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LEGAL FOUNDATION OF DETERMINING CRITERIA OF IMPROPER RENDERING OF MEDICAL AID IN RUSSIAN FEDERATION

Tatyana N. Balashova¹ Yuliya A. Chernysheva²

Abstract: This scientific paper is aimed reviewing the applicable laws governing the medical aid rendering to the Russian Federation citizens, in particular, the RF Civil Code, the Federal Law dated 21.11.2011 No. 323-FZ "On fundamental healthcare principles in the Russian Federation", the RF Law dated 07.07.1992 No. 2300-1 "On Protection of Consumers' Rights", and a number of subordinate regulatory legal acts. The article's authors tried to analyze and to reveal criteria of improper rendering of medical aid in the Russian Federation. The authors substantiated that the medical aid, as a complex of measures, which are aimed at maintaining and (or) recovering the health and which include the rendering of medical services, must correspond to the criteria of a proper quality, a proper volume, it must be rendered by highly-qualified specialists properly, at the appropriate time and

with complying with the established rights of the patients, and a notion of improper medical aid is defined. general scientific dialectical method and a complex of scientific approaches of obtaining knowledge (formally-legal, system-structural, formally-logical) is methodological the research's framework. The results, which the authors obtained, consist in the fact that as criteria of improper rendering of the medical aid, it is necessary to consider the conditions, volume, safety, quality, non-conformity of the medical aid with the goals, for which this medical aid is usually rendered, violation of the patients' rights, non-optimal choice of a technology of the medical aid rendering, violation of the rights of execution of the documentation. medical conclusion the authors formulated the basic conclusions of the research, substantiated the necessity to develop

¹ Federal State Budgetary Educational Institution of Higher Education «Bunin Yelets State University

² Federal State Budgetary Educational Institution of Higher Education «Bunin Yelets State University



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and to enshrine an enumeration of criteria of the improper rendering of the medical aid in the applicable laws.

Keywords: medical aid, medical service, public health, criteria of improper rendering of medical aid.

1. Introduction

A problem of poor rendering of the medial aid to the population is very important in Russia today. As the lawenforcement agencies are working inefficiently and the people, who suffer from unsatisfactory medical services, are passive, the population comes to believe that the health care workers, who render the medial aid improperly, are not punished for that.

In order to solve this problem efficiently, it is important and necessary to develop the legal definition "improper rendering of the medical aid (services) and to sort out the criteria, according to which the medial aid will be assessed as poor.

This scientific paper is aimed at researching the legal foundation of determining the criteria of improper rendering of the medial aid in the Russian Federation.

The research conducted by E.Kh. Barinov, A.L. Vorontsov. E.V. Vorontsova, I.V. Gertsmanova, M.V. Lyadova, I.G. Makarov, A.R. Pozdeev, A.A. Starchenko, E.S. Tuchik, S.Ya. Yakovlev and others covers various aspects of the problem of a legal definition of quality of rendering of the medical aid. However, in spite of great importance of the problems, which are examined in this research, the authors have not found any special monographs on this subject, or such research has not been made public yet.

Improper rendering of the medical aid is covered in a great number of papers by foreign scientists: Antoci, A., Maccioni, A.F., Galeotti, M., Russu, P. [16, p. 414-435], Feess, E. [18, p. 157-167], Novak, S. Email Author, Djordjevic, N. [25, p. 72-80] and others.

The problems of responsibility of the medical workers in the sphere of protection of the patients' rights abroad were examined in some scientific research: Gardiyawasam Pussewalage, H.S., Oleshchuk, V.A. [22, p. 1161-1173], Martin, G., Beech, N., Macintosh, R., Bushfield, S. [23, p. 14-29], Studdert, D.M., Mello, M.M., Sage, W.M., DesRoches,



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C.M., Peugh, J., Zapert, K., Brennan, T.A. [24, p. 2609-2617], and others.

2. Methodology

The research uses the general scientific dialectical method as well as the formally-legal, system-structural and formally-logical methods of obtaining knowledge.

The general scientific dialectical method makes it possible to research the essence of the right for the health protection and the medical aid, and the mechanisms of their implementation, to analyze the applicable laws governing the rendering of the medical aid to the Russian Federation citizens, to reveal the problems, which appear in realizing this right.

This method determines the criteria of inadequate conditions of rendering the medical aid to the RF citizens.

When analyzing the RF applicable laws the formally-legal method was used.

The system-structural method described and analyzed the legal assurance of exercising the right for health protection in considering its legal nature and future development, and determined the criteria of improper

rendering of the medical aid in the Russian Federation.

The formally-logical method made it possible to use the existing forms of thinking and the logical laws in revealing the gaps in the applicable laws.

3. Results

During the Russian Federation's transition to the market economy, the relations in the health care system were changed drastically, which were enshrined in the applicable RF constitution, which enshrined in Part 1 of Article 41, the right of each person for the health protection and the medical aid, which is rendered in the governmental, municipal and private health care organizations free of charge, through the budget funds, insurances and other receipts [1].

As a result of the large-scale health care reforms, which started in the 1990-s, the early existing efficient budget health care system, which was fully based on the state regulation, was replaced by a new system, which includes the systems of compulsory medical insurance and voluntary medical insurance, which provides for spread of paid medical services. This, in its turn, also stipulated the change of a legal



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nature of the relations, which appeared in connection with rendering the medical aid to the population in the Russian Federation.

In the new medical terminology the traditional notion "medical aid" was replace by a notion "medical service", which is not typical for the Soviet health care system, and which is now enshrined in the civil, labor and tax laws, and in the state standards (GOSTs), which govern the health care sphere. But it is necessary to say that currently the notions "medial aid" and 'medical service" are used as synonyms in the laws and regulations and at the specialized level, and the authors believe that it is incorrect in virtue of essential differences between those notions and it has some negative consequences.

Now the medical services in the RF are rendered on the basis of the Chapter 39 of the Civil Code of the Russia Federation [2]. Article 779 of the Civil Code of the Russian Federation enshrines a provision, according to which the standards of Chapter 39 of the Civil Code of the Russia Federation are applied to the sphere on rendering the medical services.

Apart from the Civil Code of the Russia Federation, a key regulatory act,

which governs the relations in the sphere of the medical aid rendering, is the law dated 21.11.2011 No. 323-FZ "On fundamental healthcare principles in the Federation" Russian (hereinafter referred to as the Federal Law on Fundamental healthcare principles in the Russian Federation) [3]. In particular, Paragraph 3 of Article 2 of the said law enshrines a provision, according to which the medical aid is a complex of measures. which are aimed maintaining and (or) recovering the health and include the rendering of services in the sphere of the medicine.

Apart from that, the relations in the sphere of rendering the medical aid in the Russian Federation are also governed by the RF Law dated 07.07.1992 No. 2300-1 "On the Protection of Consumers' Rights" [4], the Federal Law dated 04.05.2011 No. 99-FZ "On Licensing Certain Activities" [5], the RF Government Decree dated 16.04.2012 No. 291 "On Licensing of Medical Activities (except for the said activities, which is implemented by the medical organizations and other organizations, which belong to the private health care system, in the innovation center "Skolkovo")"[6], the RF Government Decree dated



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28.11.2014 No. 1273 "On program of the state guarantees of gratuitous rendering of the medical aid to the citizens for 2015 and for the planning period of 2016 and 2017" [7], the RF Government Decree dated 04.10.2012 No. 1006 "On Approval of the Rules of Rendering by the Medical Organizations of the Paid Medical Services" [8].

In spite of variety of the laws and regulations, which govern the rendering of the medical aid, at present the problem of improper rendering of medical services became important. The analysis of the applicable laws in the considered sphere of social relations will help to answer the questions what the criteria of improper rendering of the medical aid are.

The RF Civil Code in Article 309 enshrines a principle of proper performance of obligations, according to which they are performed properly in accordance with conditions of the obligation and requirements of the law, other legal acts, and there are no such conditions and requirements — in accordance with codes of business conducts or other requirements, which are usually applied.

Therefore, it is possible to sort out the following criteria of improper

rendering of the medical aid: conditions, volume, safety, quality, non-conformity of the medical aid to the goals, for which this medical aid is usually rendered, violation of the patients' rights, non-optimal choice of a technology of rendering the medical services, violation of the rules of execution of the medical documentation and others.

Rendering of the medical aid with violation of requirements of the laws on conditions of rendering the medical aid is improper.

In particular, the criteria of improper conditions of rendering the medical aid may include:

- rendering of the medical aid without a relevant license or with violation of the public health requirements for location and operation of a medical organization;
- rendering of the medical aid by a medical worker, who is not entitled to carry out the relevant medical activities;
- rendering of the medical aid by a medical worker, who is not entitled to carry out the relevant medical activities.

One of the important conditions of assuring the quality and safety of the medical aid in the Russian Federation is the medical activities licensing. The reason for this is that when carrying out



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those activities the medical worker can harm the life or health of a patient, so the applicable laws set out compulsory requirements for licensing the medical activities and special public health requirements for the medical institution.

The licensing process is implemented on the basis of the legislative acts and the subordinate regulatory acts, which are developed on their basis. The laws and regulations, which govern the licensing of the medical aid, include:

- The Federal law dated 08.08.2001 No. 128-FZ "On Licensing Certain Activities" [5];
- the RF Government Decree dated 16.04.2012 No. 291 "On licensing of the medical activities (except for the said activities, which are carried out by the medical organizations and other organizations belonging to the private health care system, in the innovation center "Skolkovo")" [6];
- Code of the Russian Federation on Administrative Offences and others.

Apart from that, the public health requirements for the medical organizations, which carry out the medical activities, are determined by the Decree of the Chief State Sanitary Doctor of the Russian Federation dated

May 18, 2010 No. 58 "On Approval of SanPiN 2.1.3.2630-10 "Public health requirements for the organizations, which carry out the medical activities" [9] as well as the license requirements, are binding for all medical organizations.

It is necessary to note that the legal framework on licensing the medical activities in Russia is behind the international standards and requires permanent improvement. If the medical aid was rendered in violation of the license requirements or public health requirements for location and operation of the medical organization, the rendered medical aid will be improper according to a criterion of conditions of its rendering, and this criterion, as it was said above, influences the safety of the rendered medical aid on the whole.

A criterion of improper conditions of rendering the medical aid is also the rendering of such aid without receiving by the medical worker of an informed voluntary consent of the patient to the medical intervention.

The federal law "On fundamental healthcare principles in the Russian Federation" as a compulsory preliminary condition of medical intervention provides for the delivering of informed voluntary written consent of the patient



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to implementation of the medical manipulations (Article 20 of the Law). The medical worker must, in a maximum accessible form, inform the patient about an order of rendering of the medical aid, its goals. methods, possible consequences and risks, on the basis of which the patient will adopt a decision about his/her consent or refusal from the medical aid. By the Order of the Ministry of Health of Russia dated 20.12.2012 No. 1177H [10] the procedure of giving the informed voluntary consent to the medical intervention is regulated. The provisions of this document extends to the medical organizations, in relation to the medical organizations, which take part in the program of providing the state guarantees of gratuitous rendering of the medical aid. If the medical aid was rendered with violation of the provisions of Article 20 of FZ "On fundamental healthcare principles in the Russian Federation", it will be considered as improper.

An indispensible condition of quality of the medical aid, which is rendered to the people, is a requirement of the laws on inadmissibility of its rendering by a person, who is not entitled to carry out the medical activities. This requirement is enshrined, in particular, in

Article 69 of the Federal Law "On fundamental healthcare principles in the Russian Federation", and in the Orders of the Ministry of Health of Russia": dated 08.10.2015 No. 707н "On Approval of Qualification requirements for medical and pharmaceutical workers with higher education on the training program "Health care and medical sciences" [11];dated 29.11.2012 No.982н "On Approval of conditions and an order of issue of the specialist's certificate to medical and pharmaceutical workers, form and technical requirements of the specialist's certificate" [12]; dated 03.08.2012 No. 66н "On Approval of an Order and time of improvement by the medical workers and pharmaceutical workers of their professional knowledge and skills by means of training according to additional professional educational programs in educational and scientific organizations" [13] and others.

If a medical worker rendered the aid without gaining the right to carry out the medical activities, the fact of carrying out such actions is regarded as a delinquency and poor rendering of the medical aid.

Besides a criterion of conditions of rendering of the medical aid, the



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criteria of volume and proper safety of the medical aid are of importance in assessing its quality.

On the basis of a criterion of volume of the rendered medical service. it is determined how the rendered medical aid corresponds to the objective demands of the patient. A qualitatively rendered medical service must be characterized by carrying out a required volume of diagnostic and remedial measures, which are determined by medical indications. However. quality of rendering the medical aid is regarded as improper with insufficient as well as excess volume of the medical manipulations.

It is very important for the rendered medical aid to be safe for life and health of a person, who takes medical advice. This requirement is confirmed by the standard of Article 7 of the RF Law "On Protection of the Consumers' Rights". A criterion of safety of rendering the medical aid reflects, in particular, optimality of the choice of medical technologies in rendering the medical aid to the patient, with account taken of minimizing the risk of applying those technologies for a specific patient, compliance with special requirements, which are set out in relation to any medical interventions, compliance by a medical and organization with the rules to keep and to use the medicaments.

Analysis of Paragraph 21 of Article 2 of the Federal Law "On fundamental healthcare principles in the Russian Federation" makes it possible to sort out some other conditions, upon which the rendered medical aid will be regarded as poor, in particular, they include:

- tardiness of the medical aid rendering;
- incorrectness of choice of a method of prophylaxis, diagnostics, treatment and rehabilitation;
- unsatisfactory degree of achieving the planned result.

In all cases of rendering of poor medical aid to the patient, in order to determine the reasons, indicating its improper rendering, it is necessary to conduct a special expert examination, which, among other things, provides a conclusion on the timely rendered medical aid, correctness of choice of methods of prophylaxis, diagnostics, treatment and rehabilitation and a degree of achieving the planned results (Part 1 of Article 64 of the FZ "On fundamental



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healthcare principles in the Russian Federation").

However, at present the expert examination of the medical aid quality is conducted only within the programs of compulsory medical insurance, since a federal law, which governs such a type of the expert examination in the other sphere, has not been passed yet. When the medical aid is rendered on a paid basis, in order to determine the quality of the medical aid the patient is entitled to use all possible legal remedies, which are provided to him/her by the RF laws.

Proceeding from the specific character of rendering of the medical aid it is possible to draw the following conclusions.

Rendering of the qualitative medical aid must clearly correspond to the requirements, which are imposed by the applicable law and subordinate regulatory acts on such activities.

Improper rendering of the medical aid can be determined as rendering of the aid, which does not correspond to the requirements imposed on it by the applicable laws.

4. Discussion

One of the important and priority aspects in the state's activities is

preservation of the population's health, since the prosperity of the state itself depends on that. It is known that duration of life in the states, which have a perfect health care system, is much higher. So, the problem of protection of the citizens' rights in the sphere of rendering of the medical aid is attracting more and more researchers and lawmakers in Russia. As of today the Russian scientists published a sufficient number of papers covering the citizens' rights in this sphere [14, p. 4]. It is necessary to agree with L.V. Kanunnikova's opinion that "cases of improper rendering of the medical aid with harming the life and health of patients set the clinicians, lawyers and medicolegists a number of tasks, which require a deep comprehensive study: a level of prevalence of improper rendering of the medical aid; prevention of delinquencies in the medical practice; a possibility of settling the conflicts at a non-court stage; a level of legal training of the medical workers; mechanisms of indemnifying the patient for damage and others." [15, p.105].

Proceeding from provisions of Article 309 of the Civil Code of the Russian Federation, and provisions of Articles of 5, 6, 10 of the FZ "On fundamental healthcare principles in the



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Russian Federation", Article 4 of the RF law "On Protection of the Consumers" Rights, it is possible to conclude that the medical aid, as a complex of measures, which are aimed at maintaining and (or) recovering the health and which include the rendering of the medical aid, must correspond to criteria of a proper quality, a proper volume, it must be rendered by highly-qualified specialists properly, at the appropriate time and with complying with the established rights of the patients, in other words - poorly rendered medical aid is the aid rendered with certain shortcomings.

At present, unfortunately, the applicable Russian laws do not have a clear definition of a notion of improper rendering of the medical aid. In this connection, improper rendering of the medical aid can be defined as an antipode of proper rendering of the medical aid and, respectively, it will be the rendering of the medical aid, which does not correspond to the requirements, which are imposed on it by the lawmakers.

5. Conclusion

The research of the criteria of improper rendering of the medical aid in

the RF makes it possible to draw a number of conclusions.

The authors suggest that the criteria of improper rendering of the aid should medical include conditions, volume, safety, quality, nonconformity of the medical aid with the goals, for which this medical aid is usually rendered, violation of the patients' rights, non-optimal choice of a technology of the medical aid rendering, violation of the rights of execution of the medical documentation and others. The authors believe that an enumeration of such criteria must be enshrined in the applicable laws, it must have an open nature in order to maximally mark the framework of the good medical aid.

If a medical service is rendered within the voluntary medical insurance, the services, which are provided for by the agreement, must be rendered in full and according to the requirements, which are set out in the agreement for rendering of the paid medical services.

In order to determine the reasons, which entailed the rendering of poor medical aid to the patient, it is necessary to conduct a special expert examination, within which a substantiated conclusion will be drawn about timeliness of rendering of the aid to the patient,



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correctness of a choice of methods of prophylaxis, diagnostics, treatment, rehabilitation and degree of achievement of the planned result.

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