
International Standards and Features of Financing in the Field of Health Care and Provision of Medical Services

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ABSTRACT: The relevance of this article is due to the fact that international standards in the field of health care and medical services are central to the field of world principles of functioning and development of medical law. The aim of the article is to conduct research on the peculiarities of international standards in the field of health care and medical services, as well as to study the prospects of their implementation in Ukraine. Leading research methods are general and special research methods, including methods of logic, analysis, comparison. The results of this study are to outline recommendations for the use of international standards in the field of health care and medical services in Ukraine and to summarize the legal framework on this issue. The significance of the results is reflected in the fact that this study can

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serve as a basis for outlining future changes in current legislation of Ukraine on the functioning of the health care system and implementation of world practices in health care. Within the framework of this study, systematized the main international and European documents that reflect the main international standards in the field of health care and medical services and ratified in Ukraine and have a direct impact on the legal framework for this area.

Keywords: standards of medical services, medical reform in Ukraine and the world, medical law, health care system, international financing

Introduction

Standards for the provision of medical services are an element of ensuring the quality of medical services and the effective functioning of health care in the country. In the field of medical care, the Directive 2011/24/EU on patients' rights to cross-border medical services have been widely used, where for the first time it is officially recognized that states have full responsibility for establishing rules in the field of governance, quality standards, safety and the organization of medical services. In addition, Council of Europe Committee of Ministers Recommendation No. R (97)17 to member states on the development and implementation of quality improvement systems (QIS) in health care¹ establishes structures and policies that support the development and implementation of "quality improvement systems" at all levels of health care delivery. Such quality improvement is possible through: organization of high-quality postgraduate education of medical workers, ensuring quality audit and accounting in medical institutions, effective work of relevant government agencies, the availability of a working system of incentives, improving the professional skills of health care providers.

Particular attention is paid to the Recommendation Rec(2001)13 of the Committee of Ministers to member states on developing a methodology for drawing up guidelines on best medical practices,² which are based on guidelines on best medical practices and clinical guidelines, which serve as an instrument of public policy. The content of this document is aimed at ensuring the functioning of the methodology for drafting guidelines for improving the quality of medical services through: ensuring the functioning of systems for reviewing services provided, testing of pilot projects, the functioning of the inspection system. Guidelines for medical practices should in the future play a

key role in the educational and clinical training of medical professionals and the long-term development of professionalism. Council of Europe Committee of Ministers. Recommendation Rec(2001)13² also provides for a number of mandatory actions for public institutions, in particular: development and implementation of national policy concepts for the development of health services and improving their quality; promoting international cooperation between states, scientific institutions, international organizations and centres; disseminating recommendations and methodologies and supporting decision-makers on the functioning of the health sector.

The current standards of medical care in Ukraine were developed on the basis of the EU TACIS program with technical support of independent states in 2004-2008, which established that countries are fully responsible for the organization and provision of medical services on their territory. Within the framework of this program, Ukraine has adopted the following regulations: the Order of the Ministry of Health of Ukraine “On monitoring of clinical indicators of quality of medical care;”³ the Order of the Ministry of Health of Ukraine “On approval of the List of clinical indicators to be monitored in the treatment of persons with hypertension and type 2 diabetes;”⁴ the Order of the Ministry of Health of Ukraine “On the creation and implementation of medical and technological documents for the standardization of medical care in the system of the Ministry of Health of Ukraine.”⁵

Recent Ukrainian research in the field of introduction and use of international standards for the provision of medical services is aimed at studying the actual content of standardization processes and the relevance of their use in Ukraine. In particular, A.M. Markina⁶ emphasizes the existence of relevant legislation, which is adopted to address specific issues of the authorized entities. In turn, N.P. Yarosh and S.I. Lupey-Tkach⁷ in their work “Current state, standardization problems of medical care and their solutions in terms of reforming health care system in Ukraine” note that it is impossible to unambiguously relate to this legal phenomenon, as this category includes the promotion of competitiveness of medical services, and the introduction of new technologies of a progressive nature, and the method of cost management in the medical field. Thus, the standards of medical services are an element of ensuring the quality of medical services and the effective functioning of health care in the country. C. Shaw et al.⁸ pointed out the problems in this area. Researchers have argued that existing systems that set or assess organizational standards fail to extend these activities to European national borders or beyond, as certification, licensing, and accreditation programs are too diverse to provide a common basis for consistent evaluation. Within the EU, joint efforts have been made to harmonize standards for medical training, medical equipment and clinical practice. However, very little attention has been paid to how such services are managed and organized, how their internal system works.

M. Lyapina et al.⁹ point to the multiplicity of international medical standards. However, researchers note that most laws and directives in the field of marketing of medical devices, for example, are more modern, and therefore the actual experience of their use is extremely limited. Therefore, in some cases their use may be dangerous, and the doctor is obliged in his/her practice to use only those for which there is relevant reliable information.

Materials and Methods

The following methods were used in the research process: general theoretical (analysis, synthesis, concretization, generalization, method of analogy, modelling) and empirical methods (study of the experience of using international standards in the field of health care and medical services in Ukraine and abroad, research of legal and scientific literature on this issue and conclusions).

One of the first international legislative acts in the field of health care and medical services was adopted in 1973 by the International Covenant on Economic, Social and Cultural Rights,¹⁰ which provides in Article 12: “States parties recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Measures to be taken by states parties to fully realize this right include those necessary to: prevention and treatment of epidemic, endemic, occupational and other diseases and their control; improving all aspects of environmental hygiene and occupational health in industry; ensuring reduction of stillbirth, infant mortality and healthy child development; creating conditions that would provide all with medical care and medical treatment in the event of illness”.

An important place in the formation of international standards in the field of health care is occupied by the Medical Care and Sickness Benefits Convention (No. 130),¹¹ adopted by the International Labour Organization, which outlines the guarantees of member states to insured persons to ensure treatment and prevention measures. In addition, the Convention defines the distribution of financial burdens in the provision of medical services and the content of the category “minimum amount of medical care,” which provides: inpatient or outpatient treatment; hospitalization of patients; general medical care; registration and issuance of relevant medical documents at the request of the patient, keeping a medical history; dental care; medical rehabilitation.

Other important international acts that laid the foundations for the formation of standards in the field of health services were: The Charter of Fundamental Rights of the European Union,¹² European Convention on Social and Medical Assistance,¹³ The European Social Charter,¹⁴ European Code of Social Security,¹⁵ a Declaration on the Promotion of Patients’ Rights in Europe,¹⁶ European Charter of Patients’ Rights,¹⁷

A Declaration on the Promotion of Patients’ Rights in Europe¹⁶ for the first time clearly defined the concept of “patient” and outlined a number of

modern principles of functioning in this area: respect for human dignity and inviolability of both physical and mental nature; respect for privacy and the right to confidentiality; the right to information about medical care; the right to consent in the process of receiving medical care; the right to the most accessible level of medical care for everyone; and the right to quality medical care that meets technological standards and is based on the principles of humanity.

In turn, the European Charter of Patients' Rights¹⁷ of 2002 approached the basic rights in the field of health care in a more structured way and formed an international standard of human rights to health care.¹⁸ The rights defined by this Charter are: the right to preventive measures; the right to consent; right of access; the right to privacy and confidentiality; the right to information; the right to respect patients' time; the right to security; the right to comply with quality standards; the right to access modern achievements; the right to individual treatment; the right to avoid unjustified suffering and pain; the right to compensation; and the right to file a complaint.^{17,19,20}

When studying the use of international standards in the field of health care and medical services, it is believed that the recommendations of some scientists on this issue are appropriate. Thus, D.D. Diachuk et al.²¹ note that to date a number of provisions of the Council of Europe recommendations have not been implemented in Ukraine, which directly indicates the lack of a systematic approach to the functioning of health care in Ukraine and the postponement of a truly effective quality management system. In this regard, the main shortcomings can be identified: the lack of connection between quality and safety standards with the actual data on health care; lack of uniform criteria for quality and safety of medical care; lack of a medical care monitoring system; lack of connection between standards and tariffs for medical services; use of outdated health care standards; lack of uniformly agreed terminology in the medical field; lack of harmonization of legislation; non-use of clinical guidelines and clinical protocols developed on the basis of evidence-based medicine in the educational and professional practice of health professionals; and lack of effective support for continuous professional development of health care providers.²²

It was also noted that a major problem for Ukraine is the functioning of the quality management system in health care, namely the exclusion of the public from the development, discussion, review, verification, and application of clinical guidelines, which in developed countries are the basic standard in this area.^{23,24}

Results and Discussion

International standards in the field of health care and provision of medical services are norms, principles and provisions enshrined in relevant international legislation, which determine the changes and scope of individual

rights in the field of health care and provision of medical services and serve as legal norms for public policy in this field. The purpose of forming international standards in this area is a key vector of any state, namely public health, protection of patients' rights, improving the quality of life of society and each individual, and developing a progressive legislative foundation for the functioning of the sphere. Signs of such standards can be outlined as follows: their scientific and practical validity; their reliability (scientific validity is proved by practical use by medical workers); their reality (standards are based on the real state of health care and the provision of medical services); and their clarity in content, specificity and clarity of wording; their relevance (compliance of international standards with the requirements and needs of the time).^{25,26}

The whole set of legislative acts at the international level is divided into the following types:

- 1) International Bill of Human Rights: the content reflects the basic inalienable human rights.
- 2) Agreements on the Prevention and Punishment of Crimes: mass human rights violations are prevented.
- 3) Convention for the Protection of Individual Populations: provide personal care from the state.
- 4) Convention for the Protection of the Individual: prevent abuse by public authorities and certain officials.
- 5) Interstate conventions on human rights: provide for the adoption of final documents binding on States parties.

Within the framework of this study, systematized the main international and European documents that reflect the main international standards in the field of health care and medical services and ratified in Ukraine and have a direct impact on the legal framework for this area (Table 1).

Table 1. The main international and European documents on the protection of the rights of consumers of medical services have been ratified in Ukraine.

No.	The name of the document	Date of signing	Date of ratification in Ukraine
1.	International Covenant on Civil and Political Rights of 16.12.1966	20.03.1968	19.10.1973
2.	Optional Protocol to the International Covenant on Civil and Political Rights of 16.12.1966	25.12.1990 (accession)	25.10.1991 (entry into force)
3.	International Covenant on Economic, Social and Cultural Rights of 16.12.1966	19.10.1973	19.10.1973
4.	Convention on the Elimination of All Forms of Discrimination against Women of 18.12.1979	19.12.1980	03.09.1981 (entry into force)

Table 1. (Continued).

No.	The name of the document	Date of signing	Date of ratification in Ukraine
5.	International Convention on the Elimination of All Forms of Racial Discrimination of 21.12.1965	07.03.1966	21.01.1969
6.	The Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of 10.12.1984	10.12.1984	26.01.1987
7.	The Optional Protocol to the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (OPCAT) of 18.12.2002	18.12.2002	21.07.2006 (ratification)
8.	Convention on the Rights of the Child of November of 20.11.1989	20.11.1989	27.09.1991
9.	International Convention for the Protection of the Rights of All Migrant Workers and Members of Their Families of 18.12.1990		Not ratified
10.	Convention on the Rights of Persons with Disabilities of 13.12.2006	13.12.2006	06.03.2010
11.	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 04.04.1997	22.03.2002	Not ratified
12.	Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights) of 04.11.1950	04.11.1950	11.09.1997
13.	European Social Charter of 18.10.1961	18.10.1961	Not ratified
14.	European Social Charter (revised) of 03.05.1996	03.05.1996	01.02.2007
15.	Framework Convention for the Protection of National Minorities of 01.02.1995	15.09.1995	01.05.1998
16.	Charter of Fundamental Rights of the European Union of 07.12.2000	07.12.2000	Not ratified

Examining the role of the European Charter of Patients' Rights¹⁷ in the formation of standards for the provision of medical services, Yu.A. Kozachenko²⁷ argues that although this document is of a recommendatory nature, all basic rights form a system of standards and are united in a powerful organization, which is successfully approved in the legislation of European countries. The European Charter of Patients' Rights¹⁷ has also received the status of a reference document and an indicator document for organizing and monitoring the functioning of the health care system and respect for patients' rights. Modern living conditions call for the expansion of the rights enshrined in the European Charter of Patients' Rights. Thus, in addition to the above standards, it is appropriate to talk about the right to adhere to quality standards, the right to respect the patient's time, the right to an individual approach to treatment, the right to

safety and safe conditions of treatment. N.F. Shishatska²⁸ examining this issue says that the right to patient safety can be considered as the right to be protected from any harm caused by unprofessional work of the medical institution in general and the employee of the medical institution in particular.

Examining the implementation of international and European standards of medical services in Ukraine and outlining the general issues of standardization, it was noted that the category “standard” should be understood as an appropriate model, which is the key one and which must meet certain qualities, properties, characteristics and also documents, the content of which has links to relevant information and data. Standardization processes, as well as the basic terminology of this process are established by the standards of the State Standardization System of Ukraine²⁹⁻³³ and standards defined by the International Committee for Scientific Principles of Council Standardization International Organization for Standardization. At the legislative level in Ukraine, the system of standards in the medical sphere is outlined in the Law of Ukraine “Fundamentals of the Legislation of Ukraine on Healthcare,”³⁴ where all medical standards are divided into state social norms and industry standards. At the same time, in accordance with the Law of Ukraine No. 1629-IV “On the National Program of Adaptation of Ukrainian Legislation to the Legislation of the European Union,”³⁵ the purpose of which is to outline the adaptation of Ukrainian legislation to EU legislation, which is defined as the achievement of compliance with the legal system of Ukraine, taking into account the criteria set by the EU to the states that intend to join it. This legislative act also defines the issue of harmonization of the national system of standards with European principles and principles of functioning of the system.³⁶⁻³⁸

Studying the problems of standardization in the medical field, A.M. Markina⁶ notes that the category of “standardization” is defined as an activity whose main purpose is to achieve the optimal degree of regulation in the field through the establishment of provisions and requirements for multiple and general use. At the same time, standardization in the medical field, the scientist determines the existence of relevant legislation, which are adopted in order to resolve specific issues of the activities of authorized entities for the provision of tangible and intangible benefits aimed at improving the physical and mental health of the patient in order to provide recipients of medical services with a positive effect.³⁹

In turn, N.P. Yarosh and S.I. Lupey-Tkach⁷ in their work “Current state, problems of standardization of medical care and ways to solve them in terms of reforming the health care system of Ukraine” note that the impossibility of such an unambiguous attitude to the category of “standardization”, as this category includes the promotion of competitiveness of medical services in all markets of medical services in the country and the world, and the introduction of new technologies of a progressive nature, the method of regulating costs in

the medical field, and meeting the needs of the population in quality medical services.⁴⁰

Conclusion

Standards for the provision of medical services are an element of ensuring the quality of medical services and the effective functioning of health care in the country. The study of the peculiarities of international standards in the field of health care and medical services, as well as the study of prospects for their implementation in Ukraine provides an opportunity to outline recommendations for the use of international standards in health care and medical services in Ukraine and generalize the legal framework.

Examining the implementation of international and European standards of medical services in Ukraine and outlining the general issues of standardization, it was noted that the category “standard” should be understood as an appropriate model, which is the key one and which must meet certain qualities, properties, characteristics and also documents, the content of which has links to relevant information and data. Standardization processes, as well as the basic terminology of this process are established by the standards of the State Standardization System of Ukraine and standards defined by the International Committee for Scientific Principles of Council Standardization International Organization for Standardization.

The significance of the results is reflected in the fact that this study can serve as a basis for outlining future changes in current legislation of Ukraine on the functioning of the health care system and implementation of world practices in health care.

It remains necessary for Ukraine to create a network to support the standards of the medical sphere and to involve professionals (representatives of medical universities, professional associations, research institutions and centers) with the tools of quality management and monitoring, quality control and audit, improving competencies in the educational process, and improving the professionalism of medical staff, harmonization of tariffs and standards.

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