medical Treatment costs

Funeral expenses

Lost maintenance

Non pecuniary damage

Before the Novelle 2008

- differentiation of: suffered physical pain, suffered fear, suffered mental pain due to reduced general life activity, suffered mental pain due to bodily deformation, etc

After the Novelle 2008

- According to the new concept of non-material damage, the violation of personal rights itself constitutes non-material damage, while the physical pain, mental pain and fear that are related to the violation of personal rights do not represent a constitutive characteristic of the term non-material damage, but only a criterion for determining the specific content of the legal standard "fair monetary compensation"

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Court practice

Review of the amounts for non-pecuniary damage for the damaged person him self

compensation for non-material damage due to violation of personal rights to physical and mental health

| Случај | Suffered physical pain | Suffered fear | Suffered mental pains due to reduced general life activity | suffered mental pain due to physical damage with permanent consequences | Total amount |
|--------------------------|----------------------------------|------------------------------|--|---|----------------------|
| Случај 1 П.бр.1239/10 | 100.000,00 денари (1600 eur) | 100.000,00 денари | 1.500.000,00 денари 24.000 eur | 500.000,00 денари 8.000 eur | 2.200.000,00 денари |
| Случај 2 П.бр.1255/12 | 1.000.000,00 денари (16.000 eur) | 500.000,00 денари(8.000 eur) | 13.000.000,00 денари 209.000 eur | / | 14.500.000,00 денари |
| Случај 3 П.бр.1114/10 | 250.000,00 денари(4.000 eur) | 300.000,00 денари4.800 eur) | 600.000,00 денари 9.600 eur | 250.000,00 денари 4.000 eur | 1.400.000,00 денари |
| Случај 4 П.бр.1809/12 | The patient has died | | | | |
| Случај 5 П4-289/18 | The claim was denied | | | | |
| Случај 6 П4-39/14 | The claim was denied | | | | |

Court practice

Amounts for the close relatives of the patient

| | Non-pecuniary damage | | | | Pecuniary damage | |
|--------------------------|---|---|--|---|--------------------------------|----------------------------|
| Case | compensation for non-material damage for mental pain suffered due to permanent disability of a close person | Suffered mental pain due to the death of a close person - husband | Suffered mental pain due to the death of a close person - father | Suffered mental pain due to the death of a close person - son | Funeral expenses | Medical treatment costs |
| Случај 1 П.бр.1239/10 | 500.000,00 денари 8.000 eur | / | / | / | / | / |
| Случај 2 П.бр.1255/12 | По 3.000.000,00 денари за родителите 48.000 eur | / | / | / | / | / |
| Случај 3 П.бр.1114/10 | Блиски лица не се јавуваат како оштетени (тужители) во овој случај | | | | | |
| Случај 4 П.бр.1809/12 | / | 800.000,00 денари 12.900 eur | 1.000.000,00 денари 16.000 eur | 600.000,00 денари 10.000 eur | 243.835,00 денари 3.900 eur | 9.900,00 денари 150 eur |
| Случај 5 П4-289/18 | Denied claim | | | | | |
| Случај 6 П4-39/14 | Denied claim | | | | | |

EU comparison

- The absence of binding value amounts in European legal systems leads to large variations even regarding the highest amounts of non-material damages awarded which vary from 50,000.00 euros to 680,000.00 euros

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Bases for liability

- Fault
- The standard of care was not followed – claim approved
- The standard of care was met – claim denied

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eHealth developments in the context of liability

The Ministry of Health refers to this eHealth activities as health informatization process that include construction and implementation of numerous software solutions and systems:

- National system for electronic scheduling of interventions and examinations – My term or often referred as My Time in international documents
- Introduction of Electronic Referral with a unique referral number related to the Health Insurance Fund
- Introduction to electronic prescription
- Electronic medical diary to record medical interventions performed on the patient
- Electronic health record for patients
- Drug register and virtual warehouse
- Register of health facilities
- Electronic Health Card

Survey results

Scale of the most used eHealth services

| Scale of the most used eHealth services | Percentage of the respondents that use the service |
|--|--|
| Issuing ePrescription | 45.7% of all respondents |
| Issuing Referral in My Term System | 35.1% of all respondents |
| Use of services with the EHC | 7.9% of all respondents |
| Services provided by the Drug register of the Agency for Drugs and Medical Devices | 4% of all respondents |
| eServices provided by the Health Insurance Fund | 3.3% of all respondents |

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Survey 2022 – medical professionals

| Question: Although I provide health services and advices over the phone, I also use other ways of online communication with the patients | Viber /WhatsApp | Messenger | e-mail | All mentioned above | I do not use this kind of communication |
|---|-----------------|-----------|--------|---------------------|---|
| Responses in % | 74.5% | 10.6% | 6.4% | 6.3% | 2.2 % |

Two types of telemedicine services

services provided by medical doctors or other healthcare professionals

- those considered as a medical act, this means that it is an extension of the existing practice of medicine, performed by healthcare professionals – the ‘teleologies’ such as teleradiology, teleneurology, telecardiology

Human/computer

- telemonitoring services
- these services are remote monitoring technologies that provide health professionals or call centre personnel with biological parameters of the patient/citizen

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Legislation in North Macedonia that regulates the eHealth activities

the main characteristic is that it is not comprehensive, as there is no specific law that refers to eHealth activities but instead, we note several patterns of eHealth regulation:

- Reliance on general provisions for certain questions. General health record legislation is used to regulate the electronic records and general data protection rules are applicable with regard data used in the eHealth system/activities.
- No specific legislation but existence/adoption of specific legal provisions or several provisions in the general healthcare legislation. This is the case with the Electronic health card regulation which legal framework has been set in the Law on Health Insurance, and the Integrated Health Information System which legal framework is set in the Law on Health Care.

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