

LEGAL REGULATION ANALYSIS OF MEDICAL CARE PROVISION TO PATIENTS WITH ONCOLOGICAL PATHOLOGY TO RESIDENTS OF VARIOUS AGES, GENDER AND OCCUPATIONAL GROUPS IN THE RUSSIAN FEDERATION

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Abstract

The recognized relevance of combating malignant neoplasms has necessitated the implementation of a unique nationwide program to combat oncological diseases in the Russian Federation and the construction of a modern integrated system, from screening and early diagnosis to timely effective treatment, which will protect a person.

Keywords: malignant neoplasms, legal regulation, oncological pathology, medical care.

INTRODUCTION

Malignant neoplasms are one of the most pressing social problems around the world. Unfortunately, morbidity and mortality from malignant neoplasms are increasing. Moreover, some experts say malignant neoplasms represent the "plague of the XXI century". This problem poses severe challenges to the public health system, as well as to society and the state as a whole.

To implement this program, the Decree of the President of the Russian Federation No. 204 of 07.05.2018, "On national goals and strategic objectives of the development of the Russian Federation for the period up to 2024", was adopted, the priority National project "Healthcare" and the Federal project "Fight against malignant Neoplasms" were developed, within which it was detailed and approved at the meeting project committee for the national project "Healthcare" dated December 14, 2018 No. 3 special passport of the federal project "Fight against oncological diseases", The following Federal documents were also amended accordingly: Federal Law No. 323-FL of November 21, 2011 "On the Basics of protecting the Health of Citizens in the Russian Federation", Decree of the Government of the Russian Federation No. 420-r of March 14, 2018 "National Strategy of Action for Women for 2017-2022".

In addition to Federal regulatory documents, technical, regulatory documents were adopted, such as:

- Order of the Ministry of Health of the Russian Federation No. 572n dated November 01, 2012, "On approval of the procedure for providing medical care in the profile "obstetrics and gynaecology (except for the use of assisted reproductive technologies)";
- Letter of the Ministry of Health of the Russian Federation dated November 2, 2017, No.15-4/10/2-7676 "Clinical

recommendations (treatment protocol) “Benign and precancerous diseases of the cervix from the perspective of cancer prevention”;

- Order of the Ministry of Health of the Russian Federation No. 376n dated June 2, 2022, “On approval of standards of medical care for adults with breast cancer”;

- Order of the Ministry of Health of the Russian Federation No. 124n dated 13.03.2019 “On approval of the procedure for preventive medical examination and medical examination of certain groups of the adult population”;

- Decree of the Government of the Russian Federation No. 1772 of December 30, 2018, “On Approval of the Rules for the Provision and Distribution of Other Inter-Budgetary Transfers from the Federal Budget to the Budgets of the Constituent Entities of the Russian Federation for the Re-Equipment of Medical Organizations providing Medical care to patients with Oncological diseases”;

- A coordination centre has been established to ensure the development and implementation of regional programs “Fight against oncological diseases” (Order No. 38 of the Ministry of Health of the Russian Federation of January 31, 2019, was adopted).

The main measures for the implementation of these documents and the achievement of control points of the Federal Project “Fight against malignant Neoplasms” include the identification of at least 100 medical organizations based on which it is planned to create outpatient cancer care centres (OCCC), the development of methods for calculating the leading indicators of the Federal Project, the signing by the subjects of the Russian Federation of acts on the approval of 85 regional programs and implementation of organizational and methodological support of issues for the development and implementation of regional programs.

An essential place in the fight against malignant neoplasms (MN) is occupied by medical examination, the conduct of which is regulated by Order No. 404n dated April 27, 2021, “On approval of the procedure for preventive medical test and medical examination of certain groups of the adult population (ed. Order of the Ministry of Health of the Russian Federation dated 01.02.2022 N 44n).

The health of a woman and the medical examination of the female population to timely detect MN, is a priority task for the state since the health of future generations depends on her health.

From 01.01.2022, a new procedure for providing medical care to adults with oncological diseases – Order No. 116n - comes into force in Russia. The exception is paragraph 3 of the Order concerning the rules for organizing the activities of the radiotherapy department of an oncological dispensary (oncological hospital), another medical organization providing medical care to patients with oncological diseases, provided for in Appendix No. 26 to the Order [Order of the Ministry of Health of the Russian Federation dated February 19, 2021 No. 116n “On approval of the Procedure for providing medical care to minors, including during the period of education and upbringing in educational organizations” [1, 2, 4].

This regulatory legal act at the stage of development has caused an ambiguous reaction in the medical and legal communities. Therefore, it has been repeatedly edited. But, despite this, even after the adoption of the document, some provisions of the Order remain very controversial.

The adopted document clearly outlines the boundaries of providing medical care to cancer patients. It is indicated that in addition to patients suffering from malignant neoplasms and neoplasms in situ, medical care should also be provided for some benign tumours (connective tissue, eyes, meninges, endocrine glands, other and unspecified localizations) [Order of the Ministry of Health of the Russian Federation dated February 19, 2021 No. 116n “On approval of the Procedure for providing medical care to minors, including during the period of education and upbringing in educational organizations” [2]. That is, the new Order includes only a part of benign neoplasms that require management by oncologists.

In the Order, the leading role in the provision of primary health care (PHC) was awarded to outpatient oncological care centres [Order of the Ministry of Health of the Russian Federation No. 116n dated February 19, 2021 “On approval of the Procedure for providing medical care to minors, including during training and upbringing in educational organizations” [2, 3]. At the same time, the document does not specify the service area and the conditions necessary for creating the centre. Most likely, creating such centres will lead to the elimination of oncologists’ offices in polyclinics and oncological departments, which are currently engaged in providing primary health care to the population.

Particular attention should be paid to the differentiation of powers and competencies of two medical specializations: oncologists and haematologists. An oncologist must establish a diagnosis of oncological disease. Still, if a malignant neoplasm is detected with localization in lymphoid, hematopoietic and related tissues, a haematologist also makes the diagnosis. According to Order No. 116n, haematologists do not participate in diagnosing polycythemia, myelodysplastic syndromes and other unspecified tumours of lymphoid and hematopoietic tissues.

At the same time, the powers of haematologists include the provision of medical care for these conditions under Order No. 930n “On approval of the Procedure for providing medical care to the population in the profile “haematology” and clinical recommendations (Order of the Ministry of Health of the Russian Federation dated November 15, 2012 No. 930n “On approval of the Procedure for providing medical care to the population in the profile “haematology”) [3]. It turns out that this

issue of Order No. 116n does not harmonize with previously adopted regulatory legal acts regarding haematologists and specific pathologies of hematopoietic and lymphoid tissues.

When studying the material of the Order, the fact of the absence of norms for providing emergency medical care to cancer patients was revealed (Order of the Ministry of Health of the Russian Federation No. 116n dated February 19, 2021, “On approval of the Procedure for providing medical care to minors, including during training and upbringing in educational organizations”) [2]. In other words, the adopted document eliminated the clause obliging emergency medical care to send or transfer a patient with suspected oncopathology to a specialized medical organization. It turns out that a patient who needs immediate and highly specialized medical care can be taken to a non-core medical institution, so the above will not be able to be implemented.

According to the new Order, a mandatory requirement for assisting cancer patients is the presence in a medical institution of three departments – chemotherapeutic, surgical and radiotherapy (Order of the Ministry of Health of the Russian Federation dated February 19, 2021 No. 116n “On approval of the Procedure for providing medical care to minors, including during training and upbringing in educational organizations”) [2]. Consequently, many highly specialized and multidisciplinary clinics that do not have even one of the listed departments will be unable to provide timely medical care. And those few clinics with all three departments will have to accept a more significant number of patients, which will inevitably lead to an increase in the expectation of expected help, an increase in queues and an increase in the burden on oncologists and nursing staff. In addition, in addition to cancer patients with a malignant course, patients with some benign tumours will also have to go to such clinics, which will also increase the burden on the medical institution and increase the number of patients, although such patients, depending on the clinical situation, require the supervision of highly specialized doctors, and not chemotherapeutic and radiotherapy treatment.

Consultation of doctors should now decide the tactics for treating cancer patients, and not only by the attending oncologist. This circumstance undermines the basic principle of the doctor’s autonomy since even in a situation where an oncologist, after collecting complaints, examining the patient and receiving some results of laboratory and instrumental research methods, makes a preliminary diagnosis and plans tactics for the management and treatment of the patient. He still has to convene a consultation, including an oncologist surgeon and a radiotherapist.

The new Order provides for telemedicine technologies to solve the organization of doctors’ consultations. Thanks to this modern technique, it is possible to consult with more experienced colleagues without redirecting the patient to other medical organizations. Of course, this simplifies this procedure due to the use of remote technologies. Still, the organization of the process itself may take some time, which is unacceptable in the situation with cancer patients who need to prescribe prompt and high-quality treatment” [2, 6].

“Another innovation should be considered the required number of beds in the departments for cancer patients. In particular, according to the Order, there should be 20 to 50 beds in the antitumor therapy department and at least 5 in the radiotherapy department for one radiological unit. Thus, despite attempts to increase the bed stock, many existing clinics do not have this requirement and, accordingly, will be unable to receive patients and provide highly qualified and timely medical care.

Free medical care can now be provided only if a referral is issued from the attending physician (Order No. 116n of the Ministry of Health of the Russian Federation dated February 19, 2021, “On Approval of the Procedure for providing medical care to minors, including during the period of training and upbringing in educational organizations”) [2,4,5]. In turn, issuing such a direction, the latter will have to follow the routing procedure adopted by the regional health authorities. It means that the choice of a medical institution will depend on the provincial health committees. It is likely in the latter’s interests to provide medical care to as many patients as possible in regional clinics since funding will increase in such a case. In other words, the right of each patient to independently choose a medical institution and a doctor, enshrined in Federal Law No. 323-FL, is violated.

The question arises about an oncologist’s organization of this procedure in such a short time. Order No. 116n regulates some terms of medical care. For example, the duties of an oncologist include the organization of a biopsy within one day after a preliminary diagnosis of oncopathology (Order of the Ministry of Health of the Russian Federation No. 116n dated February 19, 2021 “On approval of the Procedure for providing medical care to minors, including during training and upbringing in educational organizations”) [1]. The biopsy procedure requires highly qualified specialists’ participation and high-tech equipment availability. Of course, this is more acceptable in large cancer centres, which may not be in the patient’s territory.

On the one hand, a particular time is legally fixed, which allows the patient to confirm or refute the preliminary diagnosis as soon as possible. On the other hand, it is impossible to rationally organize this process in such a short time due to the lack of medical organizations in most regions that meet the above requirements. Some advantages should be considered that an oncologist can send the biopsy material for re-examination to reference centres with excellent material and technical abilities. At the same time, this procedure will not be paid for at the expense of the patient. Previously, the regulatory documentation did not provide for such a provision and all repeated studies were carried out at the cost of the patient” [1,6].

“Unfortunately, the treatment of cancer is accompanied by the side effects of therapy due to the use of potent drugs that harm almost all human organ systems. Patients need support and accompanying therapy. At the same time, the relevant

documentation has not yet been developed, which would clearly fix the symptoms and side effects of the therapy and reflect treatment options. The exception is the concurrent therapy for the development of agranulocytosis and febrile neutropenia (Order of the Ministry of Health of the Russian Federation dated November 15, 2012 No. 930n “On approval of the Procedure for providing medical care to the population in the profile “haematology”) [2, 4, 5].

Thus, as the analysis of the main regulatory legal acts regulating the provision of oncological care to the population of the country, with an emphasis on the female population, has shown, there is no regulatory framework that gives doctors the right to hospitalize patients with an established oncological disease with side complications since no insurance company will reimburse the expenses of a medical organization. A paradox arises when an oncological clinic cannot accept a patient who has side effects from chemotherapy and needs to receive inexpensive drugs. A medical organization does not have the right to do so.

That is why, both at the Federal level and the regional level, these relevant regulatory documents should be revised and updated.

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