REPORT
"JOINT STRATEGY TOWARDS SUSTAINABLE E-HEALTH MANAGEMENT"

Project: „Improving Healthcare Access through a Personal Health Monitoring System"/eHealth Monitoring/

Funded by the Interreg V-A "Greece-Bulgaria 2014-2020" Cooperation Programme co-funded by the European Regional Development Fund (ERDF) and national funds of the participating countries

Deliverable: D3.5.2 Joint Strategy towards sustainable e-health management

Beneficiary: Municipality of Kirkovo

Subcontractor: "Advanced Business Consulting" Ltd

http://www.ehealthmonitoring.eu/

I. OVERVIEW OF PROJECT "IMPROVING HEALTHCARE ACCESS THROUGH A PERSONAL HEALTH MONITORING SYSTEM"

Project "Improving Healthcare Access through a Personal Health Monitoring System"/eHealth Monitoring/ is implemented under Grant contract B2.9a.11/31.10.2017 funded by the Interreg V-A "Greece-Bulgaria 2014-2020" Cooperation Programme co-funded by the European Regional Development Fund (ERDF) and national funds of the participating countries.

The project is implemented under Priority axis 4 – "A Socially inclusive cross-border area" investment priority 9a "Investing in health and social infrastructure which contributes to national, regional and local development, reducing inequalities in terms of health status, promoting social inclusion through improved access to social, cultural and recreational".

The main objective of this project is to develop a personal mobile healthcare system on the base of the mobile video supporting device allowing ambulant patients:

- remote monitoring of the patient's state
- patient's continuous self control
- live contact from any place and any time with professional medical staff through modern communication network.

The main objective of the project is to facilitate the access to healthcare services in territories and populations that currently are not sufficiently serviced due to both geographical and mobility reasons (remote areas, elderly people, people with disabilities etc).

The project includes six work packages:

- WP 1 Project management and coordination;
- WP2 Communication and dissemination;
- WP 3 Policy integration;
- WP4 Joint monitoring system;
- WP5 Information, training and awareness raising.

Project partners:

- Lead beneficiary Centre of caring and solidarity of Komotini municipality
- Beneficiary 2 Central Union of Municipalities in Greece
- Beneficiary 3 Democritus University of Thrace - Department of Economics - Special Account for Research

- Beneficiary 5 Municipality of Kirkovo
- Beneficiary 5 Association „EURORADAR"

II. CONTENT AND AIMS OF THE REPORT

This report summarizes the work under Art. 1, (2) of Contract № 272 / 01.07.2019, signed between the Municipality of Kirkovo and Advance Business Consulting OOD.

The document is part of the implementation of Work Package 3 "Political Integration", result 3.5.2 "Joint Strategy towards sustainable e-health management".

III. METHODOLOGY

Various information sources were used to develop this report, including:

- Existing strategic documents, analyzes and studies covering the territory of Kirkovo municipality, Kardzhali district
- Public statistical information from official sources - National Statistical Institute (NSI), registers of the Ministry of
- Education and Science, Registers of the Regional Health Inspectorate (RHI), Kardzhali Social Assistance Directorate (SSA), Labor Office Directorate (LBD),

The methods for analyzing the information included:

- Descriptive analysis;
- Content analysis;
- Comparative analysis;
- Expert analysis.

IV. INTRODUCTION

HEALTH SYSTEM IN THE REPUBLIC OF BULGARIA

Healthcare is a complex system that includes activities for management, financing and provision of health services aimed at improving the health status of the population of the country. The modern health care system is based on the principles of solidarity, the right to choose and efficiency in spending the resources of the system and by its nature has both social and economic characteristics. The role of the state in health care in most countries is still paramount, although trends in the world are towards increasing liberalization of the health services market and the introduction of competition (*Health financing and management: theoretical foundations, models, problems and trends, Ministry of Finance, Republic of Bulgaria*).

The legal framework of the Bulgarian healthcare system covers the Health Insurance Act, the Law on Professional Organizations of Doctors and Dentists and the Law on Medical Establishments. Legislation and regulations in the field of control over narcotic substances, food, health and safety at work, blood transfusion, etc. are also in force. The by-laws (decrees, ordinances and instructions) are constantly being improved in order to bring it in line with the basic laws.

The legally established independence of the three parties in healthcare - consumers, service providers and funding bodies, as well as the introduction of contractual relations are the main prerequisites for the creation of a market for health services (with elements of competition between providers). This system is aimed at linking the financing of medical and health care institutions with the results of the activity and the quality of the services and guaranteeing their independent functioning (*Mitev B., 2006*).

Funding covers the collection and pooling of financial resources and their distribution among contractors (purchase of services). In the national budgets of the participating countries.

The NHIF consolidates its revenues as a buyer and distributes them by negotiating with the providers of health services. After the introduction of the health insurance system in 2000, a change was made in the mechanism of resource allocation - instead of based on the number of beds and staff, the payment of contractors is based on the results of activities and some historical indicators. The most important feature of the new system is the regulated contractual relations between the NHIF, acting as a buyer of health services, and public and private health facilities. All Bulgarian citizens have compulsory insurance, covering a certain package of medical services, which is covered by the NHIF. The health services are provided by virtue of a contract concluded between the regional health insurance funds - divisions of the National Health Insurance Fund and the contractors. The main obligations of the parties under the contract, the tariffs, the methods of payment and the procedures are specified in the National Framework Agreement (NDA), concluded every year between the NHIF and the professional organizations of doctors and dentists in Bulgaria. Contracts are also concluded between the voluntary health insurance funds and the providers of medical care.

The knowledge, skills and funding mechanisms needed to provide quality medical services to society are linked to the new market conditions.

Introduction to e-health

Over the last decade, the world economy has become significantly more digital. The information and communication technology (ICT) sector is entering all areas of social and economic life. The expectations of citizens and businesses to public institutions are growing and are directly related to ensuring more public control over their activities, improving the quality of services provided and ensuring a higher standard of living.

In the globalizing world, e-government is becoming a real and basic tool for implementing important policies that make the economic and social environment increasingly competitive and rapidly evolving. Electronic administrative services (EAS) and processes lead to improved service quality, to increased internal efficiency of the public sector and, above all, to the benefit of citizens.

The existing strategic European documents for e-government and the recommendations of the European Commission (EC) to the individual Member States are aimed primarily at achieving a new level of active, two-way communication, both within the administration and between institutions and consumers. processes provides a more open and transparent governance mechanism.

In response, Bulgaria undertakes to follow the planned path and to implement all measures related to the introduction of e-government. E-government is the implementation by administrative bodies, the judiciary, persons performing public functions and organizations providing public services of legal relationships, administrative processes and services and of interaction with users through the use of information and communication technologies, providing more high level of management efficiency.

E-government is the main platform for digital transformation of public institutions, for improving the quality of administrative services, for the transition to rational electronic processes of functioning and management in the public sector and for electronic access to the information available to public institutions. It is a tool both for comprehensively increasing the efficiency of the processes in the administration and for facilitating the interaction between the administration, the citizens and the business. In a coordinated, standardized and appropriate implementation of e-government, valuable resources are released - time, people and finances.

In e-government, four main elements are clearly distinguished: resources (financial, human, ICT, etc.), legal framework, interaction between participants in e-government and public relations. These four elements are interconnected, as public relations impose the need for digital interaction between the participants, which predetermines the existence of e-government.

The interaction between the participants in e-government is the most dynamic process, which is constantly evolving and raises the need to develop new ICT functionalities. Functionalities, in turn, predetermine the development of existing and the creation of new resources. There is also a need for a continuous process of updating the legal framework, which will adequately regulate public relations in the interaction of participants and regulate the use of both resources and newly created functionalities of ICT.

Technology has greatly supported the development of medicine over the last few decades. New generations of equipment and techniques for precise diagnostics and treatment have been created. This is not enough to solve the problems related to (1) the insufficient number of qualified medical specialists, (2) restrictions or no access to medical care for people living in remote areas and / or underdeveloped infrastructure, (3) the provision of timely medical care in relation to specific medical needs.

In their work "Telemedicine and e-health - features and application" Rusev P. and Georgieva M. reveal the following:

(1) Prospects for improving the quality of life:

- Progress in the provision of medical services - telemedicine technologies allow consultations with specialists in real time, directly in the homes of patients and thus eliminates a significant part of the travel of health professionals to remote areas;
- Funds are saved in the local economy - telemedicine helps to provide health services at the local level so that people do not have to travel outside the places they live. Health care costs account for a significant share of any local economy, especially in remote areas, so the more money is retained in the community, the better the local economy will grow.

(2) Patient perspectives:

- Access to health care - use of telemedicine services provides access to quality health care, especially for the benefit of residents of remote areas. They deserve to have the same access to health services as people living in urban areas.
- Save time, travel and other expenses - often people from isolated areas have to travel to cities for medical advice. The introduction of telemedicine facilities in remote areas saves transport costs, travel costs, as well as environmental protection, eliminating much of the necessary travel.
- Home health care (Telehome) - the home health care in question applies to patients who are discharged from hospital but need additional medical care until they recover. Studies show that through Telehome, nurses "visit" more patients in one day, and this is 30-35% cheaper than traditional home visits. (Example: The nurse talks to the patient via video link and receives up-to-date information about his vital signs. This approach allows monitoring of patients with renal failure, diabetes, cancer and other chronic diseases.

(3) Medical perspectives:

- Reduction of medical errors / accuracy of the diagnosis - it is much easier for a doctor to get a second opinion from a colleague about a patient's diagnosis through telecommunication. This reduces the incidence of improper treatment.
- Continuing medical education / lifelong learning - telemedicine can improve the educational opportunities of healthcare providers and patients without having to travel long distances and waste valuable time.

(4) Economic prospects:

- Reduction of staff costs in medical institutions;
- Savings for patient transport;
- Savings for patients;
- Increasing the use of local additional medical services (laboratories, pharmacies, etc.), as patients do not travel to other municipalities for their initial care (Maneva 2014)

V. NATIONAL AND EUROPEAN LEGAL FRAMEWORK IN THE FIELD OF ELECTRONIC HEALTH

European legislation related to eHealth

EU Member States have the primary responsibility for organizing and delivering healthcare and medical care. EU health policy therefore serves to complement national policies and to integrate health issues into all Union policies.

EU public health policies and actions aim to:

- To protect and improve the health of EU citizens
- To support the modernization of the health infrastructure
- To increase the efficiency of European health systems.

Strategic health issues are discussed by senior officials of national authorities and the European Commission in a working group on public health. The EU institutions, Member States, regional and local authorities and other stakeholders contribute to the implementation of the Union's health strategy.

The role of the European Commission is to support Member States' efforts to protect and improve the health of their citizens and to ensure the accessibility, efficiency and sustainability of their health systems. This is done by various means, some of which are:

- Proposing legislation
- Providing financial support
- Coordinate and facilitate the exchange of good practices between EU countries and health experts
- Health promotion activities.

The development of e-health is enshrined in the strategic documents, as well as in the primary and secondary law of the European Union.

EU strategic documents:

- Europe 2020 Strategy: a strategy for smart, sustainable and inclusive growth;

- EU Health Strategy "Together for Health";

- Health for growth: EU health program (2014-2020)

EHealth Action Plan 2012-2020 - Innovative Healthcare in the 21st Century

EU legislation and Community law:

- Treaty on the Functioning of the European Union (TFEU).

- Regulation (EU) № 282/2014 of the European Parliament and of the Council of 11 March 2014 establishing the third Union action program in the field of health (2014-2020)

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

- Regulation (EU) (910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and certification services for electronic transactions in the internal market and repealing Directive 1999/93 / EC.

- Regulation (EU) № 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

- Regulation (EU) (987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EU) № 883/2004 on the coordination of social security systems.

- Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011. to exercise patients' rights in cross-border healthcare.

- Directive 2005/36 / EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications.

On 25 April 2018, the European Commission adopted an **Action Plan on Digital Transformation in Health and Care**, which aims to put EU citizens at the heart of the healthcare system. This will be achieved through:

1. Safe access of citizens to and sharing health data

The Commission wants to ensure that EU citizens have secure access to a comprehensive electronic record of their health data throughout the EU. Citizens must continue to monitor their health data (wherever they are) and be able to share it securely with others for purposes chosen by these citizens, such as medical treatment or research.

The Commission recommends:

- development and adoption of a "European format for electronic exchange of health records", which would expand the existing infrastructure for digital eHealth services; and
- establishing interoperable standards that minimize barriers to the cross-border transfer of health information and data within the EU and identify incentives to adopt the common format; and

2. Better data to promote research, disease prevention and personalized health and care

The Commission recognizes that there needs to be better coordination between existing national and regional initiatives on the pooling of health data in research and personalized medicine.

3. Digital tools for citizen empowerment and personal care

In its communication, the Commission notes that the demand for health and care is constantly increasing as a result of an aging population, together with "the increasing severity of chronic conditions and multiple morbidity".

The Commission notes that "it is widely recognized that health systems must move from treatment to health promotion and disease prevention, from a focus on disease to a focus on well-being and people, and from the fragmentation of services to the integration and coordination of continuum services care".

National legislation related to eHealth

The state health policy is managed and implemented by the Council of Ministers, which on the proposal of the Minister of Health approves the National Health Strategy, which is adopted by the National Assembly.

A review of national legislation in the field of eHealth reveals the following specifics.

National health strategies in the field:

- National Health Strategy 2008-2013, adopted by a Decision of the National Assembly of 05.12.2008 and an action plan to it;
- National Health Strategy 2014-2020, adopted by the Council of Ministers on 21.01.2014 and action plan to it. It has not been adopted in this version by the National Assembly.

- With a decision of the National Assembly on 17.12.2015 an updated National Health Strategy 2020 was adopted, which is based on the National Health Strategy 2014-2020 and an action plan to it.

According to the Law on e-Government, the Ministers propose to the Council of Ministers the approval of sectoral strategies for e-government and adopt programs for their implementation. The first sectoral Strategy for the implementation of e-health was adopted by the Council of Ministers at the end of 2006. The strategy envisages the establishment of a Coordination Council to develop an Action Plan for the period 2006-2012 and to monitor its implementation. There are no approved rules, meeting materials and action plan for the implementation of the strategy, which hinders the traceability of its work. There is a lack of confidence that the organization of policy implementation activities for the development of e-health in this period is effective and leads to the achievement of the set goals.

At the end of 2014, the eHealth Development Program was adopted, which defines key actions for the establishment of the National Health Information System (NIS). The program was adopted at a meeting of the leadership of the Ministry of Health and was published on the portal for public discussion. The roadmap to the program covers a period of six years (2014 - 2020), in which three logical stages are distinguished. The program was prepared without the participation of representatives of the National Health Insurance Fund and was not coordinated with them, although the institution is indicated as a partner in the implementation of almost all measures of the document.

In the field of healthcare, the legal framework covers a number of acts, which identify provisions governing e-healthcare, incl. tools and services using information and communication technologies, exchange of information and data between patients, medical professionals and health information networks, expert systems and others:

- Health Act
- Health Insurance Act
- Law on Healthy and Safe Working Conditions
- Law on Ratification of the Framework Convention on Tobacco Control
- Law on Protection from the Harmful Impact of Chemical Substances and Mixtures
- Law on Control over Narcotic Substances and Precursors
- Law on Blood, Blood Donation and Blood Transfusion
- Law on Medicinal Products in Human Medicine

- Law on Medical Establishments
- Medical Devices Act
- Law on Recognition of Professional Qualifications
- Law on the Professional Organization of Nurses, Midwives and Associated Medical Specialists
- Law on the Professional Organizations of Doctors and Dentists (Title amended, SG No. 76/2005, effective 01.01.2007)
- Law on transplantation of organs, tissues and cells
- Food Law.

VI. E-Health

E-Health is a fast-growing field in which medical informatics, public health, healthcare business and information provided via the Internet and related technologies interact. In a broader sense, the term characterizes not only technological development, but also the approach to global thinking to improve health services at local, regional and global levels, using information and communication technologies (eHealth Development Program, Annex 4).

The e-health development program in Bulgaria defines the following main characteristics of e-health:

- Efficiency - one of the goals of e-health is to increase efficiency in health care while reducing costs.
- Improving the quality of health care - increased efficiency includes not only reducing costs but also improving quality.
- Evidence-based medicine - eHealth should support decision-making based on sound scientific assessments.
- Access - enabling citizens and patients to access medical knowledge bases via the Internet. Increasing the patient's ability to choose health services.
- Encouraging a new type of relationship between the patient and the healthcare professional, in which decisions are made with the participation of both parties.
- Training through online methods of doctors (continuing medical education) and the population (health culture, preventive information, etc.).
- Opportunity for exchange of information in a standard way between medical and healthcare institutions.
- Extending the scope of health care beyond conventional boundaries. E-health enables the population to receive health care online from highly specialized medical institutions, regardless of their geographical location.

- Ethics - e-health creates new forms of patient-physician relationships, and poses new challenges and ethical issues in relation to online practices, informed consent, confidentiality, and more.
- Equality - e-health will facilitate equal access of different social strata to health care.

The strategic goal of the introduction of e-health is to improve public health and quality of life in accordance with changing needs and use of existing and new technological opportunities, while increasing the efficiency and reducing the cost of health services (Strategy for the implementation of e-health , 2006).

Strategic goals in achieving e-health in Bulgaria are:

- Improving the quality of health services for citizens
- Orientation of the healthcare model entirely to the end user - the citizen
- Providing complete and objective information on all medical and financial activities
- Providing more complete medical information to health professionals. This will lead to full treatment and, accordingly, to a shorter period of treatment as well as to a higher working capacity of people of active working age.
- Creation and use of telemedicine infrastructures.
- Opportunity for effective communication between health professionals.
- Improving access to health information

The measures for realization of the operational goals, defined in the Strategy for implementation of the e-healthcare are in the following main areas:

1. Establishment of an integrated information system for exchange of information between employees in the field of healthcare (between medical, educational, scientific, financial and administrative units)

- Implementation of electronic health cards;
- Implementation of software applications for complex processing of information in real time, including: electronic directions, electronic prescriptions, laboratory data and other research
- Construction of complex and integrated with each other, as well as with external applications hospital information systems;
- Creation of a complete electronic-medical patient file - a set of horizontal collection of electronic health information concerning the health or health care of the citizen; instant electronic access to information about a person or population, by authorized users; providing information and support in

decision-making in order to improve the quality, safety and efficiency of patient care;

- Construction of the necessary infrastructure for normal functioning of the healthcare system - networks, connecting devices, etc.;
- Building an appropriate base for developing telemedicine projects.

2. Standardization and information security

- The construction of an information system in any field is preceded by structuring and unification of the processed information through:
- Introduction of national health information standards;
- Development of a model of the national health information network;
- Development of requirements for compatibility of information systems in healthcare;
- Implementation of security policies for health information systems;
- Access to the personal electronic health record through electronic smart cards, encrypted forms for data exchange;

3. Awareness and training

- Providing web-based services in real time;
- Providing electronically easily accessible information for the population through the implementation of portals for:
  - o providing information on different treatments;
  - o rights and obligations of health insured and providers
  - o health care; ways and level of reimbursement;
  - o health education;
  - o health prevention;
- Implementation of electronic systems for maintaining the qualification and continuing education for health professionals;
- Development of systems to support the decisions of health professionals and exchange of clinical information;
- Provision of public registers for medical institutions, for persons providing medical services, health insurance funds, pharmacies, etc.

VI. ANALYSIS OF THE SITUATION - LEVEL OF ACHIEVING THE OBJECTIVES FOR BUILDING AND DEVELOPING E-HEALTH

Health information standards

The successful construction of any information system should be preceded by standardization, structuring and unification of the processed information. The requirement for the introduction of national health information standards has been enshrined in the strategic documents since 2006 and continues to be a priority measure to this day.

From 2006 to 30.06.2016 there was a gradual postponement of the deadlines for implementation of the measure and a change in the structures responsible for its implementation and the sources of funding at the level of a strategic document.

In 2015, the Minister of Health was assigned to normatively approve with an ordinance the technologies and systems for collection and exchange of information, as well as the health information standards to be applied by the medical establishments. The adoption of the standards is a necessary step towards building a project of a National Health Information System. By order of the Minister of Health, a working group of representatives of the Ministry of Health, the National Center for Public Health and Analysis (NCPHA) and the University Specialized Hospital for Active Treatment in Endocrinology was established to prepare a draft Ordinance for approval of health information standards. The working group does not include representatives of the National Health Insurance Fund, the Executive Agency for Medicines, professional organizations, etc. thus, the necessary preconditions for taking into account the opinion of key participants in e-health have not been created.

With a report dated 12.03.2016, a draft Ordinance was submitted to the Minister of Health for approval of special rules for the provision of electronic services and exchange of electronic documents, guaranteeing information security in the exchange of information in the healthcare system. The report states that there is no legal basis for the issuance of a normative act regulating health information services and the exchange of information between all structures of the health care system. In this regard, the working group made a proposal to create a new provision in the Health Act, which would cover all health care structures with the obligation to apply special rules for the provision of electronic services and exchange of electronic documents.

A draft Ordinance for approval of health information standards applied by medical institutions has been published on the website of the Ministry of Health and the Public Discussion Portal. An appendix to the ordinance lists the titles of 12 health information standards without their content. The ordinance was promulgated at the end of November 2016 and does not provide for the mandatory application of these standards in health facilities under the Health Act and the Medicinal Products in Human Medicine Act, state, municipal and public bodies and institutions for organization, management and control of health protection and promotion activities.

Conclusion: *The lack of mandatory health information standards is an obstacle to structuring and unifying the processed information in the health care system and building an integrated health information system. The introduction of health information standards only for medical institutions is not enough to regulate and service the exchange of information for the purposes of e-health and the forthcoming establishment of the National Health Information System.*

Medical documentation corresponding to the possibilities for electronic processing

The forms, content, conditions and procedure for processing, use and storage of medical documentation and for exchange of medical and statistical information shall be determined by ordinances of the Minister of Health, coordinated with the National Statistical Institute.

The creation of medical documentation, corresponding to the possibilities for electronic processing and exchange of medical and health information, is included as a measure in the National Health Strategy 2014-2020 and the Program for Development of e-Health from 2014.

In 2015, by order of the Minister of Health, a working group was established to prepare a draft Ordinance on the forms and content, conditions and procedure for processing, use and storage of medical documentation. With a report of the working group dated 18.11.2015, a draft Ordinance and a list of medical documents in the healthcare sector and the terms for their storage were submitted to the Minister of Health. The report states that the creation of a single ordinance laying down the forms and content of medical information used by different autonomous IMPs with different subordination and different status is proving impossible. The reason given is the discrepancy between Art. 27, para. 3 of the Health and Decentralization, Privatization and Liberalization in the Healthcare System Act, which occurred after 2001. A report to the Deputy Minister of Health proposed that the creation of unified

forms for medical documentation be linked to the establishment of a National Integrated Health Information System. , which in practice postpones the adoption of the draft ordinance in the option proposed by the working group until the introduction of the system.

As of March 2020, the creation of medical documentation, classification and rules for working with it, valid for the entire healthcare system, exists only in the roadmap for the implementation of the National Strategy "eHealth", which at the time of this report , has not yet been adopted.

Conclusion: *The lack of regulation of the forms and content of medical documentation is an additional obstacle to building an integrated health information system and the effective implementation of e-health.*

Electronic health cards

The creation of an electronic health card is a key measure of all strategic documents for building e-health in Bulgaria. The National Health Strategy 2020 defines as a measure for implementation of Policy 2.6. "Development of e-health" building a National Health Information System and providing citizens with access to the system through an electronic identifier. The measure is not included in the action plan of the National Health Strategy 2020 and no responsible structures and deadlines for implementation have been set. As a motive for dropping the measure for introduction of electronic health cards from the Ministry of Health it is pointed out that a bill for amendment of the Law on Bulgarian personal documents has been proposed, which creates an opportunity for personal documents to contain data and certificates for electronic identity and qualified electronic signature. The ID card provides for the possibility of recording biometric data for the person, which makes it unnecessary to make other cards as a means of identification.

At the time of writing, citizens' access to the system through electronic health cards has not been realized.

The Ministry of Health is in the process of implementing a project № BG05SFOP001-1.002-0007-C01 "Completion of the national health information system / NHIS / - stage 1 and stage 2", funded by the operational program "Good Governance" 2014-2020 with priority eHealth.

The project is worth BGN 12,000,000.00 (6 135 502.00 euro) and is implemented in implementation of the National Health Strategy 2014-2020, Policy 2.6 "Development of e-health for the implementation of the National Health

Information System". The project includes development and introduction in the Ministry of Health of medical registers, nomenclatures, development and national implementation of a unique patient identifier, evidence-based medical standards, development of a concept and platform of NHIS, introduction of electronic health record, electronic referral, electronic prescription, of a monitoring and control system, preparation of rules for integration of the developed applications, as well as activities for information and public relations.

It is planned to implement the activity "Development and implementation of a unique patient identifier", through which all identification processes will be digitized. As a result of this activity it is expected to achieve:

- Establishment of a unified register of patients;

- Integration into the electronic identity system developed by MTITC;

- Integration with the electronic identification of the National Revenue Agency (NRA);

- Identification of patients with universal electronic signature;

- Increased level of protection and security;

- Expansion of the functions and scope of the Registration System for health insurance events and use of a Unique Identification Number / PIN CODE / for identification of patients;

- Provided possibility for use of the unique patient identifier / PIN code / by all IMP and pharmacists;

- Unified service for identification and authentication of patients.

In October 2019, the deadline for project implementation on December 28, 2019, was extended until the end of December 2020.

Conclusion: *It is not clear from the examined documents whether the electronic health card continues to be a priority and whether actions will be taken for its creation. The Law on Electronic Identification provides the opportunity in certain sectors of government for individuals to be able to identify themselves through sectoral electronic identifiers. The sectors in which sectoral electronic identifiers will be used should be determined by a decision of the Council of Ministers, on a proposal of the Chairman of the State Agency for Electronic Government, in coordination with the Commission for Personal Data Protection. It is currently unclear whether there will be a sector identifier for the Health sector.*

Access to personal health data

The personalized information system (PIS) of the National Health Insurance Fund (https://pis.nhif.bg/main/) contains information on the medical (and since 2012) medical and dental care (since 2012) used by each compulsory health insured person. reported to the NHIF.

Since 2013, the NHIF provides access to IPR through a unique access code only to compulsorily insured persons within the meaning of the Health Insurance Act, including in cases when their health insured rights are interrupted. The certificate for obtaining a unique access code is issued by each RHIF to persons who have submitted an application for issuance. The unique access code is issued for certain unified civil numbers (PIN), personal number of a foreigner (PIN) or official number from the register of the National Revenue Agency - for persons without PIN or PIN, insured in Bulgaria. In case of change of these identifiers a new code is issued. The same unique access code is used to access the personal data of the persons for whom the holder of the DCO has made a choice of personal physician - children under 18 years of age, persons of whom he is a guardian or trustee and other cases in which it is permissible to an official choice of a personal doctor is made. The personalized information system of the National Health Insurance Fund provides an opportunity to deactivate the code in case of compromise or at the request of the Public Health Insurance Fund.

Conclusion: *A unique access code has been implemented by the NHIF for access to the electronic health records of health insured persons through the personalized information system.*

Creation of an unified health information system

The creation of an integrated information system for information exchange in the field of healthcare is a key measure of the Strategy for implementation of e-healthcare in Bulgaria since 2006 and continues to be a priority in the next strategic and program documents in this area.

Its creation aims to:

- improving the quality and efficiency of health services;
- reduction of the administrative burden of the procedures for patients and providers of medical care;

- increasing the satisfaction of the citizens with the health system and the control over the reporting of the activities;
- increasing transparency; improving the decision-making in the healthcare system, etc.

Analysis of strategic and normative documents concerning the creation of the unified health information system reveals the lack of normative definition and determination of its scope. This circumstance creates preconditions for different interpretation and inconsistency in the management decisions for its construction.

The review reveals several unsuccessful attempts to build a unified health information system, as public procurement was terminated for various reasons, including: lack of a clear concept for building the system; lack of a plan for the necessary financial resources; duplication of functionalities, etc. The actions of the Ministry of Health, incl. The projects and technical specifications have not been discussed and agreed with the NHIF, as a key participant in the health information system of health care, which is not in line with the principles of sound financial management.

Conclusion*: There is a significant delay in the construction of the unified health information system. The existence of several unsuccessful attempts to conduct public procurement and the analysis of the reasons for their termination indicate significant gaps in the overall organization of the process of planning and implementation of e-health. The experience gained so far shows that the Ministry of Health is experiencing serious difficulties with the implementation of public procurement of transformation projects, such as e-health projects. Given the complexity and scale of the unified health information system, the realization of this key challenge requires a clear concept and consensus reached between key actors, political will and coordination of efforts at all levels of government.*

Electronic services in the field of healthcare: electronic prescription, laboratory data and research

The creation of an electronic direction, electronic prescription, laboratory data and research is a key measure of the Strategy for implementation of e-health from 2006 and continues to be a priority in the next strategic and program documents in Bulgaria, with the exception of the last NHS 2020, in the action plan to which such measures and activities cannot be identified. The lack of an explicit measure / activity in the action plan of the NHS 2020 complicates the correct organization and creates a risk for the realization of the goal.

The Ministry of Health is in the process of implementing the project № BG05SFOP001-1.002-0007-C01 "Completion of the national health information system / NHIS / - stage 1 and stage 2", funded by the operational program "Good Governance" 2014-2020. Through the project, by the end of 2020, it is planned to build software applications for electronic direction, electronic prescription and laboratory data.

Conclusion: *More than a decade after the realized and strategically declared need for software applications for electronic direction, electronic prescription and laboratory data, they have not been realized. A prototype of a system for electronic prescription, electronic referral and outpatient list is currently being developed. For the purposes of the prototype, the scope of the system is limited only to contractual partners of the NHIF and drugs that are paid for by the NHIF. The development and implementation of the systems at national level is expected to be implemented through the OPGG 2014-2020 project.*

VII. PROMOTION OF THE ELECTRONIC HEALTH SYSTEM - PROPOSALS

From the analysis it is clear that progress is needed in the following main directions:

- Creation of an up-to-date National Strategy for e-health and development of an "Action Plan" for the implementation;
- Creation of an up-to-date Program for development of e-health and development of an "Action Plan" for its implementation;

Without the availability of effective strategic documents in the field of e-health development, we act "piecemeal", which leads to increased investment in health care without achieving the desired result.

- Long and sufficient training of health personnel for the use of ICT;
- Based on the format of the necessary initial data requested by the Ministry of Health and the National Health Insurance Fund, the available solutions at the health care providers should be further developed and integrated with each other;
- Connectivity at national level - it is necessary to build infrastructure - a centralized network connecting health facilities, and not just separate isolated local networks;
- Establishment of national standards and policies for security and confidentiality for exchange and storage of medical information.
- Development of working telemedicine applications;

- The construction of systems should comply with the rules for interoperability;
- Construction of effective health portals for the healthcare system, as well as medical data storage centers;
- Establishment of a unified licensing policy in the healthcare system - for the used software solutions and products.

VIII. CONCLUSION

1. E-health has been a constant key priority in all government programs and national health strategies in Bulgaria over the last decade. However, its implementation is hampered by weaknesses and gaps in the operational planning of strategic goals, measures and activities at the level of the Ministry of Health, the National Center for Public Health and Analysis and the National Health Insurance Fund. The implementation is complicated by the lack of legislation on the nature and organization for the implementation of e-health, the national health information system and their components. The lack of clear annual targets, which are measurable with performance indicators, creates ambiguity in the desired degree of change and makes it difficult to assess actions. Despite the reported partial improvement in annual planning, building an integrated health information system remains an unfulfilled challenge.

2. The construction of e-health has been carried out in the conditions of very frequent structural and personnel changes, which in combination with impaired continuity has an extremely negative impact on the traceability of the processes and the achievement of the goals. The lack of a well-established coordination mechanism and an effective system for coordination of actions, projects and public procurement between the institutions creates conditions for inefficient spending of public funds and delays in the implementation of strategic priorities.

The amendments to the e-Government Act of July 2016 and the establishment of the State Agency for E-Government envisage the establishment of a system for preliminary, current and ex-post control as appropriate in the field of e-government and the use of information and communication technologies in the activity of the administrative bodies and their administrations. The effective is expected performance of the functions of the State Agency for E-Government, with the active participation of the Ministry of Health, the National Health Insurance Fund and the National Center for Public Health and Analysis, to contribute to the achievement of the goals of e-government.

3. The introduction of national health information standards is a key measure of the Strategy for implementation of e-health from 2006. The Ordinance for approval of health information standards applied by medical institutions (SG, issue 94 of 25.11.2016) is not provides for mandatory application of these standards in health care institutions under the Health Act and the Law on Medicinal Products in Human Medicine, in state, municipal and public bodies and institutions for organization, management and control of activities for protection and strengthening of health.

4. Against the background of the rapid development of e-health in other European countries, Bulgaria still does not have an integrated health information system to provide the necessary information for the needs of the management and users of health services, incl. to fulfill the country's commitments in connection with the cross-border exchange of health data. The available information systems and databases are not systematically integrated and do not give a real idea of the general state of the health care system, which complicates the process of health policy planning. Real-time data exchange between information systems and registers remains an unresolved challenge.

5. Since 2006, there has been a gradual postponement of the deadlines for implementation and change in the structures responsible for the creation of electronic direction, electronic prescription and laboratory data at the level of strategic documents, which creates risks for their effective implementation. Almost 10 years after the realized and strategically declared need for these applications, they have not been developed and implemented, which deprives patients of opportunities for faster and better service. In January and February 2017, the Ministry of Health developed a prototype of a system for electronic prescription, electronic referral and electronic outpatient list. The Ministry expects these measures to be implemented in the future within the project № BG05SFOP001-1.002-0007-C01 "Completion of the National Health Information System / NHIS / - stage 1 and stage 2", funded by the operational program "Good Governance" 2014-2020.

6. One of the main operational objectives of the Strategy for implementation of e-health in Bulgaria from 2006 is to improve access to health information. The key measure for providing electronically accessible information to the population through the implementation of portals has been a permanent priority measure since 2006 and continues to be so in the next strategic and program documents. With the Program for development of e-health from 2014, the last National Health Strategy 2020 and the project of the National Strategy "E-Health" the construction of a national health portal is envisaged. The attempts of the Ministry of Health to build an electronic health portal are not coordinated with the National Health Insurance Fund, which

hinders the implementation of a unified and shared by key participants vision and creates a risk of inefficient spending of public funds.

7. The creation of an electronic health record has been a priority measure since 2006 and aims to provide the necessary information in decision-making in order to improve the quality, safety and efficiency of patient care. Since 2006, there has been a postponement of the deadlines for its construction and a lack of a clearly defined scope of responsibilities of the Ministry of Health, the National Health Insurance Fund and the National Center for Public Health and Analysis. There is no approved and coherent concept of an electronic health file, which contains an unambiguous and comprehensive description of the architecture, information flows and interconnections, the institutions responsible for its construction and maintenance and the mechanisms for coordination and control of data accuracy. As of March 2020 a complete electronic health record has not been created. Currently, only the National Health Insurance Fund maintains a partial electronic file.

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