HEALTH CARE IN THE EU

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ЗДРАВЕОПАЗВАНЕТО В ЕС

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Висше училище по агробизнес и развитие на регионите - Пловдив

Health care is an integral part of socio-political and socio-economic life in a country. In the last two decades, in almost all countries of the world, reforms have been carried out in the health care system, aimed at more fully satisfying the medical and social needs of the population and increasing "profitability". The restructuring of health care systems worldwide is in the direction of strengthening and improving health care, ensuring equal access to comprehensive and adequate health care, oriented to the needs of every citizen.

In the health care system, health care is delivered in two main ways – the first is through the public health system, financed through the republican budget, and the second is through the mandatory health insurance system. It is financed by compulsory health insurance contributions and is organized on a social principle based on solidarity. Through it, a package of health care is provided to every insured citizen, regulated by an ordinance of the Minister of Health. Access to health care is guaranteed by a National Health Card, adopted by a decree of the Council of Ministers. Part of the financing of treatment activities in the hospital sector is also a commitment of the Republican budget.

Health care is a system of medical and non-medical, scientific and applied activities organized in society to optimize the quantitative and qualitative aspects of human reproduction. Or it is the industry that produces health services and results mainly in the form of health improvements, satisfies fundamental needs of people for their quantitative and qualitative reproduction and thus affects the other two spheres - of material and spiritual production, providing the main production human factor. Because of the heterogeneous composition of factors determining health and the uncertainty of a positive outcome from the intervention of health professionals, not all outcomes of health services represent health improvements, but these are the preferred and dominant types of outcomes. Economic criteria (eg profit, GDP production or economic return) are subordinate to the main objectives of the system. Non-economic factors for the development of society (such as health care, culture and education) are valued as essential to the civilizational process. This is also confirmed by the expansion of health and education indicators in the global indices of human development and national competitiveness. The health sector affects the economy primarily through the main results of its functioning - health improvements. Health care and related activities (such as health insurance) affect the labor market – for example, mandatory health insurance for employers increases the cost of production and reduces the competitiveness of companies; stable health insurance is a factor for

competition between companies to attract qualified workers, as well as a factor for the mobility of labor resources within a global market. The relationship between health expenditure and total public expenditure is particularly strong (usually positive). For example, for every unit of expenditure invested in public health programs to reduce smoking, 2 units are saved in avoided future costs to the state. Savings that can be invested more productively. In many developed countries, health care deficits undermine macroeconomic stability. Healthcare also has a significant impact on investments in high technology and healthcare construction.

An important impact effect of healthcare is its action as an accelerator of related sectors such as the pharmaceutical industry, medical technology, health insurance, etc. For example, pharmaceutical production is a structural high-tech industry for Germany, France, the USA, Switzerland, as well as one of the fast-growing sectors in the countries of South-Eastern and Central Europe.

The complex interrelationships between health care and the economy increase the interest in the efficiency of the sector directly related to the health care system of a given country. More efficient health care has a positive impact on the national economy and human development, which is why research on its effectiveness is of primary importance for identifying the place occupied by the health sector in Bulgaria in the EU or among countries that are geographically neighboring and historically close, as and quite distant and different.

The term "e-Health" came into use in 2000. There is still no consensus on its definition. The concept is defined differently in terms of a number of characteristics, at different levels of detail and generality.

The EU defines electronic healthcare as "the use of modern information and communication technologies for the needs of citizens, patients, and medical service providers".

E-health is a rapidly developing field in which medical informatics, public health, the provision of health services and information through the use of modern information and communication technologies interact. It characterizes not only technological development, but also a global thinking approach to improve health services at local, regional and global levels.

According to the modern understanding, electronic health care is a complex of measures based on an organizational, technological and legal framework and covering the whole aspect of functioning of the health system.

In short, the term includes much of medical informatics, but to a greater extent it prioritizes the delivery of clinical information, care, and services over functions, technologies.

Basic principles of eHealth are:

✓ Equality - eHealth will facilitate equal access of different social strata to healthcare strata of care.

✓ Efficiency - one of the main goals of e-health is to increase the quality and volume of services offered in health care, while maintaining or reducing costs;

✓ Evidence-based medicine - eHealth should support medical decision-making;

✓ Ethics - e-health care creates new forms of relationship between patient and doctor, and poses new challenges and ethical problems in relation to online practices, informed consent, practices, confidentiality, etc.; and

✓ Equal access - enabling all citizens to access medical information via the Internet.

✓ Increasing the citizen's options for choosing health services;

✓ Quality healthcare;

✓ Promoting a new type of relationship between citizens and health institutions, where decisions are made with the participation of both parties;

✓ Equal quality of health care, regardless of the geographical location of the medical facility and the nationality of the patient;

✓ Interoperability of information systems in healthcare;

✓ Adequate training of health personnel;

In a number of countries, standards are accepted as the main way to increase the efficiency of the sector with limited resources. The introduction of standards is a necessary condition for the development of electronic health care. The standards will bring benefits to all participants in the health care system - the public health sector, hospitals and health care providers, manufacturers of specialized software. The synergy between all participants in the health care system, which is achieved through the introduction of standards, ultimately brings numerous benefits to the users of health services - the patients.

When receiving out-of-hospital medical services or purchasing a medical product in another EU/EEA member state, National Health Insurance Fund insured persons will pay personally for the relevant product or service to a medical care contractor working with the public health insurance system in that country. After submitting the original payment documents to the National Health Insurance Fund, the persons will have the right to reimburse the costs, according to the Bulgarian statutory tariffs - as if the medical aid or goods were provided, resp. purchased in Bulgaria.

One of the main principles of the Framework for the development and implementation of health information standards is that patient data should be recorded at the source and thus become a by-product of the health service itself. In addition, data sets, eg "Minimum Data Set", "Core Data Set", etc., are specified in advance so that sufficient information for patient identification, diagnosis verification and treatment rationale is included in the system

Data sets should also include documentation and treatment outcomes. In this way, continuity among health care providers can be ensured in case the patient needs to refer to another specialist or health facility.

Another core principle is data management for accountability purposes. The agreed data set is used for communication and accountability between health care providers and other participants in the health care system. The agreed set of data is transferred to a common base - Data Center, where the information is available to authorized persons, according to another of the principles laid down in the Framework.

The benefits of introducing standards in the public health sector are very tangible. In a number of countries, standards are accepted as the main way to increase the efficiency of the sector, which leads to improved quality with limited resources. The standards enable the collection of statistical information for planning purposes and help the efficient and proactive management of healthcare organizations.

Standards can also help authorities exercise control over the quality of information systems in healthcare and medical devices and are a step to the next level – certification.

For providers of healthcare services such as hospitals, doctors, healthcare workers, one of the main advantages is the interaction between departments and systems that lead to an increase in the efficiency of healthcare. Reducing the cost of purchasing systems and increasing competitiveness, preserving investments are other benefits that the introduction of standards would bring to hospitals.

Standardization also has a beneficial effect on software solution providers, as they can provide modular systems in which a single product can comprehensively

cover the needs of users. In this way, software vendors get a larger market for their "standard" product and face fewer maintenance problems than with specific different solutions for individual users

The EU defines electronic healthcare as "the use of modern information and communication technologies for the needs of citizens, patients, and medical service providers".

The World Health Organization (WHO) offers the following more detailed definition: "E-healthcare is the cost-effective and safe use of information and communication technologies to support health and health-related areas, including health services, health monitoring, health literature, as well as health education, knowledge and research"

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To the extent that Community law does not contain express requirements in relation to the legal organizational form of entities providing health care, the subject of analysis is mainly the internal legal regulations of the member states. Community policy in the field of health care primarily emphasizes the quality of health care regardless of the persons who provide it, and the only rules in this direction are related to the entities authorized to offer medicinal products on the market.

Within the EU, there are also no special rules regarding the persons authorized to provide medical assistance. The quality of health care in the Community is ensured by establishing control institutions in the Member States that are completely independent in relation to the person in the health care system. The European Committee for Standardization is authorized to assess the independence of control institutions in the member states.

The subject of a comparative legal analysis is the domestic legislation of 12 member states of the European Union: Austria, Belgium, Great Britain and Northern Ireland, Germany, Denmark, Ireland, Spain, Italy, Luxembourg, Portugal, France and Sweden. The normative acts regarding health care in the mentioned countries, as well as the reports of the World Health Organization dealing with the quality of the health care offered in these countries, were analyzed.

The main approach in regulating the legal framework of medical facilities in the EU member states is its incorporation into a general healthcare law. The reason for the inclusion of the regulations for health care facilities in the health care laws is the integration of the same into the unified national health care system. Such a legislative approach is adopted in the legal system of France, Great Britain, Germany, Portugal, Sweden.

Another approach in the legislative treatment of medical institutions is to bring this matter into a special law, separate from the existing general regulations for health

care. Such special laws have been adopted in the legislation of Austria, Ireland, Belgium, Italy, Luxembourg.

The mode of establishment of medical facilities in Europe is established in two main varieties according to the particularities of the act of establishment and the authority that issues it.

In Great Britain, France and Ireland, medical institutions - non-profit legal entities - are established by order or decision of the executive body competent in the field of health - the Minister of Health (France, Ireland) or the Secretary of State (Great Britain). The order is an individual administrative act, the content of which is determined solely by the issuing authority. It explicitly states the range of health services that the legal entity is authorized to perform, the financing conditions and the reporting regime, the number of persons appointed to the medical facility, the conditions for their appointment and the amount of their remuneration. In many cases, the establishment procedure includes mandatory consultations - with the National Health Trusts, local health authorities (Great Britain), with the committees for health and social organization (France). The results of the consultation procedure are reported to the competent authority, which based on them issues or refuses to issue an order (decision) for incorporation. A similar procedure is provided for amending or revoking the founding act.

The other approach to the establishment of health facilities, observed in the legislation of Belgium, Spain, Italy, is the so-called accreditation (authorization) procedure, in which the competent health authority (Ministry of Health) gives permission to perform certain health services under precisely fixed conditions. These conditions are determined solely by the Minister of Health or are contained in the by-laws. These conditions in most cases boil down to:

- ✓ ensuring financial transparency of the activity of the legal entity.
- ✓ existence of a financial plan of the medical facility;
- ✓ providing external control for the quality of healthcare;

European laws make a significant distinction between persons who directly deliver healthcare and those who act as "commissioners". The competence of the legal entity in this regard is fixed in the order, resp. the establishment permit. Normative acts also regulate the powers of persons in connection with carrying out a side activity. In principle, the acquisition of land, the conclusion of contracts and the receipt of donations in order to support their main activity are allowed.

Citizens of the European Union today expect much more from life than ever before. However, according to data from the European Commission, one in five Europeans dies prematurely from diseases that could have been prevented. In order to improve people's health, the policy of the European Community relies mostly on prevention. At the center of this activity are programs on the topics of AIDS, cancer and the fight against drugs. These actions are accompanied by information campaigns that aim to promote healthcare, transcending the borders of individual countries. Over the past 30 years, European healthcare costs have doubled. According to the European Commission, today they reach 5-10% of the gross domestic product. For comparison in the USA they are more than 14%. The situation is worsened by demographic developments: while life expectancy rises, the birth rate falls. The demand for health care services is increasing, and with it, the costs of these services are also increasing.

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Health care financing is a set of ways of raising, distributing and spending money necessary for the reproduction of activities related to strengthening, protecting and improving health. In this sense, the financing of health care can be considered as an activity related to the management of the financial means necessary for individual health structures and the financial relationships between the participants in the health care process

Most often, in the systems of financing the systems, combinations between the individual sources in different ratios are observed. The reason is that the state necessarily retains its role in health care financing, even to a limited extent in some systems. The share of each funding source gives an idea of the competitive structure of the system and defines the main types of health care models that are applied in the world.

Ways of financing health care can be classified according to the dominant source and form of payment, according to the ownership of financial resources, etc.

Budget (government) funding

It means a set of two relatively independent indirect ways of public financing, usually considered in a consolidated form - state (through the state budget) and municipal (through the municipal budgets) financing. The share of government funding varies depending on the type of health system and its economic organization.

Health Insurance

Health insurance - fund-based indirect financing, where funds are collected from insurance contributions to cover risks of illness and other health problems. It can be social (compulsory) and voluntary (private). The amount of insurance contributions is determined most often in three ways: as a fixed amount; as a percentage of the gross remuneration and depending on the health risk.

Direct payment from consumers

A direct method of financing, in which consumers pay in whole or in part from their own income for the use of health services, for medicines and other goods with a health purpose.

In developed countries, the share of direct payment does not exceed 20% of all health costs, while in developing countries it reaches 50%.

Donation

Donation – complementary direct or indirect source of financing, the main source of which is the income of companies, non-profit organizations and households, provided to health organizations. There are three different forms of donation: corporate (sponsorship, material support and provision of services to businesses); institutional (through foundations and other non-profit organizations) and individual giving.

External funding

External financing - has as its sources funds from other governments, international and foreign non-governmental organizations and is implemented in the form of grants, humanitarian aid, credit lines, consulting services, etc.

The World Health Organization examines the regime of medical institutions at the interstate level in the form of detailed reports on the health systems of member states, declarations and opinions on the guidelines for the development of health care. Although there is no express requirement for the structure of legal entities that can be medical facilities, the World Health Organization has repeatedly emphasized the

participation of non-governmental organizations and, in particular, non-profit organizations in the public health care system.

The coordination of social and health insurance in the EU does not require unification of the national insurance legislation of the member states. Each member state has the right to adopt its own specific insurance legislation, determining the circle of insured persons, the insurance benefits, the method of financing the system (through contributions or taxes, or a mixed system). Coordination is a legal instrument through which synchronization is achieved between the insurance systems of the Member States, avoiding the undesirable consequences of the movement of insured persons within the EU. These consequences can be:

✓ Occurrence of "double" insurance if a person falls under the insurance legislation of two countries - works in a country that obligatorily insures workers, but lives in another country that obligatorily insures permanent residents in its territory, or lack of insurance if the person does not fall under the insurance legislation of any country.

✓ Unequal treatment in the granting of insurance rights and the receipt of insurance benefits between a country's own citizens and foreign citizens who reside on its territory for various reasons - work, job search, training, rest, permanent residence after retirement.

✓ Gaps in insurance that would prevent an insured person from receiving an insurance benefit because the required period of insurance under the legislation of any country is not available.

✓ Limiting the payment of insurance benefits to the territory of the state responsible for granting them.

The problems described above are solved by a regulation on the coordination of social and health insurance systems, which preserves the differences between the national insurance laws of the Member States by introducing provisions for:

✓ determination of only one applicable insurance legislation at a given time - in principle, this is the legislation of the country in which the persons exercise professional activity as employed or self-employed, even if they reside in another country;

✓ equal treatment by a country of its own and foreign citizens when exercising insurance rights and assigning insurance obligations;

✓ summation of insurance periods that have expired under the legislation of two or more countries with a view to acquiring insurance rights;

✓ the possibility of receiving insurance benefits outside the territory of the country responsible for them.

Medical assistance and services within the framework of compulsory health insurance, provided to Bulgarian health insured persons under the Law on Health Insurance, on the territory of EU/EEA member states

The Bulgarian Law on Health Insurance determines the circle of insured persons, the medical assistance and the services that fall under the health insurance package; the rights and obligations of the health insurance institution and to the providers of medical care and to the health insured persons; as well as the way of financing the mandatory health insurance system.

Categories of persons who are socially and health insured in Bulgaria, but permanently reside in another member state:

✓ Employed or self-employed persons with social and health insurance on the territory of Bulgaria and members of their families who are long-term residents on the territory of another member state will have the right to medical assistance at the expense of their competent institution - NHIF, by virtue of the rules for determination

of the applicable insurance legislation (in this case it is the Bulgarian one, because the professional activity is carried out on Bulgarian territory). These persons will, however, be integrated into the health system of the country in which they reside, even though they have not paid health insurance contributions to its health fund, and will be entitled to the same package of medical care and services to which citizens of that country are entitled (principle of equal treatment). Individuals will be able to exercise this right with form E 106.

Form E 106 is issued by the regional health insurance fund according to the address registration of the persons , in the following cases:

- For persons seconded by a Bulgarian employer to perform certain work on the territory of another EU/EEA country for a period of not less than 12 months.
- For seasonal workers - for the duration of seasonal work, but not more than 8 months.
- For cross-border workers.
- For diplomats and their accompanying family members when they are posted in an embassy in another EU/EEA country.
- For seafarers flying the flag of one Member State but residing in another Member State.

Form E 106 must be preceded by forms E 101 or E 103 – certificates for the applicable legislation. From January 1, 2008, both forms will be issued by the National Revenue Agency.

After registration in the country of residence, employed and self-employed persons can use the full health insurance package of medical care and services of that country, and the institution of residence (registration) will pay the health care providers for providing such care or service to these persons.

Family members of citizens posted to another member state are entered in part B of form E 106 by the host country's insurance institution - according to the legal definition of "family member" given in its domestic legislation.

With form E 125, this institution has the right to request from the institution responsible for the persons reimbursement of the expenses incurred for the treatment of the persons entered in E 106 - for each registered person. If a Bulgarian citizen ceases to be insured as an employed or self-employed person under the HHI, or terminates his health insurance rights in Bulgaria, the HHI (the institution that issued form E 106) will send form E 108 to the institution of residence for termination of the effect of form E 106.

A special variety of employed or self-employed persons residing outside the country of employment are the so-called cross-border workers. These are the persons who exercise their profession in the territory of one country, but live in the territory of another country, to which they usually return at least once a week. These persons are entitled to medical assistance in both countries. The family members of a cross-border worker are only entitled to emergency assistance in the competent country (in which the professional activity is carried out) and to full medical assistance in the country of residence.

Pensioners who receive old-age, invalidity or survivor's pensions are entitled to medical assistance, according to EU coordination provisions, even when they live in a Member State other than the one in which they receive their pensions. Bulgarian pensioners will be able to exercise their right to medical assistance during a long-term stay in another EU/EEA country with form E 121, issued by the Health Insurance Fund.

In the case of a temporary stay in another EU/EEA country, the insured persons can use the health care they need (according to medical indicators) upon presentation of a valid Bulgarian European Health Insurance Card (EHIC).

Access to necessary and urgent medical assistance for persons with Bulgarian health insurance during a temporary stay in an EU member state on various grounds - tourism, secondment, training, job search.

From June 1, 2004, the European Health Insurance Card (EHIC) was introduced within the EU, which gradually replaced the forms for medical assistance during a temporary stay of European citizens in a member state other than the country of their insurance.

With the introduction of the EHIC, forms E 113 – certificate for admission and discharge from hospital, and E 114 – certificate for the provision of essential benefits in kind were cancelled.

After the accession of Bulgaria to the EU, the NHIF is obliged to issue the EHIC to the health insured persons with continuous rights under the HHI. These persons have the right to necessary and urgent assistance during a temporary stay in an EU member state on various grounds - tourism, secondment, training, job search, visiting. The EHIC provides direct access to the Bulgarian health insured persons to the providers of medical assistance in the respective member state, and the type of medical assistance must be taken into account (whether it is necessary and urgent) and the expected length of stay in the other country (the latter is necessary to distinguish medical care provided with the EHIC from cases of stay for the purpose of planned treatment, for which form E 112 is required).

The Court of Justice of the European Communities and the Administrative Commission for Social Security of Migrant Workers gave an expansive interpretation of the scope of urgent and necessary assistance during a temporary stay in an EU Member State, ruling that this assistance concerns both sudden and chronic illnesses that occurred before the trip to the respective country. The reason for such an interpretation is related to the possibility for insured persons to stay in a country (during a temporary stay) and receive the treatment they need in order to realize the true purpose of their stay – tourism, study, business, job search.

However, the Administrative Commission issues a list of certain types of medical care related to chronic diseases (currently renal hemodialysis and oxygen therapy) that require special equipment. The provision of this medical assistance requires prior agreement between patients and medical service providers in their country of temporary stay. The purpose of the rule is to ensure continuity of care for chronically ill patients who are on hemodialysis or oxygen therapy while temporarily residing in a Member State other than the country where they are insured.

As the competent health insurance institution for issuing the EHIC, the NHICH is responsible for the costs of necessary and urgent medical care for Bulgarian patients within the EU/EEA. The NHIF must comply with the opinion of the foreign doctor, which is proof of the urgent nature of the medical assistance, as well as carry out subsequent reimbursement of the actual costs for the treatment of the Bulgarian health insured persons, which were incurred by the institution in the country of temporary stay, according to its legislation.

After Bulgaria's accession to the EU, Bulgarian health-insured persons can apply for permission for planned medical care in a given member state. Bulgarian patients can benefit from two procedures (which exist independently of each other) when exercising their right to planned medical care within the EU, as follows:

✓ according to the coordination regulations for social and health insurance - procedure for obtaining a prior authorization for hospital and outpatient treatment abroad from the competent health insurance institution - E 112;

✓ according to the decisions of the Court of the European Communities based on the provisions of the Treaty on the European Community, which define the principles of free movement of services and goods in the EU: receiving outpatient treatment or purchasing a medical product outside the country of insurance, without prior authorization from the competent health insurance institution.

According to the coordination regulations on social and health insurance, insured persons from one Member State who wish to receive specialized hospital treatment in another Member State must obtain prior authorization for this from their health insurance institution. Prior authorization is given by the competent institution by issuing form E 112.

For Bulgarian health insured persons, the competent institution for issuing treatment authorization in an EU member state is the National Health Insurance Fund. Bulgarian patients must submit form E 112 to the institution of the country providing the planned treatment. Based on the principle of equal treatment, this institution will integrate Bulgarian patients into its health system, as if they were health insured, according to its legislation. Bulgarian patients will be treated under the same conditions and at the same prices as the persons who are insured in the institution of residence.

The duration of treatment in the other country is determined according to the duration determined in the competent country.

Initially, the treatment should be paid to the relevant medical care provider from the institution of residence, after which the competent institution - NHIF, will carry out a subsequent reimbursement of the actual health costs, according to the tariffs of the country that provided the treatment.

The NHIF has discretion when issuing a permit (form E 112). Applying for the issuance of a prior authorization to carry out planned treatment in another EU/EEA country is carried out according to a separate procedure.

The permission depends on the condition whether the treatment falls within the package of activities paid for by the budgets of the NHIF or the Ministry of Health, and whether it is possible to provide the treatment in Bulgaria to the patients within the usual period for their medical condition.

The main hypotheses in which Bulgarian health insured persons will have the right to medical assistance in EU member states can be divided into:

✓ access to medical care for insured persons and their family members who reside in a Member State other than the country in which they are insured;

✓ access to medical assistance for insured persons and their family members in a member state during a temporary stay for various reasons – tourism, secondment, training, job search, visiting;

✓ planned treatment of insured persons abroad.

For the practical implementation of their right to medical assistance within the EU, Bulgarian citizens will use the E-forms developed by the EU.

According to the decisions of the Court of the European Communities based on the interpretation of the provisions of the EC Treaty on the free movement of goods and the free provision and receipt of services in the EU, patients of a Member State have the right to purchase medical products and receive outpatient medical services without the prior authorization of their health insurance institution. The condition is that these goods or services from outpatient care fall under the public health insurance packages of the competent institution of the other country. The expenditure incurred

may be reimbursed up to the amount that would be paid for the same service in the competent country.

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