

IMPLEMENTATION OF INTERNATIONAL QUALITY STANDARDS FOR HEALTH-CARE SERVICES

Olena Martynyuk¹, Svitlana Busel², Anna Nemchenko³

Abstract. At the contemporary stage of development of the global healthcare industry, improving the quality of medical care is the main goal and the main criterion for assessing its effectiveness. Therefore, ensuring the high quality of medical care and medical services is the responsibility of healthcare authorities, managers of healthcare facilities of any form of ownership and all medical professionals. An important mechanism for achieving this in the modern world is standardisation as a key tool for quality management. *The purpose* of this article is to study the existing international healthcare standards, analyse the state of standardisation in the healthcare sector as a basic element of providing quality medical and pharmaceutical care to the population, and to identify opportunities for implementing the best standards in the practice of the healthcare system in Ukraine. *The findings* of the study show that international service quality standards are the most important frameworks developed and maintained by international organisations to ensure consistency, reliability and security across industries. All these standards are aimed at increasing customer satisfaction, operational efficiency and international competitiveness. Keeping these standards up-to-date and compliant is essential to meet customer expectations and regulatory requirements in today's ever-changing globalised world. By systematising scientific research, the authors have established that the transformation of the healthcare system in Ukraine will be successful if the most significant domestic achievements in the healthcare sector are rationally combined with the world's best practices and international standards, the principles of healthcare contained in international human rights instruments, and the principles and norms that define the content and scope of human rights in the healthcare sector that Ukraine must implement. Moreover, it is essential to establish the world's best practices in the field of treatment of major diseases, principles of medical services, and training of staff, which will help to achieve the necessary improvement in the quality of medical care in the context of the development of the medical system of Ukraine. It is determined that in the process of adaptation of national legislation to the regulations of the European Union, all ISO 9000 standards were adopted in Ukraine as national standards and their implementation in everyday activities, including in the healthcare sector, was organised. Considering all of the abovementioned, the System of Implementation of International Quality Standards for Healthcare Services is proposed. The standards are divided into international, national, sectoral, regional and local standards by the scope of influence. According to the Donabedian triad, the objects of influence are: resources, processes and outcomes of healthcare. The types of standards are grouped by object, and the mechanisms of influence on the quality of standardisation are defined: Licensing of healthcare facilities, Accreditation of healthcare facilities, Certification of healthcare professionals. The ways of implementing international standards can be defined as direct, indirect, doctrinal and institutional, so the regulatory and legal mechanisms will operate through laws that have already been ratified in Ukraine. For example, the Law of Ukraine 'On the State Programme for Adaptation of Ukrainian Legislation to the Legislation of the European Union' allows for the formation of action chains for the implementation and reform of the Ukrainian healthcare system.

Key words: international standards, services quality, public health, medical services, standards implementation, healthcare.

JEL Classification: D18, E69, H89, I18, K39

¹ Odesa National Medical University, Ukraine (*corresponding author*)

E-mail: emartynyuk2017@gmail.com

ORCID: <https://orcid.org/0000-0002-0377-7881>

² Director of the Center for Reconstructive and Restorative Medicine (University Clinic)

of Odesa National Medical University, Ukraine

E-mail: svitlana.busel@onmedu.edu.ua

ORCID: <https://orcid.org/0009-0000-7684-8110>

³ Odesa National Medical University, Ukraine

E-mail: hanna.nemchenko@onmedu.edu.ua

ORCID: <https://orcid.org/0000-0003-0407-3744>



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1. Introduction

In the increasingly interconnected world of the modern age, the development of international service quality standards is important for businesses operating beyond their borders. The globalisation has increased the need for consistent service quality that allows companies to meet the diverse needs of consumers while navigating different regulatory environments. The delivery of healthcare services is particularly important as it is linked to people's health and lives.

In the current stage of development of the global healthcare industry, improving the quality of medical care is the main goal and the main criterion for assessing its effectiveness. Therefore, ensuring the high quality of medical care and medical services is the prerogative of healthcare authorities, managers of healthcare institutions of any form of ownership and all medical professionals. An important mechanism for achieving this in the modern world is standardisation as a key tool for quality management.

The implementation of the standardised delivery of quality medical and pharmaceutical services contributes to the rational and efficient use of labour and material resources of the healthcare sector, protection of patients' interests by ensuring a real level of social guarantees of access to quality medical and pharmaceutical care for the population, formation of structural proportionality of healthcare services and rational allocation of financial resources.

Nowadays, in the framework of Ukraine's European integration, as well as taking into account the threats and dangers to the life and health of almost every citizen of the country caused by the armed aggression of the Russian Federation and the introduction of the legal regime of martial law in Ukraine, it is important to study foreign experience in the formation and implementation of state policy in the field of healthcare, in particular, in the leading countries of the world.

The aim of this article is to examine the existing international healthcare standards, analyse the state of healthcare standardisation as a key factor in providing quality medical and pharmaceutical care to the population, and to identify opportunities for implementing the best standards in the practice of the medical system in Ukraine.

In the process of research and preparation of the article, the legal and regulatory acts of Ukraine on healthcare and standardisation, as well as scientific articles on healthcare standardisation in the world have been used.

In the process of the study, both the standard research methods and the method of systematisation

and analysis of scientific literature and bibliography were used, which allowed to analyse the legal context and fundamental principles of formation of international quality standards and their integration into the system of a particular state.

The general scientific methods of research, such as the method of systematic approach, generalisation, and prognostic. This allowed us to formalise the trends in the development of the modern standardisation system, identify specific features of standards in the healthcare sector of Ukraine, and propose certain ways of implementing international standards in the healthcare system of Ukraine.

The relevance of the study of the development of these standards lies in the need to examine how they help to effectively bridge the gaps between the requirements of the global system and the leading developed countries, and the need to ensure their consistency in the economic, legal and medical field of Ukraine.

2. Methodology of Research

The study of the development of international service quality standards in the context of globalisation is a broad field of research that has significant achievements and ongoing challenges facing scholars. Existing research highlights several key aspects. Scholars such as Maritz R., Scheel-Sailer A., Schmitt K., Proding B. (2019), and Ivanchov P. V. (2020) have made significant contributions to the development of the SERVQUAL framework, which remains a key framework for assessing service quality in various industries. Their work and the work of other scholars, Balik U., Orlova V., Danilo S. (2024), emphasise the importance of material indicators, reliability, efficiency, confidence and empathy in assessing service standards.

One of the main problems is the adaptation of service quality standards to the conditions of the local economic system. Businesses and organisations operating in cross-cultural, legal and infrastructural differences require flexible yet universal standards. The increasing complexity of global supply chains and service networks further exacerbates the problem of implementing and enforcing uniform service quality standards (Gruzin, 2024).

To evaluate quality in healthcare systems in many countries of the world, the methodology proposed by A. Donabedian (A. Donabedian triad) is widely used, which is based on the assessment of three main components, namely: assessment of healthcare system resources, assessment of diagnostic and medical care technologies and assessment of their results (Avedis Donabedian, 2003).

In accordance with this, there are three main groups of standardisation objects:

- Resources (medical and pharmaceutical institutions, information institutions, personnel and their qualifications, material and technical equipment);
- processes (treatment, diagnostic, preventive, rehabilitation, organisational and medical technologies);
- consequences of medical interventions (results of a particular type of disease treatment, diagnostic and surgical interventions, effectiveness of medicines, socio-economic indicators of any preventive measures, etc.)

The assessment of the three above groups of standardisation objects is carried out by comparing them with the established standards.

To estimate the resources of healthcare institutions, their licensing and accreditation is carried out, and the processes and consequences of medical interventions are compared with medical standards for diagnosis, treatment and rehabilitation of patients and predicted intermediate and/or final clinical outcomes.

Many scientific works of well-known foreign and domestic scientists are devoted to the study of theoretical and practical aspects of ensuring the quality of medical services and medical care through the introduction of standardisation in the field of healthcare, in particular, theoretical and methodological approaches to the formation of state social standards of medical care were analysed in (Borshch, Rudinska, Rogachevskyi, Martyniuk, Kusyk, 2022) and (Shevchuk, 2023). Separately, a wide range of issues from standardisation in the field of healthcare to the formation of methodological approaches to the creation of a single medical space and medical support for the Armed Forces of Ukraine during a special period in Ukraine were considered by (Livinskyi, Zhakhovsky, Shvets, 2022).

International legal aspects of healthcare regulation are also the focus of research: Baryshnikov M., Ivanchov P. V. (2020) and others, who analysed the implementation of international legal standards in the field of healthcare in the realities of the medical system of Ukraine. However, it is worth considering the possibility of implementing the basic principles of international standards in Ukraine in the current context of healthcare reform.

3. The Formalisation of Trends in the Development of the Standardisation System

International service quality standards encompass a comprehensive framework that defines expected levels of service delivery internationally, aimed at increasing customer satisfaction, operational efficiency and trust in the organisation. These standards are typically developed and published by international organisations, industry associations or consortia, reflecting agreement among all stakeholders on best practices and performance indicators in the service sector.

The processes of integration and globalisation are accelerating the adoption of best practices and technological innovations in various industries, which is contributing to the convergence of service quality standards and criteria. This convergence is driven by competitive pressures as businesses seek to meet international standards to gain a competitive advantage, access new markets, and ensure compliance with regulatory requirements in different jurisdictions (Balik, 2024).

The international standards of service quality have evolved significantly over time, influenced by various historical events and growing global interactions. The term service quality standards can be traced back to ancient civilisations, where informal guidelines for service excellence and quality emerged in local communities.

In the early 20th century, national standards bodies were established in some countries, such as the American National Standards Institute (ANSI) in the United States and the British Standards Institute (BSI) in the United Kingdom. These organisations aimed to unify and standardise practices within their countries, laying the foundation for more systematic approaches to quality assurance (Lingur, 2022).

The end of the 20th century and the beginning of the 21st century are characterised by accelerated globalisation and technological progress. The most widely used standards in the field of standardisation are those of the International Organisation for Standardisation (ISO), whose purpose is to ratify the ISO 9000 series of standards developed by representatives of different countries, which are based on the mechanisms for applying the process approach as a quality management method. Experts from more than 170 countries take part in the work on standards in the World Federation of National Organisations for Standardisation (WFNOS), and in general, ISO maintains relations with almost 400 international organisations working on standardisation issues.

ISO standards are recognised by the process of consensus and represent a carefully developed version of the technical requirements for products (services), which greatly facilitates the exchange of goods, services and ideas between all countries of the world.

The ISO 9000 series of standards are the most popular and widespread in the world, with a total number of over 16,000 standards. They are regularly reviewed, updated and improved, with about 500-600 standards being revised and re-adopted annually (Livinskyi, Zhakhovsky, 2022).

Currently, the following international standards of the ISO 9000 series are used, including in the healthcare sector:

- ISO 9000:2015. Quality management systems. Fundamentals and vocabulary.

- ISO 9001:2015. Quality management systems. Requirements.
- ISO 9004:2018. Quality management. Quality of an organisation. Guidance to achieve sustained success. Quality of an organisation. Guidance to achieve sustained success.)
- ISO 19011:2018. Guidelines for auditing management systems. The standard provides guidelines for audits (inspections) of quality management systems or other systems based on the principles of ISO 9000.

Meanwhile, it should be emphasised that these standards do not address the clinical aspects of medical care, but are necessary to ensure that organisations and institutions have the same requirements for all processes aimed at manufacturing products or providing quality medical services (Balik, 2024).

4. Specific Features of the Standards in the Field of Healthcare in Ukraine

Healthcare standards provide the basis for ensuring the high quality of medical and pharmaceutical care and medical and pharmaceutical services. Otherwise, it is impossible not only to ensure their systematic improvement and development, but also to assess their quality.

Standards in the healthcare system are regulatory legal acts adopted to regulate the performance of various actions by entities authorised to provide healthcare services related to the improvement of physical and mental health of both individual recipients of healthcare services and a wide range of consumers in order to achieve a positive result as a result of the provision of these services.

According to the hierarchy of standards application, there are international, national, sectoral, regional and local standards (Seniuta, 2017).

The main sources that define international legal standards in the field of health care are the documents of the United Nations, the World Health Organization, the International Labour Organization, the Council of Europe and the European Union, the World and European Medical Associations (Lingur, 2022).

Internationally, the regulatory framework aimed at ensuring health rights and access to health services for the entire global population is based on a number of legal documents and standards that differ in terms of types, types and specialisation.

National (state-level) standards are standards for models (algorithms) of medical and pharmaceutical care, medical and pharmaceutical services to the population, which are established and applied within a particular state.

In Ukraine, standardization is one of the leading management tools for quality regulation, including in the field of public health, where it is used in

conjunction with such quality management mechanisms as licensing and accreditation of healthcare facilities and certification of healthcare professionals.

Standardisation in the healthcare system of Ukraine is regulated by two laws: the Law of Ukraine 'On State Social Standards and Social Guarantees' (2000) and the Law of Ukraine 'Fundamentals of Legislation of Ukraine on Healthcare' (1993). The Law of Ukraine 'On State Social Standards and State Social Guarantees' defines the legal framework for the formation and application of state social standards and norms aimed at implementing the basic social guarantees enshrined in the Constitution of Ukraine and laws of Ukraine. In the area of healthcare, this Law defines a basic package of medical and pharmaceutical services that must be provided free of charge.

State social standards in the field of healthcare include:

- The list and scope of the guaranteed level of medical care provided to citizens in state and municipal healthcare facilities;
- standards of medical care, including the scope of diagnostic, therapeutic and preventive procedures;
- quality indicators of medical care;
- standards for preferential provision of certain categories of the population with medicines and other special products;
- standards for inpatient medical care;
- standards for the provision of medicines to state and municipal healthcare facilities;
- standards for provision of sanatorium and resort services;
- standards for the provision of food in state and municipal healthcare institutions.

The Law of Ukraine 'Fundamentals of the Legislation of Ukraine on Healthcare' establishes a list of sectoral standards in the field of healthcare and provides their definitions:

- Medical care standard (medical standard) – a set of norms, rules and regulations, as well as indicators of the quality of medical care of the relevant type, which are developed taking into account the current level of development of medical science and practice;
- clinical protocol – a unified document that defines the requirements for diagnostic, therapeutic, preventive methods of medical care and their sequence;
- rehabilitation care protocol in the healthcare sector – a unified document that defines the requirements for rehabilitation measures and their sequence in accordance with the areas of rehabilitation in the healthcare sector, taking into account the current level of development of international rehabilitation science and practice;
- material and technical equipment sheet – a document that defines the minimum list of equipment,

facilities and means necessary to equip a specific type of healthcare facility, its subdivision, as well as to ensure the activities of individual entrepreneurs who carry out economic activities in medical practice in a certain specialty (specialties) and/or are entitled to rehabilitation care in accordance with the law;

- medicine formulary – a list of medicines registered in Ukraine, including medicines with proven efficacy, acceptable level of safety, the use of which is economically acceptable.

Branch standards in the field of healthcare also include other norms, rules and regulations stipulated by laws that regulate activities in the field of healthcare and are aimed at obtaining a high-quality end result of treatment or rehabilitation.

Branch standards in the healthcare sector are developed and approved by the central executive body responsible for the formation of the state healthcare policy, i.e. the Ministry of Health of Ukraine (MoH).

The list of these documents does not include all standards related to healthcare, but it does outline the most important human rights, in particular in terms of implementation in the national healthcare system.

Therefore, in order to improve the future directions of healthcare reform in Ukraine, it is necessary, among other things, to focus on compliance with the constitutional provisions on the right to healthcare, taking into account international standards.

5. The Basic Ways to Implementation of International Standards in the Medical System of Ukraine

In this context, the main ways of implementing the norms of international medical law into the national legislation of Ukraine, as noted by M. R. Baryshnikov and P. V. Ivanchov (2020), are as follows:

- Direct – through binding decisions of the World Health Organization and the World Labour Organization, organisations of which Ukraine is a full member;
- indirect – through the conclusion and ratification of international agreements that contain obligations for the state in the field of ensuring the right to health care (Agreement on the provision of medical care to citizens of the member states of the Commonwealth of Independent States, 27 March 1997 – ratified with reservations on 01.06.2000, Agreement on Cooperation in the field of health care and medical sciences between the Ministry of Health of Ukraine and the Ministry of Health of the People's Republic of China, 31 October 1992);
- doctrinal – through the use of basic ideas and fundamental principles developed or being developed by the international community in the field of medical law (Recommendation No. R(90)3 of the Committee

of Ministers of the Council of Europe to member states on medical research on human subjects of 06 February 1990);

- institutional – by taking into account the developments and recommendations of international organisations in the field of medical law, such as the World Medical Association, the World Association of Medical Law, etc.

Nevertheless, before implementing the conceptual framework of international healthcare standards in the process of transforming the Ukrainian healthcare system, it is necessary to: organise a systematic comparison of international standards with existing regulations in Ukraine (the Law of Ukraine 'Fundamentals of Healthcare Legislation in Ukraine', concepts of reforming the healthcare system, etc;

The Law of Ukraine 'On the State Programme for Adaptation of Ukrainian Legislation to the Legislation of the European Union' defines healthcare and human life as a priority area where changes should be implemented in the first place. That is why all ISO 9000 standards have been adopted in Ukraine as national standards in the form of STATE STANDARDS OF UKRAINE (State Standards of Ukraine) and their implementation in everyday activities, including in the healthcare sector, has been organised. They are periodically updated, in accordance with the update of ISO standards, carried out by the State Enterprise (SE) 'Ukrainian Research and Training Centre for Standardisation, Certification and Quality', and have already gone through several editions (Gruzin, 2024).

The following ISO 9000 standards are currently in force in Ukraine:

- STATE STANDARDS OF UKRAINE ISO 9000:2015 (ISO 9000:2015, IDT) 'Quality management systems. Main provisions and glossary of terms' (Order of the DP (2015).

- STATE STANDARDS OF UKRAINE ISO 9001:2015 (ISO 9001:2015, IDT) 'Quality management systems. Requirements' (Order of the DP (2015).

- STATE STANDARDS OF UKRAINE ISO 9004:2018 (ISO 9004:2018, IDT) 'Quality management. Quality of the organisation. Guidelines for achieving sustainable success' (Order of the DP (2018).

- STATE STANDARDS OF UKRAINE ISO 19011:2019 (ISO 19011:2018, IDT) 'Guidelines for conducting audits of management systems' (Order of the DP (2019).

Taken together, all of the above documents form a coherent series of standards that facilitate the implementation of international healthcare achievements in the field of healthcare in the activities of domestic healthcare institutions through the recognition of common approaches, principles and methods of quality management.

Meanwhile, the Ministry of Health of Ukraine has organised work on the introduction of voluntary certification of the quality management system in domestic healthcare institutions by developing its own national standards based on international standards.

Based on the results of the study and analysis of legislative and regulatory acts on standardisation in the healthcare system of Ukraine, the authors propose the following scheme for the formation of a standardisation system for determining the service quality provision in the healthcare system (Figure 1).

Regional Standards are detailed and adapted to the specific conditions of certain regions (oblast,

one or more rayons) variants of the national standards for the provision of medical and pharmaceutical care to the population. They should contain information on how to ensure the implementation of the national standards, taking into account the capabilities of a particular region.

Regional Standards for state guarantees of free medical care should include a list of diseases, types of medical care, their scope, conditions of provision and financing.

Local Standards (standards of healthcare facilities) are models of medical and pharmaceutical care, medical and pharmaceutical services used in one or more healthcare facilities within a city or district.

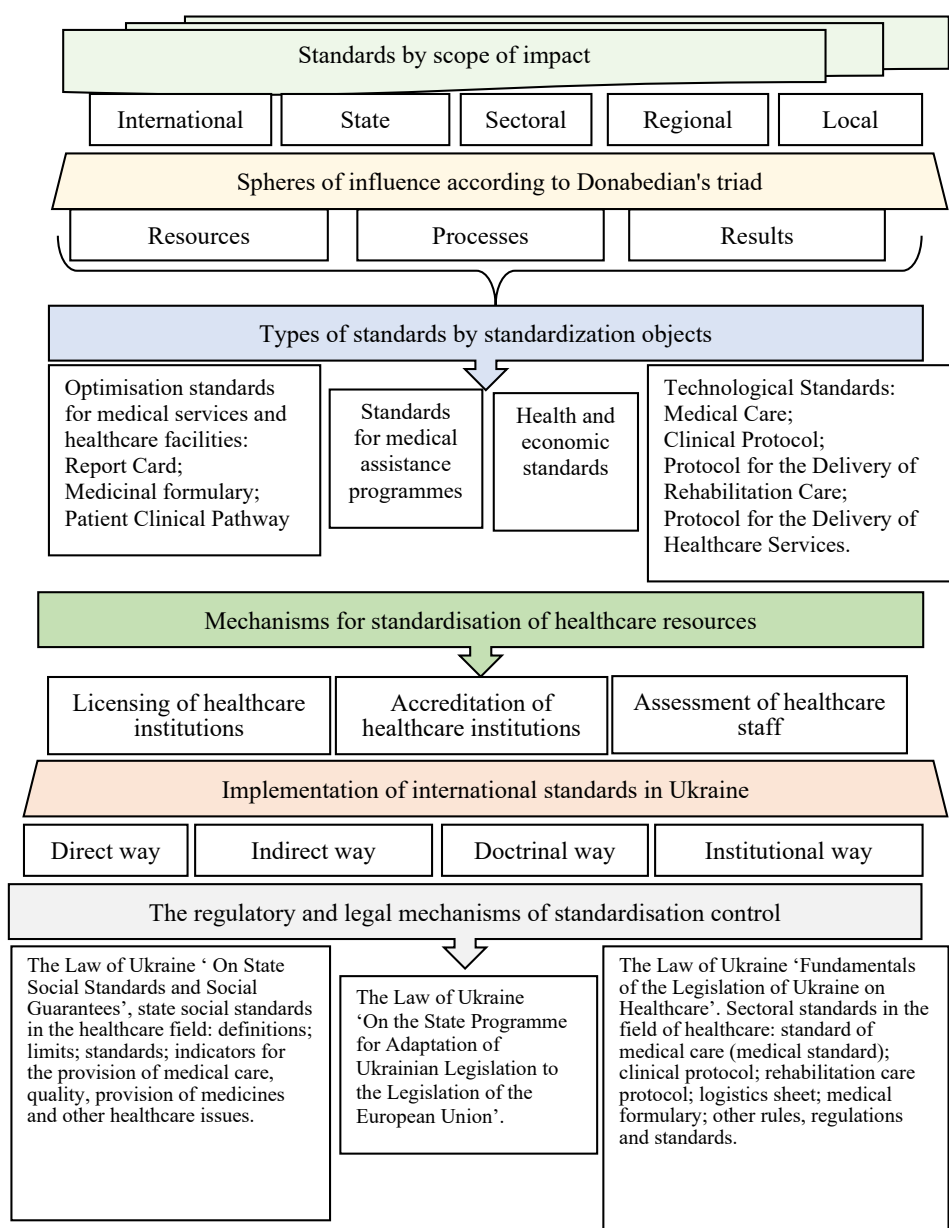


Figure 1. The system for implementing international quality standards in healthcare services

Source: The figure created by the authors on the basis of sources (Borshch, 2022; Maritz, Scheel-Sailer, 2019; Livinskyi, Zhakhovskiy, 2022; Law of Ukraine, 2000).

Local Standards define the procedure for examination and treatment of patients, taking into account the capacity of a particular healthcare facility (rules and terms of taking tests and obtaining their results, the procedure for consultations with narrow-profile specialists, criteria for transferring a patient to another department or another healthcare facility, etc.)

Local Standards should be equivalent to national healthcare standards. Similar to National Standards, they should include lists of diseases, types of medical care, their scope, terms of provision and financing.

The creation of such a quality management system in healthcare facilities is fully in accordance with modern global approaches to ensuring the quality of medical services. Implementation and maintenance of this system in accordance with the requirements of the ISO 9000 series of standards creates opportunities for healthcare facilities not only to improve the quality of medical and pharmaceutical services, but also to have a positive impact on their performance.

The quality management system covers not only issues related to the provision of medical care, but also a wide range of auxiliary processes in the activities of an enterprise or institution (resource management, improvement processes, risk management, etc.).

6. Conclusions

To summarise the results of the study within the framework of the chosen topic and objective, we can conclude the following:

The international service quality standards are the most important frameworks developed and maintained by international organisations to ensure consistency, reliability and security across industries. All these standards are aimed at improving customer satisfaction, operational efficiency and international competitiveness.

Continuous updating and adherence to these standards is essential to meet customer expectations and regulatory requirements in today's constantly changing globalised world.

The transformation of the healthcare system in Ukraine will be successful if the most significant domestic achievements in the medical field are rationally combined with the world's best practices and international standards, including the principles of healthcare contained in international human rights instruments, principles and norms that define the content and scope of human rights in the field of healthcare, which Ukraine must adhere to.

In addition, it is essential to introduce the best international practices in the treatment of major diseases, principles of medical services, and training, which will help to achieve the necessary improvement in the quality of medical care in the context of the development of the Ukrainian medical system.

It is established that in the process of adaptation of national legislation to the regulations of the European Union, all ISO 9000 standards were adopted in Ukraine as national standards and their implementation in everyday activities, including in the healthcare sector, was organised.

Since the main objects of standardisation in healthcare are: rights and duties of the people and healthcare professionals, medical information and reporting, healthcare management and organisation, personnel, education, medicines, medical services, etc., we consider it a priority to apply international standards not so much to change the principles of Ukraine's internal regulations, but rather to focus on the practical aspects of the medical system's functioning in order to improve the efficiency of medical care: treatment protocols for the main diseases, the principles of organising the provision of medical services; international qualification of diseases; training, certification and licensing of activities, etc.

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