

# БІОМЕДИЧНІ ВИМІРЮВАННЯ ТА ПРИЛАДИ

## STANDARDS OF SOCIAL RESPONSIBILITY IN THE ACTIVITIES OF THE CLINIC – DIAGNOSTIC LABORATORIES

### СТАНДАРТИ СОЦІАЛЬНОЇ ВІДПОВІДАЛЬНОСТІ У ДІЯЛЬНОСТІ КЛІНІКО- ДІАГНОСТИЧНИХ ЛАБОРАТОРІЙ

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**Анотація.** Сучасний розвиток держави і постійне посилення конкурентної боротьби вимагають пошуку нових, ефективніших стратегічних можливостей підприємств, серед яких великого значення набуває соціальна відповідальність. Комплексне соціоекономічне дослідження соціальної відповідальності в Україні нині є вимогою часу. Мета роботи – формування нормативно-правового базису соціоекономічного розуміння суті, особливостей формування та реалізації комплексного феномену соціальної відповідальності, а на цій основі – обґрунтування пріоритетних напрямів його практичного використання для потреб розвитку держави.

Проаналізовано міжнародні ініціативи в галузі соціальної відповідальності та втілення їх в Україні, зокрема в діяльності клініко-діагностичних лабораторій (КДЛ).

Клінічна лабораторна діагностика (лабораторна медицина) є однією із найважливіших складових системи охорони здоров'я, яка забезпечує надання медико-діагностичної допомоги пацієнтам в оцінюванні стану здоров'я, діагностиці захворювань, моніторингу результатів лікування, подальшому прогнозі перебігу хвороби та якості життя, що має загальнодержавне значення для збереження та покращення здоров'я населення. Якість життя хворої людини у сучасній медицині розглядається як інтегральна характеристика її стану, що складається із фізичного, психологічного, соціального компонентів. Адже більше ніж 70 % інформації для прийняття рішення щодо діагнозу лікар отримує з лабораторії. І навіть більше, у разі моніторингу пацієнтів цей відсоток зростає до 80 %.

Соціальна відповідальність багатоаспектна та багаторівнева. На індивідуальному рівні вона проявляється через світосприйняття особистістю певних принципів, засад і поведінки в суспільстві; на рівні держави – через належний рівень життя людини, культурний та моральний розвиток; на рівні підприємств – через дотримання високих стандартів надання послуг, соціальних стандартів та якості роботи з персоналом.

**Ключові слова:** відповідальність; лабораторна діагностика; сталий розвиток; ділова етика; міжнародні стандарти.

**Abstract.** The modern development of the state and the ever-growing competitive struggle require the search for new, more effective strategic capabilities of enterprises, among which social responsibility is of great importance. A comprehensive socio-economic study of social responsibility in Ukraine is now a time requirement. The purpose of the work is to formulate the legal and regulatory framework of socioeconomic understanding of the essence, peculiarities of formation and realization of the complex phenomenon of social responsibility, and on this basis – justification of priority directions of its practical use for the needs of the state development.

International initiatives in the field of social responsibility and their implementation in Ukraine, including the activities of clinical diagnostic laboratories (CDL), are analyzed.

Clinical laboratory diagnostics (laboratory medicine) is one of the most important components of the health care system, which provides medical and diagnostic assistance to patients in the assessment of health status, diagnosis of diseases, monitoring of the results of treatment, further prognosis of the disease course and quality of life having national importance for preserving and improving the health of the population. The quality of life of a sick person in modern medicine is considered as an integral characteristic of his condition, which consists of physical, psychological, social components.

After all, more than 70 % of the information to make a decision about the diagnosis, the doctor receives from the laboratory. Moreover, when monitoring patients, this percentage increases to 80 %.

Social responsibility is multidimensional and multilevel. At the individual level, it manifests itself through a person's perception of certain principles, principles, and behavior in society; at the state level – through the proper standard of living, cultural and moral development; at the enterprise level – through high standards of service, social standards and quality of work.

**Key words:** Social responsibility; Laboratory diagnostics; Sustainable development; Business ethics; International standards.

## Introduction

The economic challenge to addressing all aspects of health care has become a major challenge today, as limiting the flow of funds to social needs requires the maximum rationalization of necessary expenditures. On the one hand, the Laws and the Constitution of Ukraine require the provision of free medical services. On the other hand, in the context of the crisis of local budgets, it is necessary to find and introduce alternative sources of health financing, including laboratory medicine. In analyzing all the arguments and statements regarding the democratization of the society, one-sided interpretation of this phenomenon is viewed. Only equality of rights is addressed. However, equalization in rights is possible only on one condition, when this process is harmonized, which means – balancing of rights and responsibilities. They forget about duties, for some reason they are not allowed to speak. Lack of responsibilities gives rise to lawlessness, which in itself is a great destructive force, and in this its great social danger.

In the conditions of permanent social and economic crisis, financial factor becomes the decisive motivating factor of social behavior. This is fundamentally contrary to the legal and moral foundations of civil society development.

The transition from the declaration of human rights to the declaration of responsibilities is necessary. This should be one of the main features of civilization, and also a determining criterion in the value system of civil society of the future.

## Result of the research

A comprehensive study of the issue of social responsibility allows us to determine the quality of life and to determine their impact on it. It is inherent in the patient's involvement in the assessment of his condition and his active involvement in cooperation since only the patient can provide adequate information about the degree of satisfaction with aspects of his life related directly to the symptoms of the disease and its psychological, social and other consequences [1].

Scientists quite often refine the concepts of “social responsibility” and “sustainable development”. In our view, this is irrelevant, since the interconnection and balance of economic, social, environmental, institutional and innovation-technological components to maximize human well-being without compromising the ability of future generations to meet their needs is defined by modern scientists as “sustainable development”. The concept of “social responsibility” is a narrower but key aspect of sustainable development. Interestingly enough, the definition of corporate social responsibility given by marketing professionals is a philosophical concept that

defines a company's position in relation to its country, society, employees and the environment. The modern company understands its responsibility and strives to become a structure with a “human face” [2].

Social responsibility is an integral part of a balanced development of society because the implementation of social responsibility policy achieves the main goals of balanced development. There is no clear definition of the meaning of the concept of “social responsibility” because of its complexity. It is systemic and reflects the value system of society. In this approach, the essence of a category is characterized by a set of different dialectically interrelated types of responsibility (economic, legal, moral, political, professional, etc.). In a narrow sense, they take into account the degree of acceptance by any social entity, group of socially significant goals of the society, readiness to fulfill mutual rules and responsibilities in the process of joint activity in order not to damage the established development of society in general and individual communities, individuals. Social responsibility serves as a mechanism for the interdependence of social actors occupying different status positions in the social hierarchy [3].

In scientific literature, social responsibility is considered from an economic, environmental, and social standpoint, the basis of which is the development of positive factors influencing business and minimizing negative consequences.

Differences and discussions regarding this interpretation are explained by geographical location, economic development of the country, traditions, mentality. However, with the adoption of ISO/CD 26000: 2010 International Guidelines on Social Responsibility [4], social responsibility is understood as the responsibility of an organization, company for the impact of decisions and actions on society, the environment through transparent and ethical behavior, which:

- promotes sustainable development, including the health and well-being of society;
- respects the expectations of stakeholders;
- complies with applicable laws and international standards of conduct;
- integrated into the activities of the organization and practiced in its relations [5].

This standard has interpreted the concept of “social responsibility” and greatly simplified its understanding since different terminology does not contribute to the understanding and popularization of this concept.

Please note that this standard provides a modern understanding of the concept of social responsibility. Namely, social responsibility is the responsibility of an organization for the impact of its decisions and activities on society and the environment through transparent and ethical behavior that promotes sustainable development,

health, and well-being of society; takes into account stakeholder expectations; complies with existing legislation and complies with international standards of conduct; and integrated into the activities of the whole organization and put into practice in the relationship. Issues that are the essence of social responsibility reflect the expectations of society at a particular point in time and, therefore, are constantly changing with the problems of society and its expectations, so organizations will also change to address these problems. An important characteristic of social responsibility is the desire of the organization to be responsible and accountable for the impact of its activities and decisions on society and the environment. This involves transparency and ethical behavior. This basic understanding of social responsibility can be used in the further study of this phenomenon, and to define corporate social responsibility.

Every organization that seeks to improve its corporate social responsibility activities should regularly evaluate the processes and their impact on society. As all segments of society can contribute to sustainable development, there is a need to develop tools that can, in practice, identify and achieve goals to achieve it. This explains the need to apply the standard [4].

Adopting a socially responsible practice of managing an organization promotes greater awareness when making decisions based on a better understanding of society's expectations, risks, and opportunities associated with social responsibility. Responsible management of the organization is able to improve the organization's relationships with stakeholders. Encouragement to follow a regulatory commitment leads to decisions that are more likely to be supported and trusted by those who implement them and who they influence. The result can be improved risk management practices and a stronger reputation for the organization.

It should be noted that one of the most important capabilities of ISO, in addition to managing standards development internationally, is a unique channel of information dissemination. We look forward to the widespread use of ISO / CD 26000:2010, which will increase the number of individuals and organizations inspired by the ideas of the standard. Numerous domestic and international regulatory documents influence the formation of social responsibility in Ukraine. Fulfillment of the requirements of the normative documents of a recommendation character indicates a higher level of social responsibility of the subject. The analysis showed that the normative documents in the area of social responsibility do not create a coherent system. One of the tasks of shaping the internal social responsibility policy, which should be reflected in the corporate code, is to choose priorities, to organize and organize a set of principles and rules of socially responsible activity on

the basis of relations with all stakeholders [6]. With this research and the prospect of further exploring this direction, Ukraine is undergoing a stage of systemic transformation.

In the conditions of initial capital accumulation, an increasing problem is the social orientation of the activities of market players. Multiple-vector and profound changes in economic conditions make the search for ways of public progress on a conflict-free, non-antagonistic basis relevant. The country is working on information and organizational levels to implement the principles of socially responsible business, including adherence to its international standards. However, realities are often inconsistent with the theory. It is necessary to establish state mechanisms to stimulate systematic improvement of social responsibility of economic entities, to assist economic entities that develop and implement their own social responsibility strategies, promulgate non-financial reporting, improve the lives of territorial communities. Introduce mandatory social reporting standards, expand opportunities for various types of benefits for companies to implement socially important projects. This work is aimed at the future.

The global experience has formed the criteria for matching a company to be socially responsible. These include fair payment of taxes; fulfillment of requirements of international, state, regional legislation; production and sale of quality products; implementation of corporate programs for training, health care, moral incentives for employees; implementation of charitable and sponsorship projects; environmental protection and more. Almost all experts divide social responsibility into two large groups: internal and external (Table) [7].

**Social responsibility groups**

Internal social responsibility	External social responsibility
1. Work safety	1. Sponsorship and corporate charity
2. Wage stability	2. Environmental protection
3. Health and social insurance	3. Interaction with local authorities
4. Human Resource Development (Programs)training and advanced training	4. Participation in crisis situations
5. Assisting employees in critical situations	5. Responsibility to consumers goods and services in the provision of services

Theoretical problems of health care development are considered in the works of many economists, lawyers, and physicians. Usually, the focus is on the scarcity of resources devoted to health care, unproductive costs and low efficiency, ways to raise additional

funds and use them effectively. Unfortunately, in domestic practice, these funds are important, but they do not provide a synergistic effect, and the share of public health in Ukraine does not rise above 3.7–3.8 % of GDP. The main reason for this is the absence of a rule of law with a high level of social responsibility, the swelling of the shadow medical market, which in its essence is even tougher than the classical free market, always indifferent to social and moral issues, as well as corruption at all levels of medical service [8].

The source of funds earmarked for the national health care system is direct taxes levied on individuals and legal entities. Patients should be treated free of charge, and the state must act as the payer. Competition opportunities can be used and paid services are available that meet the additional demand for treatment, with improved service for some affluent segments of the population. In addition to public hospitals, there are also private clinics and offices whose services are paid either directly or through voluntary insurance. Usually, doctors can choose where to work in the public or private sector, and often just work part-time. However, the public health market is tightly regulated in terms of price and quality of treatment, and the private sector is not significantly expanded. State and social insurance models serve as resource redistribution. Taxes (or deductions for health insurance) are legally included in the state budget (or aggregate national insurance fund with territorial units) and then distributed according to medical needs. The full amount of public resources needed to provide public health services consists of budgetary funds and insurance fund resources. In Beveridge's health care systems, the first source prevails, and the second in Bismarck's systems. [9]. At the same time, both models rely on the special role of the state in regulating the market of medical services. Their advantages lie in the highest degree of social justice and solidarity of the population when the principle of 'healthy pay for the sick, rich – for the poor, young – for the elderly' is realized. In particular, insurance minimizes the risk of unforeseen medical expenses by combining many policies into one portfolio.

However, there is a great deal of debate among scholars and practitioners of government regulation about the appropriateness and degree of redistribution of public resources. As we can see, the economic basis of the unity of the welfare state and the effective development of health care is the allocation of public resources in its favor. The inability of the private market to ensure the equitable distribution of health care services and the social modernization of society also make public health importance. By possessing the monopoly of legitimate violence, the state, unlike other entities, has the opportunity to adjust the distribution of social goods and to make them more accessible to

vulnerable sections of the population, to detect abuse. This is also explained by the fact that human health is objectively a strong factor in the quality of life, and the Constitution of Ukraine enshrines equal access to education and health services for citizens.

The need to curb the rapid increase in unproductive health care costs in developed countries is forcing governments to introduce a cost-sharing between the state and patients (or charities).

In the medical field, its necessity is also conditioned by the possible situation of "moral hazard" when the patient, knowing that he or she is being paid by a third party (state or insurance structure), has no restrictions on additional diagnostics, medical procedures, rehabilitation measures. In developed countries, the social modernization of society is not only due to the growth of public medicine. Another trend is the growth of the nonprofit non-governmental healthcare sector. On the one hand, non-profit institutions mitigate the imperfection of the private health care market and, on the other, fill in the unprofitable niches of the market, as they seek not to profit but missions to improve the welfare, quality and life expectancy of each person.

The main reasons for the growth of health care institutions are the development of humanity, the democratization of the political and economic space in response to the complexities and challenges of post-industrial society. The social responsibility of NGOs is growing, and the state supports it. The second reason is the decentralization of health care and the strengthening of the role of regional markets in the efficient allocation of budgetary resources. The third reason is the desire to make better use of scarce health care resources. The source of the budget of public organizations is not only government subsidies, but also membership fees, funds from business activities, sponsorship, private charitable contributions, funds from municipalities. They have the opportunity, through lobbyists in parliament, to get involved in the public distribution of resources, to direct them to health care, to activate human resources, creative and intellectual potential (they usually include professionals – practitioners and volunteers), to monitor the compliance of officials with the requirements of the laws, to act arbitrators in resolving useful cases initiated by local governments. In addition, non-governmental organizations promote healthy lifestyles through non-profit marketing. Domestic health care knows the times when it has provided the country with some of the best doctors in the world and one of the best quality health care. We have faith that such times are still ahead of us. However, today our society is facing a demographic crisis in the medical community. There is a massive outflow not only of mid-level specialists but also of doctors from outside Ukraine. We are at the same time

between two different philosophies of the quality building in health care: state and patient-oriented, we lose that quality every day. The differences between the old Soviet and future market philosophies of achieving quality are very noticeable.

Medicine, medical care, medical services are a necessary component not only of high quality of life but also of the simple existence of humanity as a biological species and of each individual in particular. In the media, the quality of health care services is being discussed quite widely. As an inheritance of the past, today quite often one can observe an interesting phenomenon: in private clinics, patients are offered comfortable wards, but not always show elementary respect to patients. Doctors have learned to take money for their services, but patients are not yet of value to them. Competition in the market is still a long way from getting clinicians to think about how to provide their patients with better services than others. Profitability and lack of serious competitors fuel the desire to work to improve quality.

Recently, it has become “popular” to witness the high quality of the clinic’s equipment services. “We provide high-quality services because our clinic has the most up-to-date equipment” – this can be read, if not literally, among the lines on most clinic sites. As an element of marketing, it is justified. But unfortunately, many executives believe that equipment quality and service quality are synonymous. With the help of the equipment, you can perform a qualitative procedure, ie to provide “medical help”. But for the full service of the equipment is not enough. They have not yet invented medical equipment that could reduce queues, motivate employees or make operators polite with patients over the phone, nurses and administrators smile.

Modern high-tech medical equipment is a necessary but insufficient condition for the provision of quality medical services. Among the investors who have actively entered the healthcare market in recent years, there is a misconception that quality can only be guaranteed technologically. That is why we are observing the construction of modern clinics, laboratories equipped with the latest technology. However, they are staffed with young professionals with little professional experience. The quality of clinical analyzes is governed by a large number of certificates, standards, metrological procedures. In a chaotic market, all these measures can be carried out, but can only be declared. Why sin: licenses and certificates are bought for money. Even specialized firms have emerged. The doctor, or moreover, the patient will not be able to assess or even feel the quality or reliability of the analysis itself. Therefore, social responsibility as such simply disappears. For the patient, the placement of the office, its interior and the courtesy of the nurses are crucial.

Recently, the time factor of analyzes has increased. The faster – the better. There is no debate about social responsibility for quality. And for a doctor who recommends a particular laboratory, the amount of rewards for the number of referral patients becomes decisive, not the system of assurance. Some unscrupulous private CDLs already give back 20 % and 30 % of what they have received from the patient. This percentage is required for quality metrological assurance of the analyzes themselves. Therefore, social responsibility is reduced to zero. There is a paradoxical situation with practitioners who personally take tests for themselves and their families in one trusted laboratory, and direct patients to “bend over” – (even the term has appeared) to another. Today we need to say goodbye to yesterday’s idea of quality medical care, start building diagnostic centers or laboratories on today’s requirements and tomorrow’s ideas about medical services. The key is the international standards ISO 9001, ISO 17025 and, above all, the quality system according to ISO 15189 [10,11,12].

How have they achieved quality in leading healthcare facilities and clinics?

First, they started thinking about the patient, focused on the clinic’s activities.

Second, they set a clear goal that united the clinic staff.

Third, the clinic staff and administration acted as a team, not inspecting or dismissing their staff.

Not doing these three simple things will help neither the latest equipment nor advertising. Today there is a patient who will tell what the quality of medical services should be, and often he is ready to pay for them. Another, but equally important, aspect of medical services is laboratory diagnostics. The perfect implementation of a properly selected method of diagnosis and treatment, along with the above aspects, is an essential prerequisite for quality medical care. KDL products are an authorized report containing laboratory test results, patient data (name, age, gender, diagnosis), type of biological sample, time of collection and delivery to the laboratory, current reference intervals for each analysis, and other information. In other words, the laboratory performs and supplies the clinician with one or the other degree of reliable objective diagnostic information.

Quality in relation to CDL is a properly and timely assigned test for the patient, performed at a sufficiently analytical level with the necessary information to interpret it. Only with a well-thought-out organization and quality laboratory testing can one expect that every result reported in an authorized report will be used by a physician to make diagnostic or treatment-altering decisions. It is important to understand that, as in any field of human activity, errors can occur in the CDL. The

experience of developed countries shows, first of all, that economic reforms in the post-socialist health care system should be directed not only to structural restructuring, the formation of the Institute of Family Physicians, the insurance market but also to the establishment of non-profit units of the non-governmental sector. We have little influence on this, because at the beginning of market reforms, the state, through the legislation, first of all, promoted the development of infrastructure of the commodity, financial, information and labor markets, ie purely economic institutions. Meanwhile, the prolonged proliferation of the public health sector has the consequence of reproducing its defects and therefore requires vigilance and continuous improvement of legislation. The main drawback is that the social responsibility for identifying the needs of sick citizens and financing health care lies with the parliamentarians to whom this right is delegated during the election campaign. However, they often have opportunistic behavior, selfishness, and neglect of voters' preferences and needs. That is why even those patients who are paying taxes that are direct and unaddressed become hostages to their outside health decisions and may not receive adequate treatment. Unless there is a well-developed private health sector alongside the public sector, where market agreements are voluntary and each party's interests are more or less taken into account, the shadow sector of medicine is in place. In a welfare state where the responsibility of the government to redistribute financial flows through the budget does not conflict with human development security, the taxes collected are allocated for the benefit of improving the health of citizens, that is, the exchange of money between citizens and health care providers, mediated by the government and parliament, has only potential risks. In a non-social state, on the contrary, there is a very high variation between the state budget revenues and the social content of their distribution.

It is worth noting that the level of corruption in Ukraine is quite high and additional payments for free medical services have become well known. Of course, healthcare corruption should not be viewed as a separate, independent process, but only as an element of the overall corruption system [13–14]. Reducing the level of corruption in the medical sector is only possible with a change in the financing system: in particular, through the use of insurance mechanisms, the introduction of official fees for medical services. An important step in overcoming corruption in the medical field is to build a system of control and transparency, to redistribute functional responsibilities, and to automate workplaces. Therefore, it should be noted that these measures play an important role in the fight against corruption in the health sector. However, in the development of anti-

corruption measures in medicine, certain features should be considered, which would be characterized by complexity and timeliness. An important step is a change in the funding scheme, a public re-orientation of anti-corruption awareness, an independent and effective judicial system, transparency and control over the financing of medicine.

To some extent, the current health care reforms in Ukraine in pilot regions aim to differentiate between buyers and sellers of health care services, and financial and management autonomy for healthcare facilities. Buyers are the local governments, and central district hospitals receive the status of a utility company, which on a contractual basis provides services in exchange for the customer's money. Such a system has several advantages over the model of integrated government and health care financing since it allows impose certain requirements on the structure, volume, quality, cost of medical services provided to the population. However, European practice adds to this system the competition between providers of public-order healthcare services, which is also joined by private firms.

Clinical information content and analytical reliability determine the quality of laboratory tests that is achieved by creating a quality assurance system through standardization. The lack of standardization, which is closely linked to certification and accreditation, hinders the development of laboratory medicine in Ukraine at this stage [15].

There are over 300 international standards in the field of laboratory medicine. In Ukraine, there is still no sufficient regulatory and legal framework for the standardization of clinical and laboratory studies and laboratory services, which impedes the implementation of world-leading evidence-based medicine and causes the non-recognition of foreign laboratory results abroad. Among the various medical disciplines, laboratory medicine is the most favorable field for standardization – establishing uniform rules and assessing compliance with them in the practice. Adoption of standards that contain scientific and substantiated criteria for the proper implementation of a specific technological operation will improve the quality of laboratory research in the CDL.

The acceleration of the standardization rate will ensure the creation of a single laboratory space in Ukraine, will ensure recognition of the results of clinical and laboratory examinations of patients abroad. The requirements of standards used in laboratory medicine are analyzed. Addressing standardization will improve the quality of health care delivery, help reform the health care system, including:

- install:
  - clear rules of organization of work of any CDL;
  - requirements for a reference system in laboratory medicine that will provide the highest precision of

measurement to which the CDL can navigate, using the methods and standard specimens attested in the reference system.

- provide:
  - safe working conditions of the CDL;
  - obtaining reliable and comparable information;
  - metrological confirmation of the correctness of measurements of the whole variety of biological analytes under study.
- substantiates the selection and accurate implementation of laboratory testing techniques that are optimal correct and precise:

- regulates compliance of manufacturers with the means of analysis in their development, production, transportation of the highest conformity of product properties to the requirements of sensitivity, specificity, correctness and precision of the research methods performed with their application.

Solving the problem of standardization will improve the quality of medical care, that is: it will set rules for the organization of the work of the CDL, requirements for the help system: will provide reliable and comparative information, confirm the accuracy of metrological measurements: regulate the means of testing manufacturers of the highest accuracy of compliance of the characteristics of products with the sensitivity and specificity studies conducted with their help.

## Conclusions

In summarizing the results of the research, the following key recommendations can be formulated to ensure an adequate level of social responsibility and quality in the activities of the CDL:

- successful implementation of international standards in organizational, technical, professional and methodological competence is possible to provide if they are well trained in the field of personnel quality management;
- the success of the accreditation of diagnostic laboratories depends largely on how the requirements of the management system documentation are met by staff;
- an experienced specialist should be involved in conducting the pre-accreditation audit and in assessing the degree of compliance with the requirements of the standards.

The social responsibility of the state in health care has to foresee the constitutional principle of equal access to it for every citizen and to increase life expectancy. For this purpose it is necessary to ensure the targeted receipt of tax money that goes to health care, to adopt the Law on Social Health Insurance and to minimize the impact of shadow medicine.

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