

# The Analysis of the Legal Framework in the eHealth Field in Moldova, in the Context of European Integration

Alexandru ROŞIORU

National Health Management Center, Technical University of Moldova  
arosioru@mednet.md

**Abstract** –The analysis of the legal framework in the eHealth field in Moldova, was made in the context of European integration. This study is aimed to identify the legislative and normative gaps in the field of implementing eHealth in Moldova; initiation of changes in normative existing documents and making new papers, policies documents, plans, standards. This study reviewed all medical information systems, implemented in Moldova, to identify legal gaps exist. Also in this study was structured lead analysis and the legal basis in the field of eHealth from European Union.

**Index Terms** – eHealth, Legal framework in the eHealth field, Health Information Systems, Regulatory framework.

## I. INTRODUCTION, AIMS AND OBJECTIVES

### “Solving the legal problems is primarily in developing any eHealth systems”

The medical information systems are developing rapidly in the world. This is due to qualitative and quantitative changes in the request for medical services, the amount of information in the public health care field and development of informational skills of the society.

In this way, eHealth has a great potential to become a primary factor in developing and improving medical services.

The process of informational society development in Moldova is based on the National Strategy of Informational Society Edification “Electronic Moldova”, approved by the Government’s Decision no. 225 from March 9 [1], of medical development field in Moldova.

eHealth means the use of Internet technologies and electronic communications by providing and administrating medical services and public health care.

eHealth facilitates the prices administration, lowering medical errors and offering improved medical services for the patients.

eHealth will have a major effect on:

- The directing of health care system;
- Curative and preventive assistance;
- Increasing working efficiency in extreme situations;
- Developing medical science;
- Training and retraining of the staff;

### The principles on the basis of strategy development in eHealth field are:

- Use of excellence examples and EU requirements for developing e-health services system;
- The responsibility of local and central administration bodies in the successful development process of eHealth;

- Efficient use of extremely limited financial resources;
- Integration of eHealth services in health care system to ensure appropriate use of informational technologies;
- **Legislation to create and exploit the eHealth systems in accordance to legislation, national and international standards;**
- **Protection and security of personal data in the patient’s interest;**
- **Accessibility and transparency of information regarding public health and medical services;**
- Increasing the role of patients decision making and use of information aimed at health and medical services;
- Social orientation of eHealth care system in Moldova.

**Specific objectives** for eHealth strategy in Moldova are based on equally treated subsystems, that will contribute to successful development of medical informational space in Moldova:

- **Developing normative and legislative framework for the use of informational technologies in medicine and its adjustment to the European.**
- Implementation of the Integrated Medical Information System Concept (IMIS) to control medical and administrative information flows.
- Achieving economic and management benefits from implementing eHealth services.
- Developing telemedical services to improving the quality and accessibility of medical services and bring closer medical services to the patient’s place of residence.
- Training in using informational technologies and improving the access of medical staff to

information and education, to increase the efficiency and quality of medical services.

- Facilitating the access to information for patients and citizens on public health and personal health to increase their participation in the decisions making process.

In recent years there has been a significant increase in use of ICT in health system. There were developed and implemented administrative information for primary medicine, health insurances, Automated Informational System "state Nomenclature of drugs", management in transfusion, monitoring and evaluation of the national Program of control and prevention of tuberculosis, etc.

According to the Ministry of Health's data, although there is universal access to ICT, only 143 medical institutions have broadband Internet access, fixed and mobile, and only seven institutions use ICT for data and information traffic between the medical institutions. Despite the fact that the number of medical staff using ICT is rising, currently only 12% of the doctors use Internet and 18% - use the computer in their professional activity.

Currently in Moldova's health system are implemented telemedical pilot-projects in perinatal, neurology and ophthalmology fields. Telemedical videoconferences and educational support based on Web, are used in professional training in remote. Through videoconferences doctors and students have regular access to international classes in different specialized medical fields.

The importance of ICT to enhance the quality and accessibility to medical services is increasing every year. All EU countries have adopted national strategies within the mutual effort of European Communities, mentioned in a number of documents supranational policies in the field, developed by the European Board in the years 2000-2009. To the end of 2011, EU countries are required to assess the situation and to adopt national legislation on access to telemedical services, including accreditation, accountability, procedures for reimbursement of services, confidentiality and data security.

The documents referred are aimed to optimizing the use of health systems resources, through mentioned by insertion of eHealth services. Through eHealth technologies is improved communication between providers of medical services and increases the patient's access to health information.

Through the Communiqué COM(2008) 0689 from 4.11.2008 „Telemedicine for patients benefits, health system and society”, European Board outlines the importance of telemedicine, and for positive implementation of telemedical services suggest to EU countries great facilities, related to building confidence and acceptance of telemedical services, inserting legal clarities, solving technical problems of compatibility and standardization, as facilitating market development in the field of economic relations. .

WHO, besides the consultative support, granted to support countries' efforts in developing eHealth, designates organizations that possess expertise skills and can serve as centres of reference for developing services in the field. WHO resources can be used to priorities identification, developing eHealth policies, strengthening the legislative, normative and ethical basis in the use of health information, dissemination of experience about the practice of excellence in the field and facilitating the implementation of technical

programs at national level.

The variety of eHealth services technologies, successfully implemented, include all levels of medical assistance, from public health to robotic surgery, from providing effective economic services and accessible to communities from dense populated areas to providing qualitative medical services in poor areas.

Developing legal framework for eHealth technologies use involves an analysis of current legislation, regulation in health care and telecommunications to identify legislative and administrative barriers in implementing the referred services. In the study will be outlined the normative and legal changes necessary for creating eHealth services in Moldova.

In the analysis of international experience will be reviewed the legislation and practice of European Community in the field of eHealth services regulation, protection of personal data, access to medical confidential information, etc.

This study is aimed to identify the legislative and normative gaps in the field of implementing eHealth in Moldova; initiation of changes in normative existing documents and making new papers, policies documents, plans, standards.

This study involves several components research:

- **Analysis of existing legal framework** in using informational technologies and communications in Moldova's health care system;
- **Analysis of legislative actuality of Integrated Information Health System Concept** and of other documents at the basis of informational and communication system in health sector;
- **Outlining legislative issues within the practices framework** of SIA implementation in health sector in Moldova.
- **Documenting positive practices** of EU countries regarding the harmonization of legislation in eHealth;
- **Recommendations/proposals** regarding development, changes or improvement of legislative documents aimed to rally the *acquis communautaire*, including its adjustment in accordance with other national legislative papers recently approved.

## II. CONCLUSIONS AND RECOMMENDATIONS REGARDING LEGAL FRAMEWORK FOR IMPLEMENTING E-HEALTH SERVICES IN MOLDOVA.

The concept of eHealth changes essentially practices and rules in health sector in terms of relationships between doctors and patients, between medical institutions, on the other hand, institutions involved in financing and monitoring health sector.

Legal safety represents a prerequisite for business environment to invest in innovations, and for medical institutions and patients to benefit of new products and services. As long as the eHealth market will be characterized by the lack of legal safety, there will be blocks for progress in the field..

The key to success in the eHealth initiative is putting into question at regional and national level the legal interferences between eHealth and national policy in health.

As a result of the legal framework analysis for the

implementation of e(m)Health in Moldova have been noted the following conclusions:

**At strategic level:**

- I. Health care system in Moldova has strategic tasks of implementing e(m)Health services based on National Strategies of building a informational society „Moldova electronic”, health care system’s strategy of development during 2008-2017, National Health Policy in Moldova, Integrated Medical Information System;
- II. In the health system of Moldova were carried out various activities for implementing ICT in health care, like:  
Telemedicine and distance learning in Moldova; Automated Informational System „Mandatory Health Insurance”; Automated Informational System „Blood Service”; Automated Informational System „The improved system of epidemiological surveillance of avian influenza and other infectious diseases”; Automated Informational System „ the state Nomenclature of drugs”; Automated Informational System „Primary Medical Assistance”, „Cabimed Manager” within the University Clinics of Primary Medical Assistance; Integrated Informational System of medical Assistance and medical Imagistics within the Institute of Neurology and Neurosurgery „Hospital Manager Suite”; Integrated Informational System of medical assistance within the National Scientific Practical Center of Emergency Medicine; Informational System of statistical data collecting, Informational System of Monitoring and Evaluation of TB; mHealth – mobile Health; Automated Informational System of Primary Medical Assistance „MedEx” put into experimental exploitation; Informational System of Monitoring and Evaluation of AIDS; etc.

But all these initiatives remain sporadic, fragmented and without continuity and sustainability, mostly because of the imperfection of legislative framework of e(m)Health implementation in Moldova.

- III. Some key provisions of the normative and legal framework are outdated and needs radical review (ex. Integrated Medical Informational System Concept);
- IV. Despite the presence of some deficiencies in european legislation e(m)Health, alignment to the European legislative framework is a primary objective and vital for the development of the field.

**At legislative level:**

- V. The legislative framework in Moldova, targeting both the health system, as the general is unspecific e(m)Health and does not include express provisions for its implement;
- VI. Regardless the fact that some key provisions for e(m)Health, like, Law on patient rights and responsibilities no.263 from 27.10.2007, Law on exercising the medical profession no.264 from 27.10.2005, Law on health care no.411 from 28.03.1995, Law no. 982-XIV from 11.05.2000 on the access to information, Law no. 264-XV „On the electronic documents and digital signature” from 15.07.2004, Law no. 17 from 15.02.2007 on the protection of personal data, Law no. 241- XVI from 15.11.2007 on the electronic communications, etc. are present in national legislation, although this legislative normative framework remains **incomplete.**;

VII. After the analysis was found the lack of specific horizontal of legislation for implimen in the e(m)Health field ;

VIII. All legal useful previsions in implementing e(m)Health are reflected in very dispersed ares/fields which inflicts on the petential users e(m)Health from Moldova;

**At normative level:**

- IX. There is no legal framework to stimulate and motivate the use the eHealth technologies in health care sector, including implementation of electronic chart of the patient and traffic of electronic data;
  - It is not established of electronic medical records;
  - There are no specific rules of usage for digital signature in health system;
  - There is no normative framework on the interoperability of medical electronic data;
  - There is no framework for unification of electronic medical terminology;
  - Etc.
- X. There is no regulatory framework related to standardization in e(m)Health.

### III. RECOMMENDATIONS

In order to overcome the situation concluded after analyzing the normative legal framework in e(m)Health in Moldova are proposing:

**At strategic level:**

Based on the analysis, particularly the overcome in tie of stratedic previsions in IMIS and the need to cut the priority actions in accordance with international and european rigors required

- Developing and approving the **National Strategy of development in the field e(m)Health and Telemedicine;**

**On legislative level:**

Given the non-specific characteristics, incomplete, disperse of the legislativ normative framework in e(m)Health present in Moldova, the only solution the deficiencies would allow allignment from the start to international and european standards are:

- Development of the **LAW ON THE E(M)HEALTH IN MOLDOVA.**

**On normative level**

- Development of The analysis of the legal framework in the eHealth field in Moldova, in the context of European integration electronic medical data status;
- Establish specific rules for use of digital signature for health system;
- Develop of legal framework on interoperability of medical electronic data;
- Need to adopt the framework for the unification of medical terminology in electronic format;
- Need to develop a set of standards in medical informational technology (medical informatics). (Ex. There are not approved the standards on the electronic chart of the patient, ENV 13606);
- To prioritize the needs of implementation– example, electronic chart of the patient must become priority in implementation, to facilitate the medical access to technologies;

- To identify the nomenclature on national level and establish technologies that would provide automatic dissemination of nomenclature approved by the Ministry of Health in automatic mode;
- Establish standards for data exchange between Ministry of Health, Health Insurance Company and Health facilities (example, establish standards of electronic reports based on Statistic Ticket)

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