

Conflicts of interest in healthcare: Legal problems and prospects of improvement

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ABSTRACT

Aim: To study the problems of the legal regulation of conflicts of interest in the healthcare field in Ukraine and to propose directions for improving national legislation.

Materials and Methods: The methods of theoretical analysis, system-analytical, and comparative-legal methods provided us with the opportunity to characterise the features of the legal regulation of preventing conflicts of interest in the area under study.

Results: It is proposed to amend anti-corruption medical legislation on issues of conflict of interest in the healthcare sector. In particular, the need to introduce into legislative circulation the category and its interpretation of “conflict of interest in the healthcare sector” and “imaginary conflict of interest in the healthcare sector” is indicated. It is also proposed to introduce, at the legislative level, both oral and written forms of notification of conflict of interest, and to separately determine the procedure for electronic notification in this area. Additionally, a special register of notifications of conflict of interest in the area under study should be created.

Conclusions: An unresolved conflict of interest in the healthcare sector may indirectly limit the exercise of a person's right to healthcare and may also lead to the commission of a corruption offence in the healthcare sector. The above indicates an urgent need to improve its legal regulation.

KEY WORDS: healthcare sector, human rights, legal regulation

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INTRODUCTION

According to the data from the population survey on the level of corruption, provided in the Anti-Corruption Strategy of Ukraine for 2021–2025, the healthcare sector has been identified as the highest priority area for combating corruption (38%) [1]. The same priority area for combating corruption is indicated in the Anti-Corruption Programme of the Ministry of Health of Ukraine for 2018–2020 [2]. In the State Anti-Corruption Programme for 2023–2025, the healthcare sector is also included among the priority areas for preventing corruption (clause 2.7). It was determined that shortcomings in the legislation limit the possibilities of minimising corruption by preventing and resolving conflicts of interest (clause 1.3), and that insufficiently transparent procedures for selecting personnel for healthcare institutions, along with the dishonesty of medical workers, remain pressing problems (clause 2.7.4) [3].

However, in practice, several problematic issues of legal regulation concerning conflicts of interest in the healthcare sector arise. Among them, it should be noted that certain elements of the legal mechanism for preventing conflicts of interest in the healthcare sector are normatively enshrined, but they are fragmented, not interconnected, and contain shortcomings and gaps in legislative regulation. As a result, there is an increase in the number of offences related to corruption in the healthcare sector. All of the above determines the relevance of the chosen topic of the article.

AIM

This scientific work aims to study the problems and identify shortcomings in the legal regulation of conflicts of interest in the healthcare sector in Ukraine, to analyse the controversial issues raised by scholars, and

to propose directions for improving national legislation, taking into account foreign experience.

MATERIALS AND METHODS

The methodological basis of the study is a set of methods and techniques of scientific inquiry. In particular, the following methods were used: formal-dogmatic, systemic, semantic, epistemological and axiological, sociological, comparative-legal, statistical, as well as systemic and structural analysis.

The complexity of the study is ensured by a systemic approach, which made it possible to consider and analyse the problems of conflicts of interest in medical legal relations in the unity of their content, essence, and legal form. The use of scientific methods contributes to achieving the objectives of the article, substantiating the conclusions of the study, and proposing solutions for optimising legislation on the prevention of conflicts of interest in the healthcare sector of Ukraine, taking into account foreign experience.

RESULTS

To address the challenges of legal regulation and the prevention of conflicts of interest in the healthcare sector in Ukraine, it is necessary to amend the legislation within systemic, organisational, and institutional contexts. It should be noted that there are several components of a conflict of interest in the healthcare sector, which are summarised in Table 1 [4].

Let us consider some of them. One of the problems of legal regulation of conflicts of interest in the medical field is that the function of resolving conflicts of interest in the healthcare sector should be assigned to the authorized unit, according to the regulation on the Authorized Unit (Person) for the Prevention and Detection of Corruption [5]. However, in most healthcare institutions, conflict of interest prevention is carried out by appointing an authorized person rather than creating an authorized unit. In addition, under such conditions, the functions of the authorized person are, in most cases, assigned to legal advisers, economists, or deputy heads of healthcare institutions, which contradicts the norms of the standard regulation [5] and the Law of Ukraine "On the Prevention of Corruption" [4]. However, given the above legislative provisions, authorized persons in healthcare institutions must perform exclusively anti-corruption functions, including preventing conflicts of interest, and assigning other duties to them is illegal. To eliminate this deficiency, it is necessary to provide for the mandatory creation of separate bodies

in the research area with the involvement of public organizations, including international ones.

In the provisions of the special anti-corruption law [4], there is a discrepancy between the deadlines for reporting a conflict of interest and for its independent resolution, and it does not establish the form and procedure for reporting a conflict of interest [3]. To mitigate the above-mentioned problems, it is advisable to report a conflict of interest in the healthcare sector (real or potential) in writing or electronically, with registration in the existing record-keeping system.

One of the tools for preventing conflicts of interest in the healthcare sector may be the creation of special registers of conflicts of interest. In particular, in some foreign countries, each specific case of a conflict of interest must be recorded in a special register [6, 7]. Thus, the Law of the Republic of Moldova "On the Declaration of Assets and Personal Interests" of 17 June 2016, № 133, introduced appropriate registers in the state organization of Moldova for registering reports of conflicts of interest. It should be noted that the legislation of Moldova does not establish requirements for maintaining such registers in electronic form. In this country, they are decentralized and are maintained in each separate organization, and for certain categories of officials, a centralized register of notifications has been created, which is maintained by the anti-corruption organization of Moldova (the National Anti-Corruption Authority). Such registers should contain information on: (1) the number and date of submission of the declaration of conflict of interest, (2) the subject of the submission and their position, (3) the number of pages in the declaration, and (4) the measures taken to resolve the conflict of interest [8]. This experience can be used in national legislation on the prevention and resolution of conflicts of interest, including in the healthcare sector. There is similar experience in French legislation [9].

We believe that the national system of legislation on preventing conflicts of interest in the healthcare sector should provide for a centralized "Unified Register of Notifications of Conflicts of Interest in the Healthcare Sector," the administration of which should be entrusted to the National Agency for the Prevention of Corruption of Ukraine. The National Agency for the Prevention of Corruption of Ukraine, when administering the "Unified Register of Notifications of Conflicts of Interest in the Healthcare Sector," must determine: (1) the form of an application for an electronic notification of a conflict of interest, (2) the procedure for submitting a notification of a conflict of interest in the healthcare sector, (3) the measures

Table 1. The components of a conflict of interest in the healthcare sector

Component Number	Description
1	Private interest
2	Discretionary official or representative functions (including professional duties of a public officer and their function as a manager)
3	The existence of a conflict between private interest and authority

Table 2. Sections of the draft resolution of the Cabinet of Ministers of Ukraine “Procedure for organizing measures to prevent and resolve conflicts of interest in the bodies of the Ministry of Health of Ukraine”

Nº	Title of the section	Nº	Title of the section
I	General provisions	VII	Resolution of a conflict of interest in connection with employees joining commissions (committees, boards, etc.) in the management bodies of the Ministry of Health
II	Subjects of measures to prevent, resolve, and identify conflicts of interest in the management bodies of the Ministry of Health	VIII	Prevention of conflict of interest due to the presence of enterprises or corporate rights in the management bodies of the Ministry of Health
III	Responsibilities of employees in the management bodies of the Ministry of Health	IX	Restrictions on the joint work of close persons in the management bodies of the Ministry of Health in conditions of conflict of interest
IV	Measures to resolve conflicts of interest in the management bodies of the Ministry of Health	X	Restrictions on receiving gifts related to a conflict of interest in the management bodies of the Ministry of Health
V	Procedure for submitting a notification of the existence of a conflict of interest and its resolution in the management bodies of the Ministry of Health	XI	Procedure for recording information on the presence of a conflict of interest in the management bodies of the Ministry of Health
VI	Peculiarities of applying measures for external resolution of a conflict of interest in the management bodies of the Ministry of Health	XII	Responsibility for the violation of legislative requirements regarding the prevention and resolution of conflicts of interest in the management bodies of the Ministry of Health

used to resolve a conflict of interest in the activities of officials of public organizations in the healthcare sector, etc. Officials of legal entities under public law in the healthcare sector who have a conflict of interest and who are obliged to make a notification under the provisions of the special anti-corruption law [4] have the right to submit a notification of a conflict of interest to this register.

One of the problems of legal regulation in preventing conflicts of interest in the healthcare sector is the requirement for filing declarations by healthcare officials or service personnel in accordance with anti-corruption legislation. Thus, these persons are not subject to the obligation to file declarations and other financial control measures (except for heads of healthcare institutions of central, regional, district, and city significance).

However, Part 5 of Article 45 of the special anti-corruption law [4] does not explicitly exclude from the list of persons who may submit declarations the officials of healthcare institutions, including enterprises that provide medical services to the population based on an appropriate license and the professional activities of medical (pharmaceutical) workers (paragraph 3 of part 1 of Article 3) [10]. According to the organizational and

legal form, healthcare institutions can be established and operate as municipal non-profit enterprises or municipal institutions, and their managers can be persons appointed to the position by the authorized executive office of the healthcare institution on a competitive basis by concluding a contract with them (Article 16) [10]. Therefore, officials of municipal non-profit enterprises established as a result of the reform of healthcare institutions (except for heads of healthcare institutions at the central, regional, district, and city levels) are not subject to the special anti-corruption law [4] in terms of the obligation to declare. However, in our opinion, they should be.

In Article 23 of the special anti-corruption law of Ukraine, public associations, their members or authorized representatives, as well as individual citizens, have the right to report a real or potential conflict of interest [4], including in the field of healthcare. For more effective implementation of the norm of this Law and increasing the effectiveness of preventing conflicts of interest in healthcare, it is advisable to provide for a notification on the website of the Ministry of Health of Ukraine about non-compliance with the requirements for the prevention and resolution of conflicts of interest in healthcare. This can be

done based on the already developed Information and Analytical System "Submission and Registration of Reports of Possible Corruption of the Ministry of Health of Ukraine," supplemented with an additional option. Note that such a system was created to stimulate the transfer of reports of corruption by creating internal and external channels for the provision of information and ensuring the protection of individuals (whistleblowers) who, in good faith, report corruption offenses from harassment and prosecution. The development of such a system is caused by the need to improve procedures related to receiving, recording, and reviewing reports of violations of anti-corruption legislation in the Ministry of Health of Ukraine [11].

The Ministry of Health of Ukraine, together with the State Enterprise «Electronic Health,» has implemented the Information and Analytical System «Submission and Registration of Reports of Possible Corruption of the Ministry of Health of Ukraine» [11]. Thus, the official website of the Ministry of Health of Ukraine has already posted a link «Report corruption» to provide the opportunity to submit notifications of facts of corruption or corruption-related offenses by electronic communication (according to the appropriate form) or by telephone [11]. Also, on the website of the National Police of Ukraine, such an opportunity to prevent a conflict of interest by reporting cases of non-compliance with the requirements for preventing a conflict of interest has already been tested in practice.

To improve risk-based mechanisms for detecting conflicts of interest in the healthcare sector, it is advisable to provide in the legislation for the automated detection of risks of conflicts of interest in the activities of officials belonging to legal entities under public law in the healthcare sector, the administration of which would be carried out by the National Agency for the Prevention of Corruption of Ukraine. In this case, the experience of legal support in Romania should be taken into account, where, since 2017, the IT system "Prevent" has been operating, which is used for the automated detection of risks of conflicts of interest in the field of public procurement carried out in Romania with EU funds [8]. The IT system "Prevent" acts as a prior verification mechanism, investigating potential conflicts of interest in the electronic public procurement system of Romania. Over three years, the Prevent IT system in Romania has reviewed over 50,000 procurement procedures and 260,000 contracts, and has issued warnings regarding 123 potential conflicts of interest. As a result, the number of cases of undisclosed conflicts of interest has decreased by 52% over the three years studied [12].

In addition, to form a unified approach to compliance with the rules for preventing conflicts of interest in the area under study, it is advisable to adopt a resolution of the Cabinet of Ministers of Ukraine titled "Procedure for Organizing Measures to Prevent and Resolve Conflicts of Interest in the Bodies of the Ministry of Health of Ukraine" (Table 2).

DISCUSSION

The lack of proof of the existence of a contradiction between private interest and official authority of a conflict of interest in the medical legal relations is decisive for administrative courts in Ukraine and therefore creates additional obstacles to bringing individuals to administrative responsibility for offenses related to corruption [3]. Scientists consider of conflict of interest in the medical legal relations from two perspectives. The first is as a component of preventing corruption in the medical legal relations [13, 14]. Protection of patients' rights in courts [15] as well as conflict of interest in judicial bodies [16]. Some foreign scientists consider conflict of interest in clinical practice, in particular, M. Eccles [17], J. Bindslev [18], G. Guyatt [19], and S. Norris [20]. It is worth noting the separate works of J. Neuman on the financial aspects of conflicts of interest among commission members in Canada and the USA who develop clinical practice guidelines, emphasizing their prevalence and the lack of public disclosure in most cases [21]. For example, M. Rodwin, studying conflicts of interest in healthcare in the USA, France, and Japan, notes that they are very widespread in these countries. Doctors hide or distort information about their diagnoses while having the interests of pharmaceutical and insurance companies. Such actions by doctors undermine public trust in them, as well as in the entire healthcare system, the effectiveness of the use of medicines, and threaten the development of medicine [22]. There is no single scientific position in the legal literature on the definition of types of conflict of interest; in particular, there is no consensus when defining its content. In particular, C. Muth understands "conflict of interest" as a situation in which a person risks acting biasedly due to personal interests [23]. A similar point of view is held by domestic researchers [24]. As is known, anti-corruption legislation contains an interpretation of two types of conflict of interest: potential and real [4]. The category of conflict of interest is distinguished in the field of healthcare [10], but its interpretation of content is not provided. To eliminate this deficiency in medical anti-corruption legislation, it is necessary to introduce the term "conflict of interest" into Article 1 of the basic medical law of Ukraine.

And also to supplement the section of this law with a new Article 78-2 entitled “Prevention and settlement of conflict of interest” [10]. There is no single scientific opinion on establishing the types of conflict of interest [24]. There are 3 types of conflict of interest situations in scientific works, in addition to those provided for in the legislation, namely “prospective”, as well as “retrospective” and “imaginary conflict of interest” In our opinion, in the area under study it is necessary to foresee a “perceived conflict of interest in the field of health care” [25]. This type of conflict of interest is provided for by international standards and OECD recommendations [8]. In Canada, this type of conflict of interest prevention is provided for in the health care sector [26]. The lack of a definition of this term indicates that national anti-corruption medical legislation [4, 10] does not meet international standards in the area under study.

CONCLUSIONS

Legal methods for resolving conflicts of interest in the healthcare sector should be provided for in special medical legislation at the legislative level. This is due to the need to increase the effectiveness of measures to prevent the corrupt behavior of medical professionals, as well as the significant harmful consequences for the protection of human rights in the healthcare sector. In our opinion, the category of “perceived conflict of interest in the field of healthcare” should be provided for in Article 1 of the Law of Ukraine “Fundamentals of the Legislation of Ukraine on Healthcare”. Thus, the term “perceived conflict of interest in the healthcare sector” should be understood as a situation in which the private interests of persons exercising their official or representative powers in the healthcare sector, their managerial decisions, may improperly influence the performance of their official duties, despite its actual absence.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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