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LEGAL SUPPORT OF THE MECHANISM OF THE QUALITY CONTROL OF HEALTHCARE SERVICES IN UKRAINE

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The authors consider the main stages of the development of the health care quality (HCQ) provision in Ukraine: the state (budget) system of healthcare; the stage of the new economical mechanism introducing; the independence of the country with the appearance of market mechanisms of economics. The authors focus on legal support of mechanism of the quality control of healthcare services and analyze the legislation system in the field of state quality control. The article describes different ways of internal and external healthcare quality control: health care standardization, licensing, accreditation, self-rating of medical workers; expert rate; clinical audit; monitoring of the indicators quality system; certification. The article proposes ways of harmonization of the national legal framework and adaptation to the relevant norms of international law.

Key words: health care quality, internal and external healthcare quality control.

The world experience of the healthcare sector reforming indicates the necessity of the gradual and planned legal providing of the qualified health care. It can be achieved through wide establishment of different ways of health care quality control in the healthcare sector. The process of the healthcare sector reforming lasts in Ukraine and it is necessary the synergy of doctrine, legislation and practice. The legal base, that regulates the questions of the health care quality for the population, consists of such main acts: Law of Ukraine of 07.07.2011 № 3611-VI “About changes in Fundamentals of legislation of Ukraine about the healthcare regarding the improvement of the health care provision”, the Order of the Ministry of Health of Ukraine dated September 28, 2012 No. 752 “About the procedure of control of the health care quality provision», the Order of the Ministry of Health of Ukraine dated August 1, 2011 No. 454 “On Approval of the Concept of Quality Management of Health Care in Ukraine until 2020”.

In Radysh Y. [4] opinion, principles and forms of control of the health care quality provision, that are existing now, do not meet the needs of the present time and cannot meet the consumers and providers needs of the healthcare. It forces to search for new approaches and methods to the formation of the control mechanisms of the health care services quality, that will be adequate to the modern stage of the healthcare development, for creation of effective legal means of regulating, according the international norms of law.

In the scientific literature, Nyzhnyk N. et al. [3] believe that control is the system of observation and inspection of the functioning process and factual state of manageable object with the aim of rating reasons and effectiveness of accepted by this object decision and results of its fulfilments; it is the detection of the deviation from requirements, that are formulated in this decisions; it is the elimination of the unfavorable consequences of decisions’ fulfilments and informing of competent authorities about that.

Malynovckyi V. [1] writes that the functions of the control in the healthcare system, from the point of society view, firstly, are in providing of accessibility of information about the healthcare sector; secondly, control is the condition of law compliance, order, protection of human rights and liberties.

Such scientists as Grando A.A., Yarmenchuk A.D., Reshetnykov A.V., Tregubov Y.G., Dmytrieva N.V., Lusan S.G. concentrate their attention at the necessity of the departmental control improvement in the public administration of the healthcare sector. However, there is not enough number of well-grounded researches of the present system of the state control of the health care quality provision in the Ukrainian health care organizations (HCO).

The problem of the health care quality (HCQ) provision has its own history. Smiianov V.A. [5] underlines three main stages of the development of the HCQ provision in Ukraine:

The state (budget) system of healthcare (until the middle of 80-th years of the XX c.)

The stage of the new economical mechanism introducing (second part of 80-th years of the XX c.)

The independence of the country with the appearance of market mechanisms of economics (since 90-th years of the XX c. until now).

The state (budget) system of healthcare had the vertical, centralized system of administration. The style is administrative command system. The healthcare develops at the ground of unified norms of planning, financing of health care and firm budget discipline. The cost recovery at the services of healthcare, which were provided to the population free of charge, was made for the costs of the public

consumption funds. The receipt of money from the state budget determines the current upkeep of the healthcare. The economical effectiveness of the healthcare in this period is not self-aim.

The functioning of the healthcare in that period had clearly outlined, closed sectoral character. All processes of the HCQ system administration were only in boundaries of healthcare sector.

In such conditions, the system of the HCQ provision had such characteristics:

- HCQ control was departmental and had multi-staged sectoral character;
- System was not responsible for HCQ;
- HCQ rated by using quantities indicators, that were created by the state statistical service;
- Indicators of activities of healthcare institutions usually reflected the amount of given help;
- Main attention was paid to the control of permanent or constant loss of working capacity;
- Standardization was only sectors of medicaments and equipment of HCO;

The number of unsatisfied patients with the quality of health care increased.

In 1987, the Resolution of the USSR Government and CC of the CPSU "Main directions of the development of the healthcare of the population and the restructuring of the healthcare in 12-th five-year plan and till the 2000 year" came out. It was said that the necessary condition of the intensification of HCO activity was increase of HCQ effectiveness. For achieving of this aim, the main mechanism should be the change at the economical methods of administration. The decision started the development of economically rated relations in the healthcare. Besides the budget, financing, contractual and paid services were introduced.

Instead of the previous principle of financing (at the bed and the number of visits) the long-termed financing per capita started. The main source of financing became the budget costs based on the expenses per year. The system of planning was changed; the plan norms for therapeutic and prophylactic institutions were clarified.

At the start of the 90-th years of the XX c. big hardships in introducing of the new economical mechanism appeared. It was because of the total worsening of the economic situation in country and intra-sectoral character of the experiment. The state budget deficit of the healthcare after the collapse of the USSR played the main role in the reform crisis. In this period, like and in previous, citizens – the consumers of the health care services – do not became the full members of the process of healthcare reforming. They were completely excluded from the sphere of economic relations.

Last years it was done some work for methodological improvement of the HCQ provision in Ukraine at the state level. Appropriate normative acts witness about it.

The HCO's state accreditation, that was introduced in Ukraine since 1997 (Resolution of the Cabinet of Ministers of Ukraine dated July 15, 1997 No.765 "About the approval of the procedure of state accreditation of healthcare institutions" with the next changes, the order the Ministry of Health of Ukraine dated March 14, 2011 No. 142) rated the HCO activity at the ground of expert rate of its accordance to definite accreditation standards.

During 2000-2017 normative acts that raised the role of the licensing of medical practice in provision of prerequisites for the HCQ provision were accepted in Ukraine. The work to standardize the medical practice was done.

The state program of the adaptation of the Ukrainian legislation to the EU legislation (Law of Ukraine dated March 18, 2004 No. 1629-IV) means the harmonization of the national system of standardization with the European principles. In Ukraine the mechanism of creation medical, technological and normative documents according the principles of evidence-based medicine is introducing now. In the ground of its mechanism normative acts are valid, especially the National Health Reform Strategy for Ukraine 2015-2020 and Order of the Ministry of Health of Ukraine dated August 1, 2011 No. 454 "On Approval of the Concept of Quality Management of Health Care in Ukraine until 2020". Now the HCQ provision is regulated by the Procedure of the HCQ control that was approved by the Order of the Ministry of Health of Ukraine dated September 28, 2012 No. 752.

According to the p.3 of the Procedure, HCQ is the health care provision and using other measures for organization of the provision by healthcare, according to the standards in the healthcare sector. The rate of HCQ is definition of the accordance of given health care to the established standards in the healthcare sector. The control of the HCQ provision is made by using the next methods: internal and external HCQ control; self-rating of medical workers; expert rate; clinical audit; monitoring of the indicators quality system; certification according to the requirements of the valid Ukrainian legislation and EU legislation.

The internal control of the HCQ provision is carried out by the HCO administration and/or by the HCO medical councils within the limits of authority determined by the legislation. The external control of the HCQ provision is carried out by bodies of state executive power within the limits of powers determined

by the legislation, especially by the way of control compliance with license conditions of the economic activity from the medical practice, the HCO accreditation, certification of doctors, junior specialists with medical education, professionals with higher non-medical education, who work in the healthcare system, conducting clinic-expert rate of quality and amount of health care.

Such constituents realize the control of the HCQ provision:

- structure, process and results of health care;
- organization of the health care provision;
- realization-control of the administrative decisions;
- accordance to the qualification requirements of medical workers, including the heads of HCO;
- study of the patient's opinion about given health care;
- ensuring the rights and safety of patients while providing them health care.

The HCQ control takes place in cases of patient's deaths; primary invalidation of able-bodied persons; disagreements of the established diagnoses; non-compliance the health care standards, clinical protocols, logs of technical equipment by HCO; patient's complaints or complaints from persons who look after patients.

At the state level, the Main accreditation commission and License commission of the Ministry of Healthcare of Ukraine and regional administrations of healthcare realize the current external control of HCQ (accreditation and licensing).

Accreditation is the rate of activity of the therapeutic and prophylactic institution, according the requirements of standards that characterize structure, process and conclusive results of the institution work.

According to Law of Ukraine "About the licensing of forms of economic activities" dated March 2, 2015 No. 222-VIII, licensing is the instrument of state regulating of economic activities, that are subjected to licensing, that is directed at the providing of the realization of the unified state policy in the sphere of licensing, protection of the economic and social interests of the state, society and separate consumers.

In the sector of healthcare licensing is the receipt of the permission (license) and instrument of state control requirements of the legislation that can be used to medical practice, forensic medicine and forensic psychiatric examinations.

The Procedure of the state accreditation of therapeutic and prophylactic institutions independently from the ownership form and administrative subordination is regulated by the Resolution of the Cabinet of the Ministers of Ukraine dated July 15, 1997 No.765 and accepted according to it the Order of the Ministry of Health of Ukraine dated March 14, 2011 No.142. These documents say that the accreditation is obligatory for all HCO and takes place no earlier than in 2 years after the start of the subject activity. According to this resolution, special accreditation commissions realize accreditation. In the result of activity of such accreditation commission, accreditation certificate with the expiration date for 3 years gives out. Until the end of the expiration, date of the accreditation certificate the therapeutic and prophylactic institution must undergo the procedure of the recurrent accreditation.

In medical scientific literature the discussion about the role and necessity of state control after the activity of separate doctor or therapeutic and prophylactic institution continues. The arguments «cons» the control are its moral onerousness and unwillingness from the side of the providers of the health care services. Arguments "pros" from the side of patients are obligations and constancy of control as guarantor of provision of appropriate quality of healthcare services. Therefore, the licensing process is considered as preliminary control, the main function of which is the provision of some level of quality of health care services by the subjects of entrepreneurship, which are functioning at the market of health care services.

According to art.7 of Law of Ukraine "About the licensing of the forms of economical practice" the forms of the economical practice that must be licensed are:

- medical practice;
- pharmaceutical activity (production of remedies, wholesale and retail of remedies, import of remedies);
- the activity of cord blood banks, the other tissues and cells of human;
- taking, remaking and conservation of donor blood and its components, realization of them and made from them remedies by HCO;
- cultivation of plants, production, preservation, buying, realization, import and export at or from territory of Ukraine, annihilation of narcotic, psychotropic substances, precursors.

The researchers of the problem of licensing and accreditation of HCO have different ideas about the commission structures.

Nadiuk Z.O. [2] proposes to improve the licensing and accreditation procedures by the introduction to the commission structure such specialists as: doctor-expert from epidemiology; doctor-expert from the questions of municipal hygiene; doctor-representative of the professional association; doctor-representative of the other therapeutic and prophylactic institution; tax-inspector; auditor-accountant; lawyer; expert from the medical insurance; representative of the regional patients association. The civil servants (the workers of the Ministry of Health of Ukraine) will be: doctors-experts from epidemiology and municipal hygiene, lawyer, auditor-accountant. The program of licensing and accreditation must include:

- correspondence of the conditions of the health care provision to the sanitary-hygienic and meteorological standards;
- providing of qualified health care provision;
- providing of the effectiveness of the health care provision;
- providing of the legitimacy in the activity of therapeutic and prophylactic institution;
- analysis of the financial-economic reports and conclusion about economical expediency of existence.

This approach is transitional to the European model of the HCO certification, which is difficult to implement in Ukraine at one moment. Therefore, we should gradually bring closer the system of HCQ control to the best world practices.

In conclusion, we can say that implementation of the system of continuous improvement quality on the ground of health care standardization, licensing and accreditation, introducing of the clear mechanisms of doctor salaries, according the quality indicators of treatment, structure, process and result. It will allow changing the present command-bureaucratic philosophy of the quality control to the quality management and much more improving the health care quality control to the population of Ukraine.

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Реферати

ПРАВОВЕ ЗАБЕЗПЕЧЕННЯ МЕХАНІЗМУ КОНТРОЛЮ ЯКОСТІ МЕДИЧНОЇ ДОПОМОГИ В УКРАЇНІ

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У статті авторами розглянуто особливості забезпечення якості медичної допомоги в Україні на трьох етапах: в умовах державної (бюджетної) системи охорони здоров'я; на етапі впровадження нового економічного механізму; на сучасному етапі функціонування ринкових механізмів економіки. Особливу увагу зосереджено на правовому забезпеченні механізму контролю якості медичної допомоги та аналізі системи законодавства у сфері державного контролю якості. На основі розгляду різних методів внутрішнього та зовнішнього контролю якості медичної допомоги, зокрема таких, як стандартизація, ліцензування, акредитація, самооцінка медичних працівників, експертна оцінка, клінічний аудит, моніторинг системи показників якості, сертифікація. запропоновано шляхи гармонізації національного законодавства в сфері державного контролю якості медичної допомоги та його адаптації до відповідних норм міжнародного права.

Ключові слова: якість медичної допомоги, внутрішній і зовнішній контроль якості медичної допомоги.

Стаття надійшла 28.11.18 р.

ПРАВОВОЕ ОБЕСПЕЧЕНИЕ МЕХАНИЗМА КОНТРОЛЯ КАЧЕСТВА МЕДИЦИНСКОЙ ПОМОЩИ В УКРАИНЕ

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В статье авторами рассмотрены особенности обеспечения качества медицинской помощи в Украине на трех этапах: в условиях государственной (бюджетной) системы здравоохранения; на этапе внедрения нового экономического механизма; на современном этапе функционирования рыночных механизмов экономики. Акцентировано внимание на правовом обеспечении механизма контроля качества медицинской помощи и анализе системы законодательства в сфере государственного контроля качества. На основе изучения различных методов внутреннего и внешнего контроля качества медицинской помощи, в том числе таких, как стандартизация, лицензирование, акредитация, самооценка медицинских работников, экспертная оценка, клинический аудит, мониторинг системы показателей качества, сертификация, предложены пути гармонизации национального законодательства в сфере государственного контроля качества медицинской помощи и его адаптации к соответствующим нормам международного права.

Ключевые слова: качество медицинской помощи, внутренний и внешний контроль качества медицинской помощи.

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