REVIEW ARTICLE

CONTENTS

The system of international legal standards in the medical sphere: Universal and regional dimensions

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ABSTRACT

Aim: A comprehensive theoretical and legal analysis of international legal standards in healthcare, determining their content, classification and regulation features at universal and regional levels. Tasks include analyzing the concept of international health law standards, investigating historical formation stages, systematizing international legal acts, determining universal and regional protection features, analyzing specialized standards for certain population categories, and investigating implementation mechanisms at national level.

Materials and Methods: Employ general scientific and special legal methods including dialectical, system-structural, historical-legal, comparative-legal, and formal-legal approaches, along with classification and systematization methods to structure international legal acts and create scientifically based typology. The empirical base consisted of 189 sources for the period 1948-2025: universal international acts of the UN and specialized organizations (23 documents), regional European agreements (15 acts), specialized conventions for individual categories of the population (18 documents), declarations and charters of a non-conventional type (12 acts), scientific publications (121 works). The search was carried out in the following databases: UN Treaty Collection, Council of Europe Treaty Office, WHO Global Health Observatory, Google Scholar, ResearchGate, PubMed.

Conclusions: establish that international healthcare standards constitute a specific category with both general features (obligatory, universal, abstract) and special properties (specificity, scientificity, practicality, reliability). The evolutionary development from 1940s declarative principles to modern detailed norms reflects transition from state-centric to patient-oriented approaches. The multi-level structure includes universal/regional standards, mandatory/recommendatory norms, and general/special provisions, creating flexible legal regulation addressing diverse healthcare subjects' needs.

KEY WORDS: international legal standards, healthcare rights, patient rights, medical law, healthcare regulation, human dignity, medical ethics, legal protection

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INTRODUCTION

The relevance of the study of international legal standards in the field of health care is due to several factors of the modern development of international law and global challenges in the field of health care. In the context of the COVID-19 pandemic, which demonstrated the interdependence of national health care systems and the need for coordination of international efforts, the issues of the effectiveness and efficiency of international legal mechanisms for protecting the right to health have become particularly acute. Modern global challenges, such as the cross-border spread of infectious diseases, inequality in access to medical services, the development of biotechnology and artificial intelligence in medicine, require a review and improvement of existing international standards. In addition, the growing role of non-state actors in the field of health care, including international organizations, NGOs and private providers of medical services, requires a new understanding of the subject composition of international legal relations in this area.

The theoretical and practical significance of the study lies in the need to systematize and analyze international legal standards of health care in the context of their constant expansion and complication. The fragmentation of international health care law due to the presence of numerous universal and regional documents adopted by various international organizations creates problems for law enforcement and requires scientific understanding of their correlation and hierarchy. The issue of implementing international standards at the national level is of particular relevance, in particular in the context of the European integration processes of Ukraine and the need to bring national legislation into line with European health care standards. The study of international legal standards in this area is of practical

importance for improving national health care policy, protecting patients' rights and ensuring the quality of medical services in accordance with international requirements.

AIM

The aim of the study is a comprehensive theoretical and legal analysis of the system of international legal standards in the field of the right to health, determining their content, classification and features of legal regulation at the universal and regional levels. To achieve the goal, it is necessary to solve the following tasks: analyze the concept and essence of international legal standards of the right to health; investigate the historical stages of the formation and development of international standards in the medical and legal sphere; systematize and classify international legal acts regulating the right to health; determine the features of universal and regional standards for the protection of the right to health; analyze specialized international standards for certain categories of persons; investigate the mechanisms for implementing international legal standards at the national level.

MATERIALS AND METHODS

The methodological basis of the study is a set of general scientific and special legal methods of cognition. The dialectical method was applied as a general scientific approach to the study of international legal standards in their development and interconnection. The system-structural method was used to analyze the system of international legal acts and their internal interconnections. The historical-legal method allowed us to trace the evolution of international standards of the right to health from the initial declarative principles to modern detailed norms. The comparative-legal method was used to compare universal and regional standards, as well as to analyze different approaches of international organizations to regulating the right to health. The formal-legal method was used to analyze the content of international legal norms, their structure and legal techniques. Methods of classification and systematization allowed us to structure international legal acts according to various criteria and create their scientifically based typology.

Criteria for inclusion of materials: for international legal acts (universal conventions and pacts ratified by more than 50 states, regional agreements of the Council of Europe and the EU in the field of health care, specialized documents to protect the rights of certain categories of the population (women, children, persons with disabilities), declarations and charters adopted by international organizations after 1948. For scientific publications (articles in peer-reviewed journals on international law and medical law for 1990-2023, monographs and dissertation studies on the issues of international health care standards, publications by leading experts of the WHO, the Council of Europe and other international organizations, works in Ukrainian, English, French and German.

Data sources: international databases (UN Treaty Collection, Council of Europe Treaty Office, WHO Global Health Observatory, EUR-Lex (EU law database), International Labour Organization database), наукові бази даних (Google Scholar, ResearchGate, PubMed, Scopus, Web of Science, HeinOnline Legal Database).

Total number of analyzed sources: 189, including universal international acts: 23 (including the Universal Declaration of Human Rights of 1948, the International Covenants of 1966, UN and ILO conventions), regional European documents: 15 (European Social Charter, Convention on Human Rights and Biomedicine, European Charter of Patients' Rights of 2002), specialized conventions: 18 (conventions on the rights of women, children, persons with disabilities, migrant workers), declarations and charters of a non-conventional type: 12 (Jakarta Declaration, Charter of the Right to Health), scientific publications: 121 (of which 67 are in English, 54 in Ukrainian).

Chronological framework of the analysis: main period: 1948-2023 (from the adoption of the Universal Declaration of Human Rights to the present); key stages: 1940-1960 - the formation of basic principles, 1970-1990 - the development of specialized standards, 2000-2023 - a patient-centered approach.

Time frame of the study: the study was conducted during 2024-2025 with an emphasis on the analysis of the current state of international legal standards and their impact on the national legislation of Ukraine in the context of European integration processes.

REVIEW AND DISCUSSION

Human rights represent the ability of an individual to freely carry out his actions and independently determine the forms and scope of his own behavior to ensure various life needs through the use of public goods within the framework established by regulatory and legal documents. International legal norms in this area were formed over a long period of time through the cooperation of numerous countries to develop common approaches to human rights issues. States orient their policy towards compliance with generally recognized principles, guaranteeing the protection of human rights

by all available means. They are responsible for fulfilling their obligations both to their own citizens and to the world community to ensure the rights and freedoms of the individual. Due to the increased attention of international organizations, about 300 various documents were adopted - declarations, conventions and charters. International legal documents in the field of human rights are usually regarded as international standards, since they are created on the basis of traditional norms that were formed as a result of the recognition by states of the binding nature of the rules of conduct proclaimed by the UN General Assembly through declarations or recommendations [1].

It should be noted that the bulk of international instruments and protection mechanisms emerged in the 1940s of the twentieth century. Human rights institutions contributed to the adoption of both global and regional legal instruments. The establishment of the United Nations and the approval of its Charter marked the beginning of a fundamentally new period in international relations regarding human rights. The UN Charter imposed on countries the obligation to ensure human rights and freedoms, excluding any forms of discrimination. On December 10, 1948, the UN General Assembly adopted the Universal Declaration of Human Rights - one of the most important documents in the field of human rights protection. Its introductory part and thirty articles enshrine civil, political, economic, social and cultural rights of the individual [2].

According to S. Shevchuk, international standards in the field of human rights are universally accepted norms of international law that determine the legal status of an individual at the global level, fix a catalog of fundamental rights and freedoms, establish the obligations of states to observe these rights and freedoms, and also outline the boundaries of their potential or permissible restriction [3]. According to N. Krestovska and L. Matveeva, international legal standards in the field of human rights are legal principles enshrined in international agreements that determine the lowest acceptable standards of behavior of a state in relation to persons staying on its territory [4].

It is worth noting that such an interpretation does not cover the full range of international legal principles that regulate fundamental human rights, since they are formulated not only through international agreements (as noted above - "established in a contractual manner"), but also through documents of a non-contractual type. In addition, it is unnecessary to specify the nature of such principles as "norms of minimally acceptable treatment", since the standard is essentially a "normative minimum", from which the state can deviate only by increasing or detailing it [5]. For his part, Y. Rymarenko offers the following interpretation: international human rights standards are specific criteria for these rights, fixed in international agreements and other international documents, which states should strive to achieve or which they are obliged to ensure [6].

However, from our point of view, the most successful definition that encompasses all the key characteristics of international legal standards of human rights is the formulation of O. Rudneva. The researcher suggests interpreting international legal standards of human rights and freedoms as universal principles and general norms that form exemplary models of consolidation, implementation and (or) protection of human rights, reflect the reference understanding and practical implementation of human rights, their independent and functional significance for the state and society [7].

It should be noted that international legal standards in the field of health care constitute a type of international legal standards. By this concept we mean the principles and provisions enshrined in international legal documents that regulate the rights of the individual in the field of health care, their essence and boundaries. The importance of such standards lies in the fact that they serve as certain legal or moral and political guidelines in the field of health care for state national policy [8].

International legal standards in the field of health care have special characteristics that can be divided into general and specific. General ones include properties inherent in all international standards; these include: determination of the specific scope and content of human rights; mandatory nature; features of the application of sanctions; universality; possibility of various interpretations; high degree of abstraction; historical variability of content. Specific characteristics of international legal standards in the field of health care are: accuracy, clarity and accessibility of formulations; scientificity; timeliness; practicality; reliability [9].

In legal scientific literature, international legal standards in the field of health care are divided into different categories according to certain criteria. In particular, by deontic status they are divided into mandatory - those whose compliance is formally necessary for states and can be ensured by international political and legal sanctions, and recommendatory - formally optional, but also supported by international political sanctions. According to ontic status, international standards are classified into nominal (textual) - these can only be the names of human rights and freedoms used in international documents, and factual - those that contain specific indicators of the content and scope of human rights and freedoms. By the range of subjects, they are divided into general (apply to all categories and groups

of society) and special (relate to the rights of certain groups, social communities - women, children, people with disabilities). Depending on the geographical scope, they are divided into world (also called global or universal) and regional standards. According to the subject of adoption, international legal standards in the field of health care are classified into international standards of the United Nations, the World Health Organization, the International Labor Organization, the Council of Europe, the European Union, etc. [10].

Thus, the way of external expression of international legal standards of the right to health care is international legal acts. That is, international legal acts become a source and correlate with international legal standards as a form and content, respectively.

Universal international agreements are distinguished by the fact that almost all countries of the world community participate in them. In the field of health care, these include: 1) international acts adopted by the UN: a) the International Bill of Human Rights, which consists of the Universal Declaration of Human Rights of 1948, the International Covenant on Economic, Social and Cultural Rights of 1966 and the International Covenant on Civil and Political Rights of 1966; b) international agreements regulating the rights of specific population groups (in particular, the Declaration on the Rights of Persons with Disabilities of December 9, 1975, the Declaration on the Rights of Mentally Retarded Persons of December 20, 1971, the Convention on the Elimination of All Forms of Discrimination against Women of December 18, 1979, etc.); 2) conventions approved by the International Labor Organization (in particular, Convention No. 130 concerning Medical Assistance and Sickness Assistance of 1969) [11].

Part 1 of Art. 25 of the Universal Declaration of Human Rights establishes the following provision: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control" [12]. In addition, the Universal Declaration of Human Rights establishes other rights that are inseparably linked to the right to health or provide the prerequisites for its exercise (the right to life, the right to physical integrity, the right to privacy, etc.). The right to the highest attainable standard of physical and mental health is regulated by Article 12 of the International Covenant on Economic, Social and Cultural Rights. In order to guarantee the realization of this right, part 2 of the said article of the Covenant obliges States to take the necessary measures to: a) ensure the reduction of stillbirths and infant mortality rates and to promote the healthy development of children; b) improve all aspects of environmental sanitation and industrial hygiene; c) prevent, treat and combat epidemic, endemic, occupational and other diseases; d) create conditions that would guarantee all people medical assistance and medical care in case of illness [13].

The International Covenant on Civil and Political Rights does not contain provisions that directly regulate the right to health care, but it enshrines other rights and prohibitions that mediate the possibility of fully realizing the right to health care, in particular the right to humane treatment and respect for the inherent dignity of the human person (Article 10), the prohibition of torture, cruel, inhuman or degrading treatment or punishment (Article 7), the prohibition of discrimination (Part 1 of Article 2), etc. [14].

As for international treaties regulating the rights of certain categories of persons, the right to health protection is enshrined in them along with other rights. For example, Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women establishes the prohibition of discrimination against women in the field of health protection, Article 14 – the right of women living in rural areas to access appropriate medical care [15]. Article 24 of the Convention on the Rights of the Child establishes the right to the highest attainable standard of physical and mental health [16]. The right to health protection, as well as the rights that mediate its implementation, are regulated in a similar way in other acts of this group.

International legal documents of a non-treaty type contain provisions of a general, declarative nature that proclaim the right to health protection as the highest value (such as the Jakarta Declaration on the Leading Role of Health Promotion in the 21st Century), or enshrine only certain rights in this area (the right to privacy and informed consent - the Charter on the Right to Health). The document that more thoroughly regulates the right to health protection is the Declaration on Patient-Centered Health Care, which enshrines the following principles: respect, choice and empowerment, patient involvement in health policy-making, accessibility and support, and information [17].

It should be noted that the Conventions approved by the International Labor Organization concern the labor activities of children, mothers, persons with disabilities, etc. and are aimed at establishing such labor standards for various categories of workers that will not have a negative impact on the health of each of them [18].

Regional international agreements and documents are characterized by more in-depth regulatory and

legal regulation of relations in the field of health care. An example is the European Social Charter. In particular, Article 11 of the Charter establishes the obligation of the States Parties to the Charter to introduce measures that provide for: 1) the elimination, as far as possible, of factors that impair health; 2) the provision of advisory and educational services aimed at strengthening health and forming a sense of individual responsibility for one's own health; 3) the prevention, as far as possible, of epidemic, endemic and other diseases [19].

Article 13 of the European Social Charter, in order to ensure the effective exercise of the right to social and medical assistance, obliges the Contracting Parties:

to ensure that any person who lacks sufficient means of subsistence and is unable to obtain them either by his own efforts or from other sources is provided with appropriate assistance;

to ensure that persons who benefit from such assistance are not discriminated against on this ground in their political and social rights;

to ensure that everyone, through appropriate public or private services, can receive any advice and any individual assistance which may be required to prevent, eliminate or alleviate personal or family deprivation [20].

Among the instruments adopted at the international level is the Convention on the Rights of Persons with Disabilities of 2006. This instrument enshrines the rights of persons with long-term physical, mental, intellectual or sensory impairments which may hinder their full and equal participation in society. The Convention was adopted to promote, protect and ensure the full and equal enjoyment by all such persons of all the rights and fundamental freedoms due to them as to others, and to maintain respect for their inherent dignity. This international legal instrument contains a significant number of guarantees ensuring the observance of political, civil, social, economic and cultural rights. Thus, in accordance with the provisions of Article 25 of the Convention, States Parties recognize that a person with disabilities has the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. In addition, States Parties must take all measures to ensure access by persons with disabilities to health services, taking into account the gender aspect, especially during the medical rehabilitation of such persons.

Another important international legal document in the field of health care is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997, which also established a number of important human rights in the field of health care, in particular the rights of patients. It emphasizes the need for respect for the individual as an individual and as a member of society and emphasizes the importance of ensuring human dignity. The Convention is binding on the states that have ratified it. This document notes that the European Court of Human Rights may provide advisory opinions on legal issues related to its interpretation [21].

A decisive stage in the development of international standards guaranteeing the protection of the right to health was the adoption in 2002 of the European Charter of Patients' Rights. It was adopted at a meeting of national public organizations of European countries in connection with the failure of EU states to fulfill a number of obligations, which led to a deterioration in the state of ensuring patients' rights. The Charter was drafted by the Active Citizens Network, a European network of civil society organizations for the protection of patients' and consumers' rights. The Charter's significance lies in the fact that it is part of a civil society movement in Europe that has contributed to the involvement of patients in the formation of health policy. The document defines a list of patients' rights, namely: the right to preventive measures; the right to access information; the right to consent; the right to free choice; the right to privacy and confidentiality of information; the right to compliance with quality standards; the right to respect for the patient's time; the right to safety; the right to access to modern achievements; the right to avoid unnecessary pain and suffering; the right to individualized treatment; the right to file a complaint; the right to compensation [21].

CONCLUSIONS

The analysis of international legal standards in the field of health care allows us to formulate a number of important scientific conclusions. First, it was established that international legal standards in health care constitute a specific category of international legal standards, which are characterized not only by general features (obligatory, universal, abstract), but also by special properties - specificity, scientificity, practicality and reliability of formulations. This dual nature emphasizes the complexity of legal regulation of relations in the field of health care at the international level and the need to take into account both the general principles of international law and the specifics of the medical sphere.

Secondly, the study showed the evolutionary nature of the development of international health care standards - from the general declarative principles of the 1940s to the detailed norms of modernity that regulate specific aspects of medical activity and patients' rights. Particularly significant is the transition from a state-centric model to a patient-oriented approach, which was

reflected in the adoption of the European Charter of Patients' Rights in 2002 and other specialized documents. This process indicates a change in the paradigm of international health law towards strengthening the role of the individual as the main subject of legal relations.

Thirdly, the systematization of international legal acts in the field of health demonstrates their multi-level structure, which includes universal (global) and regional standards, mandatory and recommendatory norms, general and special provisions for individual categories of persons. Such differentiation creates a flexible system of legal regulation that allows taking into account the diverse needs of subjects of health law - from general principles of ensuring the right to life to specific guarantees for vulnerable groups of the population (persons with disabilities, children, women).

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CONFLICT OF INTEREST
The Authors declare no conflict of interest

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