

НОРМАТИВНО-ПРАВОВОЕ РЕГУЛИРОВАНИЕ ЛЬГОТНОГО ЛЕКАРСТВЕННОГО ОБЕСПЕЧЕНИЯ В РОССИЙСКОЙ ФЕДЕРАЦИИ

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В Российской Федерации на сегодняшний день существует организованная система лекарственного обеспечения для льготных категорий граждан. При этом, нормативно-правовое регулирование находится в процессе постоянного совершенствования путем принятия новых законодательных актов и внесения изменений в уже существующие. В основе данного процесса лежат равные возможности и права всех граждан в получении бесплатной лекарственной помощи. Тем не менее, существуют льготные категории населения, для которых были приняты дополнительные подходы к организации лекарственного обеспечения.

Цель. Анализ нормативно-правовых актов применительно к соответствующим льготным категориям населения.

Заключение. Установленная нормативно-правовая база, регулирующая лекарственное обеспечение льготных категорий граждан, как на федеральном, так и на региональном уровнях, позволяет пациентам получать необходимую лекарственную терапию, которая является жизненно необходимой. При этом, для получения данной помощи является обязательным наличие определенного диагноза или социального статуса. В перечень льготных категорий граждан входят далеко не все пациенты. Следовательно, существующее нормативно-правовое регулирование здравоохранения нуждается в дальнейшем совершенствовании.

Ключевые слова: лекарственное обеспечение; организация здравоохранения; льготные категории; лекарственные препараты; законодательство.

STATUTORY REGULATION OF SUBSIDIZED PHARMACEUTICAL PROVISION IN RUSSIAN FEDERATION

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At present in the Russian Federation (the RF), an organized system of pharmaceutical provision of benefit-entitled citizens is used. With this, statutory regulation is under continuous improvement through adoption of new regulatory acts and amendments to already existing ones [1]. The basis of this process is equal opportunities and rights of all individuals for free provision with medical drugs. Nevertheless, there exist benefit-entitled categories of citizens for whom additional approaches to organization of pharmaceutical provision were adopted.

Aim. Analysis of statutory regulation applicable to the existing benefit-entitled citizens.

Conclusion. The established normative framework regulating pharmaceutical provision of benefit-entitled citizens both on the federal and regional levels, permits patients to receive the



necessary life-saving medicinal therapy. With this, an obligatory condition for receiving such assistance is presence of a certain diagnosis or a certain social status. Far not all patients are included into the list of benefit-entitled citizens. Hence, the existing statutory regulation of healthcare requires further improvement.

Keywords: *pharmaceutical provision; organization of healthcare; benefit-entitled categories; medical drugs; legislation.*

At present in the Russian Federation (the RF), an organized system of pharmaceutical provision of benefit-entitled citizens is used. The statutory regulation is under continuous improvement through adoption of new regulatory acts and amendments to the already existing ones [1]. The process is based on the equal opportunities and rights of all individuals for free provision with medical drugs. Nevertheless, there are benefit-entitled categories of citizens for whom additional approaches to organization of pharmaceutical provision were elaborated.

Statutory regulation of pharmaceutical provision of benefit-entitled categories of citizens on the federal level. According to Federal Law №178 of July 17, 1999 «Concerning State Social Assistance», measures of social support are taken in the form of rendering additional free medical assistance that envisages provision of certain categories of citizens with the necessary medical drugs (MD) on medical prescription out of federal budget resources («Provision of Certain Categories of Citizens with Necessary Medical Drugs» program) [2].

On the basis of Article 6.1 of the given Federal Law, the «List of Medical Drugs, including Medical Drugs Administered by Medical Commissions of Medical and Prophylactic Institutions...» is approved by a federal organ of executive power participating in formulation of State policy and in statutory regulation in the sphere of healthcare and social development. Here, the given list of MD is approved by Government of the Russian Federation. Since January 1, 2019 in effect is the list approved by Decree of Government of the RF of December 10, 2018 №2738-p [3].

It is important to note the following categories of citizens who have the right for receiving the state social assistance in the form of a package of social services:

- 1) disabled war veterans;
- 2) participants of the Great Patriotic War (the GPW);
- 3) veterans of combat operations from the list of persons mentioned in items 1-4 of Article 3 of Federal law «On Veterans» (as amended by the Federal Law №40-FL of January 2, 2000);
- 4) servicemen who were doing military service in military posts, establishments, military educational institutions not included into the active army, in the period from June 22, 1941 to September 3, 1945 for not less than six months; servicemen awarded orders and medals of the USSR for the service in the stated period;
- 5) individuals awarded the badge «Citizen of Blockaded Leningrad»;
- 6) individuals working for servicing anti-aircraft defense objects, local anti-aircraft objects, engaged in building of defenses, naval stations, aerodromes and other military objects within the rear boundaries of battle fronts, in operational zones of active fleets, in the near-front zones of railways and motor ways in the period of the GPW, and also crewmembers of ships of cargo fleet who were interned at the beginning of the GPW in harbors of other countries;
- 7) members of the families of perished (deceased) disabled veterans, participants of the GPW and combat veterans, members of families of personnel of groups of self-protection of point and crash crews of local

anti-aircraft defense, and members of families of perished workers of hospitals of Leningrad;

8) disabled individuals;

9) disabled children.

Monetary resources for financial provision of social support of federal benefit-entitled categories of citizens who live in the regions, are remitted from the federal budget to the regions in the form of interregional transfers and subventions on the basis of calculation of requests taking into account the number of citizens having the right for a package of social service in part of pharmaceutical provision. So, *a list of benefit-entitled categories of population, a list of MD for these individuals are to be approved on the federal level, here, financing of this medicine assistance comes from the Federal budget resources* [2].

To note, this scheme is used for approval of «Program of Cost-Intensive Nosologies» on the federal level. The history of this program starts with Order of Ministry of Health and Social Development (MHSD) of the Russian Federation №159 of March 9, 2007 «On Measures for Provision of Separate Categories of Citizens with Necessary Medical Drugs» [4]. This statutory document excluded diseases that are most cost-intensive in terms of pharmaceutical provision (7 nosologies) from the program of provision with necessary medical drugs (PNMD program) that was based on the social insurance principle, and shifted them to direct financing from the Federal budget of the Russian Federation. In result, expensive medical drugs for therapy of these 7 cost-intensive nosologies were excluded from PNMD program.

On the basis of Order on MHSD, these nosologies were *hemophilia, mucoviscidosis, pituitary nanism, Gaucher disease, some malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, individuals after transplantation of organs and/or tissues*. Pharmaceutical provision of patients with these diseases, as it was mentioned

above, is realized from the Federal budget resources. The mentioned above Decree of Government of the Russian Federation №2738-p of December 10, 2018 [3] approved a new list of medical drugs for 2019 and also stated a list of medical drugs for PNMD program. It should be noted, on January 1, 2019, Federal law «On Amendments to FL ‘On Fundamentals of Health Protection of Citizens of Russian Federation’» adopted by the State Duma on July 26, 2018 and approved by the Federation Council on July 28, 2018, came into force according to which the list of cost-intensive diseases was supplemented with such nosologies as *hemolytic-uremic syndrome, juvenile arthritis with systemic debut, I, II, VI types mucoviscidosis*.

Financing of pharmaceutical provision of this category of benefit-entitled individuals is determined by the Program on the State Guarantees to Deliver Free Medical Care to the Citizens of the Russian Federation (Program of the State Guarantees, PSG). On December 10, 2018 Government of the Russian Federation approved PSG to deliver free medical care to the citizens of the Russian Federation for 2019 and for the planned period of 2020 and 2021 (approved by Enactment of Government of the Russian Federation №1506), which stated the following: «Financial support of purchase of medical drugs for treatment of individuals with hemophilia, mucoviscidosis, pituitary nanism, Gaucher disease, some malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic-uremic syndrome, juvenile arthritis with systemic debut, I, II, VI types mucoviscidosis, of individuals after transplantation of organs and/or tissues is to be provided from the budgetary allocations of the Federal budget according to the list of medical drugs formed in the established order and approved by Government of Russian Federation...»

In result, medical drugs for pharmaceutical provision of patients with cost-intensive

nosologies are purchased by Healthcare Ministry (HM) of the Russian Federation centrally and then distributed over the regions on the basis of the approved request. Thus, *both a list of cost-intensive nosologies and a list of medical drugs for treatment for these diseases are approved on the federal level; in turn, financing of this pharmaceutical provision is realized from the Federal budget.*

From the given examples it follows that provision with medical drugs according to the lists of MD approved on the federal level is out of budget resources of the Federal budget of the Russian Federation. On the contrary, pharmaceutical provision of benefit-entitled citizens on the regional level is based on another legislative framework with different principles.

Statutory regulation of pharmaceutical provision of benefit-entitled citizens on the regional level. On the basis of part 1 of Article 16 of FL «On Fundamentals of Protection of Health», the authorities of the governmental bodies of constituents of the Russian Federation in the health protection field are established [5]:

«1. Authorities of the governmental bodies of constituents of the RF in the sphere of health protection include:

...3) elaboration, approval and realization of the territorial PSG to deliver free medical care to the citizens of the Russian Federation including the territorial program of compulsory health insurance (CHI)...»

Here, in Article 81 the following is said about lists of MD and of population groups:

«2. Within the territorial PSG to deliver free medical care to the citizens of the Russian Federation, the governmental bodies of the constituents of the Russian Federation specify:

...5) a list of MD dispensed to the population in accordance with the List of groups of population and categories of diseases, in outpatient treatment of which medical drugs and medical products are dispensed

on prescription free of charge, and also in accordance with the List of groups of population, in outpatient treatment of which medical drugs are dispensed on prescription with fifty percent discount ...».

It is important to note that benefit-entitled groups of population specified in point 5 of part 1 of Article 81 of FL «On Fundamentals of Protection of Health», are referred to the so called ‘*regional beneficiaries*’. Despite this, the given point contains no indication that the «List of Groups of Population and Categories of Diseases» (of regional beneficiaries) is to be approved by Government of the Russian Federation, besides, there is no norm for approval of the list of MD for these purposes by Government of the Russian Federation.

It should be noted once again that on December 10, 2018 Government of the Russian Federation approved PSG to deliver free medical care to the citizens of the Russian Federation for 2019 and the planned period of 2020 and 2021 [6]. Section V «Financial Provision of the Program: states as follows:

«The following kinds of medical assistance are financed from the budgetary resources of the constituent entities of the Russian Federation:

...provision with MD according to the List of groups of population and categories of diseases, in outpatient treatment of which medical drugs and medical products are dispensed on prescription free of charge;

...provision with MD according to the List of groups of population, in outpatient treatment of which medical drugs are dispensed on prescription with fifty percent discount...»

Thus, *for medical assistance to regional beneficiaries in outpatient conditions, MD are purchased at the expense of the budget of a constituent of the Russian Federation.*

In its turn, section VIII of PSG «Requirements to Territorial Program in Part of Determination of Order, Conditions of Medi-

cal Care, Criteria of Availability and Quality of Medical Care» states the following:

«In part of determination of the order and conditions for rendering medical care, the Territorial program should include:

...a list of MD dispensed to the population according to the List of groups of population and categories of diseases, in outpatient treatment of which medical drugs and medical products are dispensed on prescription free of charge, and also according to the List of groups of population, in outpatient treatment of which medical drugs are dispensed on prescription with 50% discount; the List should be not less than the List of life-saving and essential MD approved by Decree of Government of the RF for the respective year with exclusion of MD used only in inpatient conditions...»

In territorial PSG to deliver free medical care to the citizens, these lists of MD for regional beneficiaries are supplements to the program. Thus, on the basis of FL «On Fundamentals of Protection of Health» and PSG, *the authorities of the constituents of the Russian Federation include formation of the mentioned above list of MD and financing of*

pharmaceutical provision in accordance with the given list.

However, Enactment of Government of the Russian Federation №890 of 30 July, 1994 «On Government Support of Development of Medical Industry and Improvement of Provision of Population and Medical Institutions with Medical Drugs and Medical Products (Enactment) approved in 1994 and last amended in 2002, is not cancelled [7]. The main goal of this regulatory document is development of pharmaceutical industry in the Russian Federation for improvement of provision of the population with medical drugs and medical products. Besides, this Enactment is also aimed at provision of healthcare institutions with medical drugs and medical products, although with ubiquitous introduction of the system of CHI, since 1994 medical drugs in medical institutions rendering inpatient medical assistance, are financed out of the funds of CHI.

In Supplement 1 to this Enactment, a list of groups of population and categories of diseases is stated in outpatient treatment of which the medical drugs and medical products are dispensed on prescriptions free of charge (Figure 1).

Social groups

- Participants of civil and GP wars
- Parents and wives of servicemen died in result of wounds...
- Veterans of combat operations in the territories of other countries
- Children of the first 3 years of life and children from multichild families under 6 years of age
- Disabled individuals of group I, non-working disabled individuals of group II, disabled children under 18 years of age
- Individuals exposed to irradiation

31 group of diseases

- | | |
|---|---|
| • Infantile cerebral paralyses | - Myocardial infarction |
| • Mucoviscidosis (ill children) | - Transplantation of organs and tissues |
| • Oncological diseases | - Diabetes |
| • Hematological diseases | - Pituitary nanism |
| • Tuberculosis | - Multiple sclerosis |
| • Systemic chronic severe skin diseases | - Mental diseases |
| • Bronchial asthma | - Schizophrenia and epilepsy |
| • Rheumatic fever and rheumatoid arthritis, | - AIDS, HIV-infected |
| systemic lupus erythematosus, | - Parkinson's disease... and others |
| • Bekhterev's disease | |

Fig. 1. A list of groups of population and categories of diseases in outpatient treatment of which the medical drugs and medical products are available on prescriptions free of charge

From the presented data it may be concluded that there exists a group of diseases in which a patient has the right for subsidized pharmaceutical provision on the regional level. Here, if the diagnosis made by the physician, differs from the given list of diseases, a possibility for subsidized provision remains if the patient belongs to one of the indicated social groups.

Besides, according to Supplement 2 to the given Enactment, a list of the population groups is approved in whose outpatient treatment the medical drugs are dispensed on doctor's prescription with 50% discount from free prices. These categories include:

- Pensioners receiving old-age pension, or a pension for disability or loss of breadwinner in minimal size.

- Working disabled individuals of group II, disabled individuals of group III recognized as unemployed according to the established procedure.

- Citizens (including temporarily directed or detached for service) participating in works for disaster control in Chernobyl APP in 1988-1990 in the exclusion zone or engaged in other works in Chernobyl APP; servicemen and reservists attracted to works for elimination of the consequences of Chernobyl disaster in these years irrespective of the dislocation and the kind of works performed, and also representatives of senior officers and enlisted soldiers of the internal affairs bodies serving in the exclusion zone in 1988-1990.

- Individuals who suffered political repressions in the form of imprisonment, exile, expel, dispatch to special settlements, engagement in forced labor in conditions with limitation in freedom including participation in the 'working columns of NKVD', other limitations of the rights and freedoms including unjustified certification, with later rehabilitation; representatives of repressed nations subjected to repressions in the territory of the Russian Federation who suffered repressions

on the national or other ground; individuals recognized as suffered from political repressions including representatives of repressed nations subjected to repressions in the territory of the RF on the national or other ground.

- Servicemen including those transferred to the reserve (retirement) who were doing service in the period from June 22, 1941 to September 3, 1945 in the military posts, military establishments, military educational institutions not included in the active army, and awarded the medal «For the Victory over Germany in the Great Patriotic War 1941-1945» or «For the Victory over Japan».

- Individuals working in the period of GPW in the anti-aircraft defense objects, in local anti-aircraft objects, engaged in building of defenses, naval stations, aerodromes and in other military objects within the rear boundaries of battle fronts, in the near-front zones of railways and motor ways, and also crewmembers of ships of cargo fleet who were interned at the beginning of the GPW in harbors of other countries; individuals attracted by the local authorities to collection of munitions and demining of territories and objects in the years of the GPW.

- Individuals who were working in the rear in the period from June 22, 1941 to May 9, 1945 for not less than 6 months, excluding the period of work in temporarily occupied territories of the USSR or individuals who worked for less than six months and were awarded orders and medals of the USSR for selfless work in the years of the GPW.

It should be noted that in the PSG for rendering free medical care to citizens for 2019 and for the planned period of 2020 and 2021 in the section «Program Financial Support» is it said: «Provision of citizens with MD registered in the established order in the territory of the RF for treatment of life-threatening and chronic progressing rare (orphan) diseases leading to shortening of patient's life or to disability, included into the

list, is realized out the budgets of the constituents of the Russian Federation ...» [6].

This list was approved by Enactment of Government of the Russian Federation №403 of 26 April, 2012 «On the Order of Management of the Federal Register of Indi-

viduals Suffering from Life-Threatening and Chronic Progressing Rare (Orphan) Diseases Leading to Shortening of Patient's Life or to Disability, and of its Regional Segment» [8] which includes 24 diseases (List-24) (Table 1).

Table 1

Life-Threatening and Chronic Progressing Rare (Orphan) Diseases Leading to Shortening of Patient's Life or to Disability

№	Nosological Form	Code in ICD-10
1.	Hemolytic-uremic syndrome	D59.3
2.	Paroxysmal nocturnal hemoglobinuria (Marchiafava-Micheli disease)	D59.5
3.	Aplastic anemia not otherwise specified	D61.9
4.	Hereditary deficit of factors II (fibrinogen), VII (labile), X (Stuart-Prower)	D68.2
5.	Idiopathic thrombocytopenic purpura (Evans syndrome)	D69.3
6.	Defect in complement system	D84.1
7.	Premature puberty of central genesis	E22.8
8.	Disorders in metabolism of aromatic amino acids (classic phenylketonuria, other kinds of hyperphenylalaninemia)	E70.0, E70.1
9.	Tyrosinemia	E70.2
10.	'Maple syrup' disease	E71.0
11.	Other kinds of disorders in amino acid metabolism with branched chain (isovaleric acidemia, methylmalonic acidemia)	E71.1
12.	Disorders in fatty acid metabolism	E71.3
13.	Homocystinuria	E72.1
14.	Glutaricaciduria	E72.3
15.	Galactosemia	E74.2
16.	Other sphingolipidoses (Anderson Fabry disease, Niemann-Pick disease)	E75.2
17.	Mucopolysaccharidosis, type I	E76.0
18.	Mucopolysaccharidosis, type II	E76.1
19.	Mucopolysaccharidosis, type VI	E76.2
20.	Acute intermittent (hepatic) porphyria	E80.2
21.	Disorders in copper metabolism (Wilson disease)	E83.0
22.	Imperfect osteogenesis	Q78.0
23.	Pulmonary (arterial) hypertension (idiopathic) (primary)	I27.0
24.	Juvenile arthritis with systemic debut	M08.2

Note: ICD-10 – the 10th revision of the International Statistical Classification of Diseases and of Related Health Problems

As it was noted above, Enactment of Government of the Russian Federation №1390 of November 20, 2018 «On Amendments to Some Enactments of Government of the Russian Federation Concerning Improve-

ment of Pharmaceutical Provision» (came to force on January 1, 2019) added five diseases (hemolytic-uremic syndrome, juvenile arthritis with systemic debut, I, II, VI types mucoviscidosis) from the List-24 to the list of

cost-intensive nosologies f [9].

Conclusion

Thus, today the statutory regulatory base is established that controls pharmaceutical provision of benefit-entitled citizens both on the federal and regional levels. These regulatory mechanisms permit patients to receive life-saving medical therapy. Here it should be noted that the obligatory condition for receiving this assistance is a certain diagnosis or belonging to a certain social status (for example, a specific group of disability). Far not all patients are included in the list of benefit-entitled categories of citizens.

As a result, the pharmaceutical provision at the stage of primary medical care does

not envisage regulatory mechanisms for such groups. A vivid example is patients with rare diseases not included into the List-24. Often, due to absence of the regulatory substantiation, pharmaceutical provision is obtained only after passing through different juridical authorities. This is associated with long time periods, while treatment is required immediately after the diagnosis is established.

So, the existing statutory regulation of the healthcare needs further improvement. It is indisputable that this is a long and painstaking process associated with deficit of budgetary funds due to costly and long-term therapy. However, life and health of citizens of the Russian Federation depend on its realization.

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Дополнительная информация [Additional Info]

Источник финансирования. Бюджет ФГБОУ ВО Рязанский государственный медицинский университет им. акад. И.П. Павлова Минздрава России. [Financing of study. Budget of Ryazan State Medical University.]

Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, о которых необходимо сообщить в связи с публикацией данной статьи. [Conflict of interests. The authors declare no actual and potential conflict of interests which should be stated in connection with publication of the article.]

Участие авторов. Нагибин О.А. – сбор и обработка материала, написание и редактирование текста, Манухина Е.В. – сбор и обработка материала, написание текста, Комаров И.А. – концепция статьи, редактирование. [Participation of authors. O.A. Nagibin – collection and processing of material, writing and editing of text, E.V. Manukhina – collection and processing of material, writing of text, I.A. Komarov – the concept of article, review.]

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Цитировать: Нагибин О.А., Манухина Е.В., Комаров И.А. Нормативно-правовое регулирование льготного лекарственного обеспечения в Российской Федерации // Российский медико-биологический вестник имени академика И.П. Павлова. 2019. Т. 27, №4. С. 520-529. doi:10.23888/PAVLOVJ2019274520-529

To cite this article: Nagibin OA, Manukhina EV, Komarov IA. Statutory regulation of subsidized pharmaceutical provision in Russian Federation. *I.P. Pavlov Russian Medical Biological Herald.* 2019;27(4):520-9. doi:10.23888/PAVLOVJ2019274520-529

Поступила/Received: 16.09.2019

Принята в печать/Accepted: 16.12.2019