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## Provision of Medicines to Russian Citizens at the Expense of the Federal Budget: Features and Challenges

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**Abstract.** Despite the large number of government programs aimed at providing quality medical care and medication to certain categories of citizens, we are faced with significant shortcomings. In this article, the authors will examine the key Russian healthcare programs funded through federal subsidies and evaluate their pros and cons. The authors explore the legal regulations that govern these programs and identify the specific categories of citizens they are designed for.

**Keywords:** federal subsidy, medication provision, subsidized medication provision for the population, medical care

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### A brief overview of the main directions of preferential drug provision

Drug provision in the provision of medical care is carried out in a hospital or outpatient setting. If we consider outpatient admission, then it is carried out within the framework of preferential drug provision for citizens for free or at the expense of citizens' own funds. To ensure the latter, the state regulates prices for VED (vital and essential medicines) [1]. In a hospital setting, free medical care is also provided, funded from the funds of the healthcare system under the compulsory

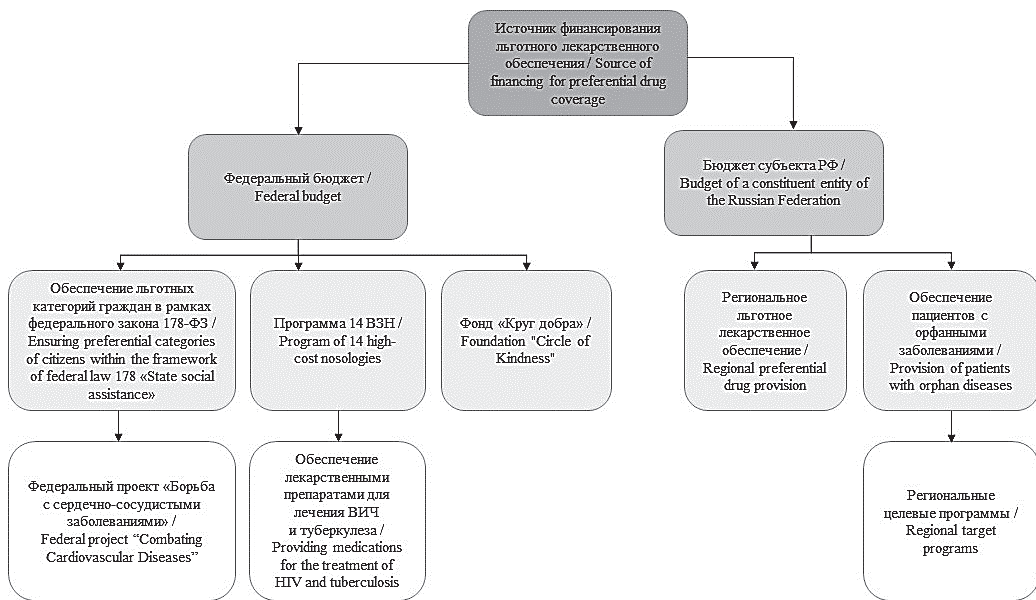
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health insurance policy or under the VMP program — high-tech medical care, etc. Preferential drug provision for citizens and services within the framework of compulsory medical insurance and VMP is carried out thanks to the program of state guarantees [2].

Considering the main directions of preferential drug provision more specifically, we will divide them as follows: the federal budget and the budget of the subject of the Russian Federation (Figure).



Main directions of preferential drug provision

Source: compiled by the authors

The federal benefit is provided within the framework of Federal Law No. 178-FZ [3], the program 14 VZN (14 high-cost nosologies) [4], the list of which is defined by Federal Law No. 323-FZ dated 11/21/2011 Decree of the Government of the Russian Federation dated November 26, 2018, No. 1416 “On the basics of public health protection”, as well as the foundation “The Circle of Goodness”. It is important to say a few more words about the 14 VZN program, since it ensures, for its part, the availability of medicines for the treatment of HIV and tuberculosis. As for the Circle of Goodness Foundation, it is a fund to support children with severe life-threatening and chronic diseases, including orphan (rare) ones. The decree on the creation of the fund was signed by Russian President on January 5, 2021. The Foundation provides thousands of children with the necessary treatment and provision of expensive drugs that are not registered in Russia. Funds to the Circle of Good come from increased personal income tax for citizens

whose incomes exceed 5 million rubles per year [5]. It should also be noted that within the framework of Federal Law No. 178-FZ, an important Federal project “Combating cardiovascular Diseases” is being implemented, which provides for the prevention of cardiovascular diseases by reducing tobacco and alcohol consumption, as well as motivating citizens to exercise and proper nutrition. According to the project administrators on the official website, it is planned to re-equip at least 140 vascular centers and 469 primary vascular departments with modern equipment [6].

Let’s briefly consider the budget of a constituent entity of the Russian Federation within the framework of the topic under review. It is divided into regional preferential drug provision within the framework of Federal Law 178-FZ “On State Social Assistance”, namely Chapter 2 “State social assistance provided in the form of providing citizens with a set of social services” and provision for patients with orphan diseases, which is regulated by regional target programs.

### **Medical provision of citizens at the expense of the federal budget**

The program for providing necessary medicines is carried out from a federal benefit within the framework of the implementation of Federal Law 178-FZ “On State Social Assistance”. Categories of citizens who are entitled to such assistance:

- people with disabilities (all groups);
- children with disabilities;
- participants and invalids of the Great Patriotic War;
- former minor prisoners of concentration camps;
- persons awarded the badge “To a resident of besieged Leningrad”;
- combat veterans;
- persons exposed to radiation at the Chernobyl nuclear power plant.

The source of financing in this case is the federal budget, namely subventions and inter-budgetary transfers. The amount of funding depends on the number of citizens in the Federal Register maintained by the Pension Fund of Russia (PFR). The amount is calculated using the following formula:

$$\Sigma = \text{number of citizens} \times \text{cost standard} \times 12 \text{ months.}$$

Even though this program is aimed at providing high-quality and timely assistance to many people in need, it has several significant problems, which we will consider in detail later. So, the problems of the program of providing necessary medicines:

- the absence of the “insurance principle” of the program, i.e. the possibility of monetization of benefits;
- insufficient funding, which is confirmed by a low standard — about 1008 rubles per month;
- “severe patients” remain in the program;
- provision only according to the list of VED.

We will also take a closer look at the program for providing medicines for the treatment of 14 high-cost nosologies, which was also mentioned earlier, but in a more “concise form”. It should be noted that the program has been implemented since 2008, then it included only 7 nosologies, in 2019 5 more nosologies were added, and in 2020 2 more nosologies were added to the program. We will indicate a complete list of these nosologies:

- hemophilia;
- cystic fibrosis;
- pituitary nanism;
- ZNO (malignant neoplasms) of lymphoid, hematopoietic and related tissues;
- multiple sclerosis;
- conditions after organ and/or tissue transplantation;
- Gaucher disease (this disease can lead to severe or disabling symptoms that may be irreversible [7]);
- hemolytic-uremic syndrome;
- juvenile arthritis with systemic onset;
- mucopolysaccharidosis of type I, II and VI;
- aplastic anemia, unspecified;
- hereditary deficiency of factors II (fibrinogen), VII (labile) and X (Stewart — Prauer).

The categories of citizens who are provided with assistance under this program are persons included in the Federal Register of 14 VZN (federal or regional benefit). However, currently, in accordance with the Decree of the Government of the Russian Federation dated 30.07.1994 N 890 (ed. dated 02/14/2002) “On state support for the development of the medical industry and improving the provision of medicines and medical devices to the population and healthcare institutions” [8] a beneficiary who retains the right to a social package under the ONLS program (“Provision of necessary medicines”) is simultaneously entitled to a regional benefit in accordance with a social group (disabled people 1 and 2 non-working group) or in accordance with the categories of diseases on the list in accordance with Resolution No. 890. At the same time, due to the limited financing of the regional benefit program, it is recommended to stick to one benefit. This requires an individual review and assessment of each case by sending a request to the Department of Health (DOH).

When implementing the program of providing medicines for the treatment of 14 high-cost nosologies, the source of funding is also the federal budget, including a subvention to the subjects of the Russian Federation for logistics. Since in this case there is a personalized need for assistance, the regions provide protection for applications. This is due to the fact that in practice, the allocated state budget for the year is spent much faster and the risk increases that the patient may be left without the prescribed medicines due to a shortage of funds. The All-Russian Union of Patients has repeatedly expressed its concerns that doctors may be forced to be guided not by medical, but by economic considerations when prescribing treatment due to lack of funding [9]. Let’s clarify that centralized purchases are carried out by the federal state institution “Federal Center for Planning and Organization of Drug Provision for Citizens” of the Ministry of Health of the Russian Federation. On their official

website, you can find detailed information on concluded government contracts for the supply of medicines for the current period.

Finally, let's look at the problems of the drug supply program for the treatment of 14 high-cost nosologies. There are several important problems here:

- newly identified patients;
- there may be delays in deliveries (44-FZ);
- provision of generics (more budget-friendly analogues of original medicines);
- forced purchases from the Republic of Belarus;
- redistribution of medicines between regions, for example, in 2022, medicines worth about 2 billion rubles were redistributed, but at the same time additional costs and logistical difficulties arose.

There is another important federal project aimed at combating cardiovascular diseases. Thanks to this project, it is possible to provide outpatient care for patients who suffered:

- an acute cerebrovascular accident;
- a myocardial infarction;
- coronary artery bypass grafting;
- coronary artery angioplasty with stenting;
- catheter ablation for cardiovascular diseases.

This direction has some special features. It has been implemented only since 2020. Citizens who do not receive assistance under the federal benefit have the right to security, and the period for providing patients varies from 1 year to 2 years. The amount of funding for the program is about 10 billion rubles. For this category of patients, the provision of medicines for free during the year is provided (a list of medicines consisting of 31 names of INN (international nonproprietary names) has been approved). This became possible thanks to the approval by the Ministry of Health of the Russian Federation of the order of the Ministry of Health of the Russian Federation dated January 9, 2020, No. 1h [10]. Previously, patients could receive the necessary medicines for free, only during their stay in the hospital. The purchase of medicines is carried out at the expense of regional subsidies from the federal budget. Now let's look at the problems faced by the state in the implementation of this project. In 2020–2021 a number of adverse situations occurred: the late approval of the list of medicines, COVID-19, a problem with medical examination, as a result, large residues of medicines that could not be sold to the needy population. Also, the late issuance of preferential prescriptions (the continuity of treatment in the outpatient clinic and the epidemiological situation) had a negative impact. As a minus, we can also note the limitation of the program in terms of the list of diseases and, accordingly, medicines. However, according to the Decree of the Government of the Russian Federation dated 05/06/2022 No. 823 “On Amendments to Appendix No. 8 to the State Program of the Russian Federation ‘Development of Healthcare’” [11] and Order No. 639n dated September 29, 2022 (amendments to the Order of the Ministry of Health of the Russian Federation dated 09/24/2021 No. 936n) [12] the list of medicines was expanded by 8 INN

for the treatment of 5 conditions in combination with chronic heart failure with a reduced ejection fraction (the disease is characterized by a marked decrease in the contractility of the left ventricle. The left ventricular ejection fraction is less than 40%), as well as the possibility of redistributing drug residues for patients at the expense of the budget of the subject of the Russian Federation.

Finally, the last program that we will consider in the framework of this topic is the drug supply program through the Circle of Goodness Foundation. Within its framework assistance is provided to:

- children under the age of 18 + 1 year for continuing treatment;
- children suffering from orphan diseases;
- patients undergoing pathogenetic treatment registered in the Russian Federation, Europe, and the USA. Three drugs for the pathogenetic treatment of spinal muscular atrophy (SMA) have been registered in the Russian Federation: Nusinersen (Spinraza), Risdiplam (Eurisdi) and Onasemnogen abeparvovek (Zolgensma). The drugs are approved in the USA and Europe.

In addition to the above, the fund provides medicines, both registered and unregistered in the Russian Federation, medical devices, as well as medical care in Russia and abroad. The purchase of drugs is carried out by the Ministry of Health of the Russian Federation (only medicines registered in the Russian Federation) and the Circle of Goodness Foundation. Thanks to the fund, 76 severe life-threatening and chronic diseases are being treated, including rare (orphan) diseases and 14 diseases, the provision of medicines for which is carried out by the Circle of Good Foundation in accordance with Part 9.2 of Article 83 of Federal Law No. 323-FZ dated 11.21.2011 “On the Basics of protecting the health of Citizens in the Russian Federation”, and other medical assistance on request [13]. The Fund purchases medicines and medical products in over 60 names and 9 names, respectively, as well as technical rehabilitation equipment. The Foundation can be proud that over 5,150 children have already been provided with the necessary medicines and medical services, and over 95 billion rubles have been allocated for medical care and the purchase of medicines and medical devices.

## Conclusion

Thus, the state strives to create quite a lot of favorable conditions for providing categories of citizens who really need medical and medicinal care. There are many different federal and regional social support programs, but we do not always see that the implementation of these programs is successful. Problems can arise for various reasons, for example, due to sudden circumstances (COVID-19) or an increase in the number of beneficiaries, which increases the financial burden on both the federal and regional budgets, which in turn requires a rapid revision of the terms of preferential drug provision. Unfortunately, this is not always feasible as it takes a lot of time to analyze the problems that have arisen, make decisions and implement them. Nevertheless,



the vast majority of citizens of different ages and categories receive the necessary medical care and medicines, which allows them to consistently maintain a good standard of living and improve their health, and in some cases increase their life expectancy.

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## Лекарственное обеспечение граждан РФ за счет средств федерального бюджета: особенности и проблемы

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**Аннотация.** Несмотря на большое количество государственных программ, направленных на реализацию качественного медицинского и лекарственного обеспечения особых категорий граждан, мы сталкиваемся с тем, что они имеют существенные недостатки. В данной статье рассмотрены ключевые программы в сфере здравоохранения в РФ, которые финансируются



за счет федеральной льготы, а также оцениваются их плюсы и минусы. Авторы показывают, какими нормативно-правовыми актами регулируются рассмотренные программы и для каких категорий граждан они предусмотрены.

**Ключевые слова:** федеральная льгота, лекарственное обеспечение, льготное лекарственное обеспечение населения, медицинская помощь

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