

## COMPUTER TECHNOLOGY AND EHEALTH. TRENDS AND REGULATORY FRAMEWORK

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### Abstract

*The paper aims to identify key aspects of the essence of eHealth (digital hospitals, clinical information systems, computerized medical records, telemedicine) as a priority European policy and how it is reflected in the national legislation of Bulgaria. In this sense, the aim of the study is first to highlight the typical European trends in the development of eHealth through continuous and well-established processes of application of digital technology to healthcare and their incorporation into the Community policies as a legal framework, and second to analyze national processes and stages of digitalization of healthcare and the health insurance system in terms of the creation of functioning and adequate eHealth. Based on the analysis performed, the authors have drawn conclusions about trends in and legal effects of the regulatory framework related to the efficiency of healthcare and the effective management of the health insurance systems.*

**Keywords:** eHealth, digitalization of healthcare, National Health Strategy

**JEL Codes:** J81, K31

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### Introduction

The implementation of eHealth is a crucial step towards qualitatively different stages of healthcare and control of health insurance systems. Supported entirely by IT tools and processes, eHealth is expected to improve drastically the quality of and access to healthcare, including by overcoming the limits of the national systems.

The paper deals with the application of computer technology to modern healthcare. In this sense, the relevance of the subject is undisputable. On the one hand, this is due to the advent of digitalization in all spheres of public and private life. On the other hand, healthcare is among the most sensitive social issues and the State has the duty to ensure best quality care corresponding to modern trends. The interconnectedness of digitalization and healthcare is a concern not only of national institutions, but also of civil society. This issue has yet to be studied in its depth and complexity by legal scholars, and such studies would contribute to the clarification of a number of concepts and processes with a view to their proper legal regulation. The exploration of the issue in terms of its interdisciplinary aspects, namely its correlation to computer technology, presents a new perspective that could contribute to the proper practical interaction between healthcare stakeholders.

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In that sense, the **objective of this paper** is on the one hand to outline the typical European trends in the development of eHealth through continuous and well-established processes of application of digital technology to healthcare and their incorporation into the Community policies as a legal framework, and on the other hand to analyze national processes and stages of digitalization of healthcare and the health insurance system in terms of the creation of functioning and adequate eHealth.

In pursuance of this objective, the authors have undertaken the following **tasks**:

1. outline the general parameters of the nature and instruments of eHealth;
2. identify the main acts of European legislation, which constitute the sources of the process;
3. outline the stages of application of digital technology to the national legislation governing eHealth;
4. draw conclusions about the significance of and risks to the introduction of eHealth.

Methodologically, the paper employs the methods of legal research, namely the legislative method combined with the comparative method, for the purpose of comparing national with European norms.

The study complies with the legislation at European and national level existing as of 25 February 2020.

### **1. EHealth on European level**

EHealth is a major European policy arising from the need to improve the access to treatment and the quality of healthcare and is associated with tools and services using information and communication technologies. It includes the design of systems for exchange of information and data between patients, healthcare providers, hospitals and professionals, and consists of health information networks, electronic health records, telemedicine services, portable equipment to monitor the condition of patients, software to determine the work schedule of operating rooms, etc. In practical terms, the development of eHealth involves processes and tools related to digital hospitals, clinical information systems, computerized health records, remote healthcare, telemedicine and mobile healthcare. In this sense, it not only implies and consists in data exchange within health information networks and integrated health records systems, but also opens completely different horizons in front of medicine by marching towards telemedicine services, robotic surgery and research and development in the field of the “Virtual Physiological Human”.

The above goals of eHealth have been formulated at the level of the European Union as follows:

1. improve the health of patients by providing life-saving information even outside the boundaries of the state through eHealth tools,
2. improve the quality of and access to healthcare through the inclusion of eHealth in health policy and coordination between EU countries,
3. improve the efficiency, distribution and ease of use of eHealth tools by involving professionals and patients in the adoption and implementation of relevant health strategies as stated by the Commission (Overview of the aims, 2018).

The systematic development of eHealth as a Community policy is based on the strategy for a digital single market in Europe as a crucial step in achieving interoperability and adoption of standards for digital technologies in the EU. It includes the preparation and adoption of a number of instruments by European authorities, among which the most important are:

√ A recent transnational regulation addresses the issue on cross-border interoperability of electronic health record systems (Commission Recommendation on cross-border interoperability of electronic health record systems, 2008).

√ Directive 2011/24/EU which provides for the establishment of a network of national authorities responsible for eHealth in order to optimize interoperability between electronic health systems and continuity of care and access to safe and quality health care.

√ The issue is addressed also in Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, 2012).

√ Another transnational document is Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 2018).

√ It is addressed also in Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, 2008).

A number of European initiatives are related to the implementation of these acts, including the EU Measures to promote information and communication technologies in healthcare, and the associated Work Program for Standardization, Telemedicine (Tools to access information remotely), eTen – trans-European e-services of public interest (Database to search for projects in the field of eHealth) and others.

## **2. EHealth at national level**

**At the national level**, in line with Community policies, the Bulgarian state has gradually and systematically adopted corresponding acts of legislation and strategic documents on the digitalization of healthcare. The underlying instrument is the **National Health Strategy 2014-2020 (21.12.2013)** which provides guidance for the development of eHealth systems for the purpose of “complete functional interoperability, according to European and national standards and a high level of information and network security.” Based on this strategy, a **Roadmap to the Development of eHealth** was adopted in 2014. It seeks to develop and improve a software environment for information exchange, electronic health records, electronic registers, medical audits, electronic prescriptions, analysis capabilities, integrated identifier. This Roadmap indicates that the principal place in the design and further development of the eHealth system is occupied by the electronic medical record as a tool for coordination and provision of quality healthcare through the sharing of data by authorized persons, after obtaining the consent of the data subject.

In further development of the Strategy, the Program for Development of eHealth was adopted in 2014, which includes measures and actions to implement the main strategic objectives over the envisaged stages 1, 2 and 3. The Council of Ministers proclaims in the Program that “the purpose of the project is to build a system with a set of electronic services – electronic health records, electronic prescriptions, electronic referrals, electronic fit notes and others, which will exchange information and ensure transparency of the process of diagnosis and treatment of each patient, by ensuring access to all information online at any time”

(Program for Development of eHealth, 2014). In the spirit of Community policies, the Council of Ministers stated in the Program that “the incorporation of healthcare processes into a single national system with the ability to control and exchange information in real time using modules for monitoring key indicators ensures interconnectedness of all processes through the applied innovative technology and allows for adequate analysis and intervention by the Ministry of Health.” (Program for Development of eHealth, 2014). The Program identifies the main expectations from the introduction of the eHealth system, which can be analytically summarized as follows:

- √ reduce errors and duplication of medical activities and the administrative burden of the different procedures to the benefit of health care providers, patients and the system in general;

- √ improve the quality and efficiency of health services and thus the making of timely and adequate management decisions within the system;

- √ introduce uniform mechanisms for planning and forecasting of the processes in healthcare;

- √ increase transparency of medical and health insurance information and make possible its provision to all stakeholders.

The latest **National Health Strategy 2020** and in particular Policy 2.6 “Development of eHealth” sets out the concrete stages of the introduction of eHealth, namely:

1. Adoption of national standards for health information and statistics and of policies on security and interoperability of information systems in healthcare.

2. Establishment of National Health Information System and ensuring public access to the system through an electronic identifier.

3. Expansion and upgrade of a modular health information system through real-time exchange of information among stakeholders in the health sector: electronic referrals, electronic prescriptions, laboratory data and research, electronic health records.

4. Introduction of information and communication technologies into the healthcare infrastructure by providing connectivity to all providers of medical services through computer networks, communication devices, Internet access.

5. Provision of hardware capability for centralized electronic registers and electronic databases, introduction of secure user authentication.

6. Development of web-based services operating in real time and tools to ensure information security through encrypted data exchange.

7. Design, refinement and implementation of a concept for the development of telemedicine in the various health sectors: emergency, outpatient and inpatient care, and in the process of provision of long-term care and integrated health services in the community and building a network of connections between them.

However, in analyzing the nature and effects of eHealth, we should not ignore the dangers to **the legal framework**, consisting in the inability to predict or even forestall the real threats to patients and providers through statutory and regulatory mechanisms. These risks can be summarized as follows:

- √ placing patients and medical services consumers under constant supervision, monitoring and surveillance, in view of the trend of increasing the role of prevention and its integration into the health service;

- √ the exchange of health information and its provision to different individuals and entities involved in the processes poses the very real threat of infringing unlawfully and unrecoverably upon personal civil rights;

√ possible impairment of fundamental ethical principles underlying the relationship between the physician and the patient, related to online professional practice, informed consent, privacy and equality (Galeva, Danova & Grigorov, 2018);

√ a shift in the healthcare values model and emergence of a real threat of it being commercialized. Thus, the European Economic and Social Committee proclaims with good reason that a functional eHealth system requires designing and implementing an "interoperability framework for health information systems", which unifies principles and standards for data exchange based on the five V's (Volume, Velocity, Variety, Veracity, Values) in order to prevent exploitation for purely commercial ends (Opinion of the European Economic and Social Committee on the "Impact of the digital healthcare revolution on health insurance", 2017).

### **3. Conclusion and Recommendations**

EHealth is an inevitable consequence of the overall trend of digitalization of all public processes. On the one hand, the society is obviously undergoing processes, both at European and national level, related to the continuous adoption, updating and refinement of statutory and regulatory instruments aimed at creating a functional, harmonious, efficient and up-to-date healthcare system. At the same time, it is difficult to anticipate the appropriate mechanisms to safeguard the rights of individuals and to ensure privacy and personal data protection.

As rightly stated by the Council of Ministers in the National Scientific Program for eHealth, at the national level eHealth is facing a number of obstacles such as lack of interoperability between different software products and systems used by physicians and medical institutions; inadequately regulated protection of personal data; lack of transparency in the use of the collected data; voluminous medical records, which are prepared using software systems that require manual entry of a significant portion of the information (National Scientific Program for eHealth, 2018).

Healthcare is a conservative field, sensitive to changes. At the same time, it is subjected to the turbulent processes of digitalization and this requires the adaptation of the healthcare system to the new realities. It is undeniable that eHealth is the path to quality health services to the benefit of patients, given its ability to quickly and efficiently collect, analyze and archive data, resulting in better medical services, timely diagnosis and adequate treatment. But its successful implementation will take the concerted efforts of all stakeholders involved at the various levels of the process: government authorities implementing the policy, healthcare providers and computer experts, all seeking to create an operational, compatible and, above all, secure healthcare system.

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