



ANALYSIS OF THE IMPLEMENTATION OF THE FEDERAL ASSURANCE PROGRAM OF SUPPORTING BENEFICIARIES WITH INDISPENSABLE MEDICINAL PREPARATIONS IN THE SUBJECTS OF THE RUSSIAN FEDERATION

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The aim of the research was to study the main indicative indicators of the implementation of The Federal Program “Provision of Essential Medicines” in 20 constituent entities of the Russian Federation based on the results of 2018 and 2019.

Materials and methods. The analyzed data were provided on the basis of the request cards specially designed by the health authorities of 20 subjects of the Russian Federation located in seven federal districts.

Results. It has been established that the funds allocated to the constituent entities of the Russian Federation, directly depend on the number of beneficiaries who retained the right to receive state social assistance in the form of a set of social services. These funds also correlate with the indicator “Population of the subject of the Russian Federation”. In all the studied constituent entities of the Russian Federation, more than 50% of the total number of people who retained the right to preferential drug provision in 2018–2019, asked for medical help as part of the program “Provision of Essential Medicines”. Herein, in the constituent entities of the Russian Federation, the average cost of one prescription amounted to 1,107.2 rubles in 2018 and 1,297.2 rubles in 2019. The estimated indicator “The average actual expenditures per 1 citizen entitled to state social assistance in the form of a set of social services, amounted to 1,723.0±90.2 rubles in 2018 and 1,526.8±80.5 rubles in 2019, which is higher than the approved input normative (823.3 rubles and 861.8 rubles in 2018 and 2019, respectively).

Conclusion. Thus, an excess of average actual expenditures per citizen entitled to state social assistance in the form of a set of social services, was notified over the standards established by the decrees of the Government of the Russian Federation. The revealed discrepancy between the normative and actual expenditures can also be an indirect confirmation of the fact that the most needy beneficiaries with chronic diseases remained in the program “Provision of Essential Medicines”.

Keywords: assurance program of supporting beneficiaries with indispensable medicinal preparations, federal beneficiaries, medicine assistance

Abbreviations: GSA – government social assistance; MA – medicine assistance; MP – medicinal preparation; SSS – a set of social services; NIA – No information available; IA – inapplicable; SIMP – supporting with indispensable medicinal preparations.

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АНАЛИЗ РЕАЛИЗАЦИИ ФЕДЕРАЛЬНОЙ ПРОГРАММЫ ОБЕСПЕЧЕНИЯ НЕОБХОДИМЫМИ ЛЕКАРСТВЕННЫМИ ПРЕПАРАТАМИ В СУБЪЕКТАХ РОССИЙСКОЙ ФЕДЕРАЦИИ

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Цель. Изучить основные индикативные показатели реализации федеральной программы ОНЛП в 20 субъектах РФ по итогам 2018 и 2019 гг.

Материалы и методы. В исследовании анализировались данные, предоставленные на основании специально разработанных карт-запросов органами управления здравоохранением 20 субъектов РФ семи федеральных округов.

Результаты. Установлено, что объем выделенных субъектам РФ финансовых средств напрямую зависит от количества льготополучателей, сохранивших право на получение государственной социальной помощи (ГСП) в виде набора социальных услуг (НСУ), а также коррелирует с показателем «Численность населения субъекта РФ». Во всех исследуемых субъектах РФ более 50% граждан из общего числа лиц, сохранивших право на льготное лекарственное обеспечение, в 2018–2019 гг. обращались за лекарственной помощью в рамках программы ОНЛП, при этом в целом по субъектам РФ средняя стоимость одного рецепта составила 1107,2 руб. в 2018 г. и 1297,2 руб. в 2019 г. Расчетный показатель «Средняя сумма фактических затрат на 1 одного обратившегося гражданина, имеющего право на ГСП в виде НСУ» составила 1723,0±90,2 руб. в 2018 г. и 1526,8±80,5 руб. в 2019 г., что выше утвержденных нормативов (823,3 руб. и 861,8 руб. в 2018 и 2019 гг.).

Заключение. Таким образом, отмечено превышение средних фактических затрат на одного гражданина, имеющего право на ГСП в виде НСУ, над установленными постановлениями Правительства РФ нормативами. Выявленное несоответствие может являться косвенным подтверждением того, что в программе ОНЛП в основном остались самые нуждающиеся льготополучатели, имеющие хронические заболевания.

Ключевые слова: программа обеспечения необходимыми лекарственными препаратами, федеральные льготополучатели, льготное лекарственное обеспечение

Сокращения: ГСП – государственная социальная помощь, ЛЛО – льготное лекарственное обеспечение, ЛП – лекарственный препарат, НСУ – набор социальных услуг, нд – нет данных, нп – не применимо, ОНЛП – обеспечение необходимыми лекарственными препаратами.

INTRODUCTION

One of the main federal programs of medicine assistance (MA) is the assurance program of supporting beneficiaries with indispensable medicinal preparations (SIMP) in accordance with the standards of medical care through federal budget subsidies to the constituent entities of the Russian Federation (RF) [1–4]. The main aim of the program is to ensure a high-quality and timely provision of federal beneficiaries with medicinal preparations. The Program of supporting with indispensable medicinal preparations (SIMP), is implemented on the principle of social insurance, which involves the consumption of a set of social services (SSS) including drug

provision. This Program concerns not all the citizens assigned to the persons entitled to benefits, but only those who have a real need for MPs on account of their diseases [2]. At the same time, since 2006, federal beneficiaries have been legally provided with the possibility of refusing the SSS and receiving a monthly cash payment [2, 4, 5].

The functioning of the medicine assistance (MA) system is of high social significance, as it helps to maintain beneficiaries' health's and increases the level and quality of their lives. However, at present, no more than 20% of residents of the Russian Federation (mostly the citizens with chronic diseases) have retained the right to receive

benefits in kind under the SIMP program. Consequently, in the regions of the Russian Federation, there is a shortage of financial resources that can be used to purchase the necessary drugs for federal beneficiaries [1, 4, 5].

An important indicator of the SIMP program implementation in the constituent entities of the Russian Federation, is the amount of allocated funding; the proportion of the patients who have retained the right to receive the government social assistance (GSA) in the form of a set of social services; the proportion of the citizens who have applied for medical care under the SIMP program, actual costs per one beneficiary who have applied (taking into account pharmaceutical services); the number of prescriptions written; the average cost of one prescription. The indicators of the SIMP program implementation in various constituent entities of the Russian Federation have some differences, which are due to the structure of the beneficiaries' morbidity, the amount of funding, the range of purchased drugs, etc. [3].

THE AIM of the research was to study the main indicative indicators of the federal SIMP program implementation in 20 constituent entities of the Russian Federation based on the results of 2018 and 2019.

MATERIALS AND METHODS

A multicenter study was carried out on the territory of 20 constituent entities of the Russian Federation. The choice for the analysis of the Russian Federation constituent entities was due to the fact that they have different demographic, socio-economic and infrastructural indicators. Taking into account the fact that administrative and territorial structure of the Russian Federation is represented by 85 constituent entities, the sample of our study included about 24% of the country's regions. Based on the analysis of regional characteristics, the situation in the medicine assistance (MA) sector of federal beneficiaries of various federal districts of the Russian Federation, has been characterized.

The data analysis was carried out on the basis of request cards, specially developed by the government health agencies of 20 constituent entities of the Russian Federation in seven federal districts, including:

- 5 constituent entities of the Russian Federation of the Central Federal District: Belgorod, Voronezh, Smolensk, Tula regions; the city of federal significance Moscow;
- 4 constituent entities of the Russian Federation of the Volga Federal District (VFD): Kirovskaya, Samaraskaya oblasts, Chuvashskaya republic, Republic of Tatarstan;
- 4 constituent entities the Far Eastern Federal District (FEFD) of the Russian Federation: the Republic of Sakha (Yakutia), Sakhalin Region, Khabarovsk Territory, Zabaikalsky Territory;
- 2 constituent entities of the Russian Federation in the Southern Federal District (SFD): Astrakhan Region, Krasnodar Territory;

- 2 constituent entities of the Russian Federation of the Ural Federal District: Chelyabinsk, Kurgan regions;
- 2 constituent entities of the Russian Federation of the Siberian Federal District (SFD): Omsk Region, Altai Territory;
- 1 constituent entity of the Russian Federation of the Northwestern Federal District (NWFd): The Republic of Karelia.

The request cards were developed at the Department of Management and Economics of Pharmacy at Samara State Medical University (the Ministry of Health of Russia) and in structure, they corresponded to the objectives of the study.

The research program included a comparative assessment of the following data:

- the total amount of financing in the analyzed constituent entities of the Russian Federation (including the cost of pharmaceutical services);
- the number of beneficiaries who have retained the right to receive the government social assistance (GSA) in the form of a set of social services (SSS);
- the total amount of costs associated with medicinal products delivered up to beneficiaries;
- the average proportion of beneficiaries in the total number of the Russian Federation constituent entities;
- the proportion of beneficiaries who have retained the right to receive the government social assistance (GSA) in the form of a set of social services (SSS);
- the indicator of the appealability of beneficiaries for medical care under the SIMP program;
- the number of prescriptions under the SIMP program;
- the actual costs per one beneficiary who have applied (taking into account pharmaceutical services);
- the average cost of one prescription in the Russian Federation constituent entities.

In the analysis, the following kinds of methods were used: comparative, structural, logical and content. The statistical processing of the numerical material was carried out by methods of descriptive statistics, using the statistical software package IBM SPSS Advanced Statistics 24.0 No. 5725-A54 (IBM, USA). The statistical patterns were revealed in the generalized data. As for methods of generalization, they were represented by grouping and calculating of the summary indicators for the population as a whole, and for the selected groups. For all quantitative features, the arithmetic mean and root-mean-square (standard) errors of the mean were estimated, as well as the median, the determination of 10% and 90% percentiles. In the text, the descriptive statistics are presented as $M \pm SD$, where M is the mean, and SD is the standard deviation for a normal distribu-

tion of a trait, or Med for an abnormal distribution of a trait. To determine the nature of the distribution of the obtained data, the Kolmogorov-Smirnov test with the Lilliefors normality test, and the Shapiro-Wilk test were used. The Lilliefors test is a normality test. To assess the relationship between the indicators, the Pearson correlation coefficient (r -Pearson) was used. The differences were considered significant if the probability was more than 95% ($p < 0.05$)

RESULTS

To study the features of the federal SIMP program implementation in the Russian Federation, a comparative analysis of the main indicative indicators of the program has been carried out. Herewith, the results of studying 20 Russian Federation constituent entities based on 2018 and 2019, have been used. The analysis showed that the amount of the funds allocated to the Russian Federation constituent entities, depends on the number of the beneficiaries who have retained the right to receive the government social assistance (GSA) in the form of a set of social services (SSS) (r -Pearson in 2018 and 2019 – 0.95 and 0.94, respectively, $p < 0.05$), and also correlated with the indicators “Population of the constituent entity of the Russian Federation” (r -Pearson in 2018 and 2019 was 0.98, $p < 0.05$) (Tables 1, 2).

Table 1 shows that the amount of funding for the SIMP program implementation in the studied regions of the Russian Federation, varied from 204.8 to 7651.6 million rubles in 2018 and from 241.8 to 7744.8 million rubles in 2019, while the maximum amount of funding (more than 1 billion rubles) was in Moscow (the city of federal significance), Krasnodar Territory, the Republic of Tatarstan. In total, in 2019, the volume of MA financing, including pharmaceutical services, in the studied constituent entities of the Russian Federation amounted to 18.57 billion rubles, which was 0.5% more than in 2018 (18.48 billion rubles). The average change in the volume of financing in the constituent entities of the Russian Federation in 2019 relative to 2018, was (mean \pm root-mean-square error) $3.13 \pm 1.10\%$.

Based on the data presented in Table 2, it can be concluded that the amount of MPs costs under the SIMP program, was directly related to the total amount of funding for the program (r -Pearson 0.94 in 2018 and 0.95 in 2019, $p < 0.05$), the indicators “The number of beneficiaries who have retained the right to receive the government social assistance (GSA) in the form of a set of social services” and “The population of the constituent entity of the Russian Federation”. In total, under the SIMP program, federal beneficiaries received MPs at the amount of 17.35 billion rubles in 2018 and 17.57 billion rubles in 2019. In 2018, the median of MPs costs amounted to RUB 487.0 million rubles (the range within 159.8–6,181.8 million rubles), in 2019 – 452.95 million rubles (the range within 151.5–4,912.1 million rubles). The average change in this indicator in 2019 relative to 2018 was $+7.33 \pm 3.01\%$. The

maximum values were also reported in Moscow, Krasnodar Territory and the Republic of Tatarstan.

The maximum number of federal beneficiaries (over 100,000 people), live in the same constituent entities of the Russian Federation that had the largest amount of funding for the program. The minimum number of federal beneficiaries (no more than 20 thousand people), is registered in the following constituent entities of the Russian Federation: Sakhalin and Astrakhan regions, Republic of Karelia (these regions had the smallest amounts of funding). In total, the number of federal beneficiaries in 2019 compared to 2018, practically did not change (-0.03%), the average change in the studied constituent entities of the Russian Federation was $-1.29 \pm 0.95\%$. The maximum reduction in the number of federal beneficiaries was recorded in the Kurgan region (-14.41%), the largest increase in the number of beneficiaries was in the Voronezh region ($+6.65\%$).

When analyzing the proportion of federal beneficiaries in the total population of the constituent entity of the Russian Federation, it was determined that the median value of this indicator was 2.6% (10th and 90th percentiles 2.2 and 3.1%, respectively) in 2018 and 2.5% (10th and 90th percentiles 2.2 and 3.0%, respectively) in 2019 (Table 3). The largest proportion of federal beneficiaries in the structure of the population of the Russian Federation constituent entity (more than 3.0%) is reported in the Republic of Sakha / Yakutia, Moscow and the Republic of Karelia.

Table 3 shows that the proportion of the persons who have retained the right to receive the government social assistance (GSA) in the form of a full set of social services (SSS), differs significantly in separate constituent entities of the Russian Federation, with the median being 27.3% (10th and 90th percentiles 18.6 and 62.8%, respectively) in 2018 and 25.2% (10th and 90th percentiles 17.4 and 59.8%, respectively) in 2019. More than 50% of citizens eligible for medicine assistance under the SIMP program, have retained the right to receive benefits in kind in the Republic of Sakha/Yakutia, Smolensk and Sakhalin regions. The lowest value of this indicator was reported in the Belgorod Region (13.6% in 2019). In general, in the analyzed period, the proportion of beneficiaries in the total population and the proportion of the persons who have retained the right to receive the government social assistance (GSA) in the form of a set of social services (SSS), has not undergone significant changes in the studied constituent entities of the Russian Federation.

More than 50% of the citizens from the total number of persons, who have retained the right to medicine assistance in 2018–2019, appealed to a medical organization, they were prescribed MPs under the SIMP program (Table 3). According to the indicator “Appealability of federal beneficiaries for receiving medicine assistance under the SIMP program”, several typological groups of the constituent entities of the Russian Federation can be distinguished:

Table 1 – Comparative analysis of the quantitative characteristics of the federal SIMP program implementation in the constituent entities of the Russian Federation in 2018–2019

| No. | Constituent entity of the Russian Federation | Allocated funds for a year, mln. RUB | | | Medicinal preparations distributed at the amount of mln. RUB (excluding pharmaceutical services) | | | Number of beneficiaries who have retained the right to receive medicine assistance according to SIMP program (at end of reporting period), ths. people | | |
|-----|--|--------------------------------------|------------------|-------------------------|--|------------------|--------------------------|--|-----------------|-------------------------|
| | | 2018 | 2019 | Change compared to 2018 | 2018 | 2019 | Change compared to 2018 | 2018 | 2019 | Change compared to 2018 |
| 1 | Moscow | 7,651.60 | 7,744.78 | 1.22% | 6,181.8 | 4,912.12 | -20.54% | 491.18 | 472.41 | -3.82% |
| 2 | Krasnodar Territory | 1,840.00 | 1,800.00 | -2.17% | NIA | NIA | IA | NIA | NIA | IA |
| 3 | Republic of Tatarstan; | 1,668.22 | 1,671.25 | 0.18% | 1,298.54 | 1,562.88 | 20.36% | 115.93 | 117.54 | 1.39% |
| 4 | Chelyabinsk region | 981.60 | 992.30 | 1.09% | 722.8 | 885.7 | 22.54% | 76.28 | 76.65 | 0.48% |
| 5 | Altai Territory | 784.60 | 786.10 | 0.19% | 633.4 | 689.5 | 8.86% | 59.12 | 58.80 | -0.53% |
| 6 | Omsk region | 686.70 | 675.20 | -1.67% | 572 | 612.9 | 7.15% | 51.39 | 51.39 | 0.00% |
| 7 | Voronezh region | 564.76 | 583.21 | 3.27% | 524.45 | 526.42 | 0.38% | 44.60 | 47.57 | 6.65% |
| 8 | The Republic of Sakha (Yakutia) | 553.20 | 505.57 | -8.61% | 487.01 | 424.5 | -12.84% | 38.57 | 39.66 | 2.80% |
| 9 | Belgorod region | 530.54 | 516.66 | -2.62% | 520.764 | 506.807 | -2.68% | 39.62 | 39.39 | -0.59% |
| 10 | Tula region | 495.20 | 478.20 | -3.43% | 418.2 | 481.4 | 15.11% | 36.90 | 36.40 | -1.36% |
| 11 | Khabarovsk Territory | 434.70 | 375.30 | -13.66% | 298.98 | 309.35 | 3.47% | 27.89 | 26.87 | -3.66% |
| 12 | Zabaikalsky Territory | 423.20 | 432.50 | 2.20% | 319.2 | 348.2 | 9.09% | 32.00 | 30.80 | -3.75% |
| 13 | Kirovskaya oblast | 410.80 | 402.69 | -1.97% | 398.04 | 378.99 | -4.79% | 31.86 | 31.37 | -1.53% |
| 14 | Kurgan region | 349.98 | 320.07 | -8.55% | 290.8 | 326.4 | 12.24% | 25.39 | 21.74 | -14.41% |
| 15 | Chuvashskaya republic | 344.21 | 309.65 | -10.04% | 207.3 | 243.9 | 17.66% | 24.54 | 23.52 | -4.17% |
| 16 | The Republic of Karelia | 287.68 | 267.30 | -7.08% | 178.06 | 224.91 | 26.31% | 20.13 | 19.96 | -0.85% |
| 17 | Smolensk region | 269.60 | 265.30 | -1.59% | 197.7 | 243.5 | 23.17% | 20.82 | 20.70 | -0.58% |
| 18 | Sakhalin region | 204.80 | 198.2 | -3.22% | 159.8 | 151.5 | -5.19% | 14.30 | 14.60 | 2.10% |
| 19 | Astrakhan region | NIA | 241.76 | IA | NIA | 203.52 | IA | NIA | 19.00 | IA |
| 20 | Samaraskaya oblast | NIA | NIA | IA | 923.2 | 910.31 | -1.40% | 70.44 | 69.48 | -1.35% |
| | Total | 18,481.39 | 18,566.04 | +0.46% | 17,346.34 | 17,574.10 | +1.31% | 1,762.07 | 1,761.54 | -0.03% |
| | Mean change | | | -3.13 ±1.10% | | | +7.33 ±3.01%* | | | -1.29 ±0.95% |

Note: NIA – No information available; IA – inapplicable; * – taking into account the actual volume of distribution in the Krasnodar Territory.

Table 2 – Correlation between indicators of the SIMP program implementation in 2018–2019

| Indicator | | Funds allocated for a year | Costs of dispensed MPs | Number of beneficiaries | Population | Proportion of patients who have retained the MA rights* | Appealability by results of the year** | Actual costs per month*** | Number of prescriptions | Average cost of one prescription**** |
|---|------|----------------------------|------------------------|-------------------------|------------|---|--|---------------------------|-------------------------|--------------------------------------|
| Funds allocated for a year | 2018 | 1.00 | 0.98 | 0.95 | 0.98 | 0.86 | 0.44 | 0.90 | 0.85 | 0.75 |
| | 2019 | 1.00 | 0.96 | 0.94 | 0.98 | 0.86 | 0.61 | 0.90 | 0.86 | 0.56 |
| Costs of distributed medicinal preparations | 2018 | 0.98 | 1.00 | 0.99 | 0.95 | 0.93 | 0.53 | 0.97 | 0.80 | 0.74 |
| | 2019 | 0.96 | 1.00 | 1.00 | 0.95 | 0.93 | 0.64 | 0.98 | 0.81 | 0.59 |
| Number of beneficiaries* | 2018 | 0.95 | 0.99 | 1.00 | 0.93 | 0.95 | 0.58 | 0.99 | 0.77 | 0.71 |
| | 2019 | 0.94 | 1.00 | 1.00 | 0.93 | 0.95 | 0.63 | 0.99 | 0.77 | 0.59 |
| Population | 2018 | 0.98 | 0.95 | 0.93 | 1.00 | 0.79 | 0.42 | 0.88 | 0.84 | 0.73 |
| | 2019 | 0.98 | 0.95 | 0.93 | 1.00 | 0.79 | 0.51 | 0.89 | 0.82 | 0.60 |
| Proportion of patients who have retained the MA rights* | 2018 | 0.86 | 0.93 | 0.95 | 0.79 | 1.00 | 0.60 | 0.96 | 0.67 | 0.66 |
| | 2019 | 0.86 | 0.93 | 0.95 | 0.79 | 1.00 | 0.74 | 0.95 | 0.69 | 0.52 |
| Appealability by results of the year** | 2018 | 0.44 | 0.53 | 0.58 | 0.42 | 0.60 | 1.00 | 0.61 | 0.51 | 0.14 |
| | 2019 | 0.61 | 0.64 | 0.63 | 0.51 | 0.74 | 1.00 | 0.61 | 0.53 | 0.44 |
| Actual costs per month*** | 2018 | 0.90 | 0.97 | 0.99 | 0.88 | 0.96 | 0.61 | 1.00 | 0.71 | 0.69 |
| | 2019 | 0.90 | 0.98 | 0.99 | 0.89 | 0.95 | 0.61 | 1.00 | 0.73 | 0.58 |
| Number of prescriptions | 2018 | 0.85 | 0.80 | 0.77 | 0.84 | 0.67 | 0.51 | 0.71 | 1.00 | 0.35 |
| | 2019 | 0.86 | 0.81 | 0.77 | 0.82 | 0.69 | 0.53 | 0.73 | 1.00 | 0.15 |
| Average cost of one prescription**** | 2018 | 0.75 | 0.74 | 0.71 | 0.73 | 0.66 | 0.14 | 0.69 | 0.35 | 1.00 |
| | 2019 | 0.56 | 0.59 | 0.59 | 0.60 | 0.52 | 0.44 | 0.58 | 0.15 | 1.00 |

Note: * – The number of beneficiaries who have retained the right to receive the government social assistance (GSA) in the form of a set of social services (SSS); ** – Appealability by results of the year (proportion of the citizens who have been prescribed MPs, out of the total number of persons who have retained the MA rights); *** – Taking into account pharmaceutical services

Table 3 – Selected indicators of the SIMP implementation program in constituent entities of the Russian Federation in 2018–2019

| No. | Constituent entity of the Russian Federation | Percentage of beneficiaries in the total population, % | | Proportion of patients who have retained the MA rights, % | | Appealability by results of the year (proportion of the citizens out of the total number of persons who were prescribed MPs, and have retained the MA rights), % | |
|--------------------------------------|--|--|-----------|---|-------------|--|-------------|
| | | 2018 | 2019 | 2018 | 2019 | 2018 | 2019 |
| 1 | The Republic of Sakha (Yakutia) | 4.0% | 4.1% | 63.1 | 63.1 | 57.0 | 98.8 |
| 2 | Moscow | 3.9% | 3.7% | NIA | NIA | 70.5 | 72.3 |
| 3 | The Republic of Karelia | 3.2% | 3.2% | 32.5 | 32.8 | 68.0 | 66.3 |
| 4 | Kurgan Region | 3.0% | 2.6% | 25.3 | 25.2 | 74.0 | 81.4 |
| 5 | Zabaikalsky Territory | 3.0% | 2.9% | 34.8 | 32.8 | 60.0 | 60.0 |
| 6 | Republic of Tatarstan | 3.0% | 3.0% | 34.4 | 35.2 | 80.6 | 80.2 |
| 7 | Sakhalin Region | 2.9% | 3.0% | 62.4 | 56.4 | 54.2 | 54.4 |
| 8 | Omsk Region | 2.6% | 2.7% | 28.8 | 28.6 | 60.1 | 56.7 |
| 9 | Belgorod Region | 2.6% | 2.5% | NIA | 13.6 | 63.8 | 61.6 |
| 10 | Altai Territory | 2.5% | 2.5% | 23.9 | 24.3 | 68.0 | 68.0 |
| 11 | Kirovskaya Oblast | 2.5% | 2.5% | 19.3 | 19.1 | 72.8 | 70.2 |
| 12 | Tula Region | 2.5% | 2.5% | 18.5 | 18.5 | 64.2 | 65.2 |
| 13 | Samaraskaya Oblast | 2.2% | 2.2% | 27.3 | 27.4 | 60.4 | 59.7 |
| 14 | Smolensk Region | 2.2% | 2.2% | 75.5 | 76.4 | 61.0 | 63.0 |
| 15 | Chelyabinsk Region | 2.2% | 2.2% | 22.0 | 22.0 | 100 | 100 |
| 16 | Khabarovsk Territory | 2.1% | 2.0% | 32.1 | 31.1 | 50.6 | 51.6 |
| 17 | Chuvashskaya Republic | 2.0% | 1.9% | 18.7 | 18.0 | 74.0 | 61.7 |
| 18 | Voronezh Region | 1.9% | 2.0% | 15.8 | 16.5 | 53.1 | 54.2 |
| 19 | Astrakhan Region | NIA | 1.9% | NIA | 23.6 | NIA | 57.7 |
| 20 | Krasnodar Territory | NIA | NIA | 21.4 | 21.7 | NIA | NIA |
| Mediana (10th and 90th percentiles)* | | 2.5 | 2.5 | 27.3 | 25.2 | 66.1 | 64.1 |
| | | (2.1–3.5) | (2.0–3.4) | (18.6–62.8) | (17.4–59.8) | (60.1–74.0) | (58.7–76.3) |

Note: * – for constituent entities of the Russian Federation with available information; NIA – No information available; IA – inapplicable

Table 4 – Indicators of actual costs, the number of prescriptions and the average cost of one prescription under the SIMP program in the constituent entities of the Russian Federation in 2018–2019

| No. | Constituent entity of the Russian Federation | The money actually spent on one beneficiary who appealed for MA per month, rubles (including pharmaceutical services) | | | Number of prescriptions, thousand pieces | | | Average cost of one prescription, rub. (including pharmaceutical services) | | |
|-------------|--|---|---------|---------------------------|--|---------|---------------------------|--|----------|---------------------------|
| | | 2018 | 2019 | Change relativeto 2018, % | 2018 | 2019 | Change relativeto 2018, % | 2018 | 2019 | Change relativeto 2018, % |
| 1 | Moscow | 2,960.8 | 2,769.4 | -6.5% | 4,898.9 | 3,176 | -35.2% | 1,261.9 | 1,546.6 | 22.6% |
| 2 | Republic of Tatarstan | 1,105.8 | 1,327.5 | 20.1% | 2,029.9 | 2,200.8 | 8.4% | 729.4 | 794.4 | 8.9% |
| 3 | Krasnodar Territory | NIA | NIA | IA | 980.8 | 1,178.2 | 20.1% | NIA | NIA | IA |
| 4 | Samaraskaya Oblast | NIA | NIA | IA | 796 | 704,5 | -11,5% | NIA | NIA | IA |
| 5 | Altai Territory | 1,313.8 | 1,443.0 | 9.8% | 740.7 | 789 | 6.5% | 855.2 | 873 | 2.1% |
| 6 | Omsk Region | 1,723.0 | 1,943.0 | 12.8% | 616.5 | 657.6 | 6.7% | 1,036.5 | 1,034.1 | -0.2% |
| 7 | Kurgan Region | 1,293.1 | 1,293.1 | 0.0% | 551.7 | 559.6 | 1.4% | 527.1 | 597.8 | 13.4% |
| 8 | Kirovskaya Oblast | 1,523.7 | 1,526.8 | 0.2% | 499.3 | 426.1 | -14.7% | 797 | 889 | 11.5% |
| 9 | Chelyabinsk Region | 946.0 | 1,118.6 | 18.2% | 492.2 | 409.7 | -16.8% | 1759.4 | 2,511.3 | 42.7% |
| 10 | Tula Region | 1,469.3 | 1,689.6 | 15.0% | 419 | 563.3 | 34.4% | 998.5 | 854.7 | -14.4% |
| 11 | Belgorod Region | 1,717.4 | 1,741.1 | 1.4% | 417.8 | 350.7 | -16.1% | 1,246.6 | 1,445.3 | 15.9% |
| 12 | Zabaikalsky Territory | 1,095.0 | 1,162.0 | 6.1% | 362.7 | 358.1 | -1.3% | 1,063 | 1,178 | 10.8% |
| 13 | Chuvashskaya Republic | 1,846.5 | 1,400.7 | -24.1% | 329.6 | 320 | -2.9% | 628.9 | 762.2 | 21.2% |
| 14 | Voronezh Region | 1,909.4 | 1,894.2 | -0.8% | 315.8 | 311.1 | -1.5% | 1,790.5 | 1,827.3 | 2.1% |
| 15 | The Republic of Karelia | 1,751.6 | 1,406.6 | -19.7% | 314 | 357.1 | 13.7% | 567.1 | 629.9 | 11.1% |
| 16 | Sakhalin Region | 2,202.0 | 1,590.0 | -27.8% | 293 | 235.1 | -19.8% | 545 | 644 | 18.2% |
| 17 | The Republic of Sakha (Yakutia) | 1,839.8 | 903.2 | -50.9% | 232 | 188 | -19.0% | 2,099.2 | 2258 | 7.6% |
| 18 | Smolensk Region | 2,285.9 | 2,380.4 | 4.1% | 212.5 | 236.3 | 11.2% | 930.2 | 1,030.4 | 10.8% |
| 19 | Khabarovsk Territory | 1,764.5 | 1,859.8 | 5.4% | 162.9 | 163.2 | 0.2% | 1,987.8 | 1,895 | -4.7% |
| 20 | Astrakhan Region | NIA | 1,534.3 | IA | NIA | 78,9 | IA | NIA | 2,579.47 | IA |
| Mean change | | -1.2 ± 4.4% | | | -1.9 ± 3.8% | | | +10.0 ± 2.9% | | |

Note: NIA – No information available; IA – inapplicable

1. regions with a high value of this indicator (over 70%): The Republic of Tatarstan, Chelyabinsk, Kurgan, Kirov regions, Moscow.
2. regions with a value of this indicator in the range from 60 to 70%: Chuvashskaya Republic, Republic of Karelia, Altai Territory, Tula, Belgorod, Smolensk, Samara, Omsk Regions, Zabaykalsky Territory.
3. regions with a value of this indicator in the range from 50 to 60%: the Republic of Sakha / Yakutia, Sakhalin, Voronezh regions, Khabarovsk Territory.

It should be notified that the indicator "Appealability of federal beneficiaries for medicine assistance under the SIMP program" does not depend on the proportion of the persons who retained the right to receive benefits in-kind under the SIMP program (*r*-Pearson 0.05 in 2018 and -0.04 in 2019, *p* > 0.05).

In 2018, the standard of financial costs for each federal beneficiary was 823.30 rubles per month, in 2019 it was 861.80 rubles [6]. It was established that the amount of actual costs (taking into account the costs of organizational measures – pharmaceutical services) per month per one beneficiary who appealed for MA, depends on the amount of funding to the program in the constituent entities of the Russian Federation (*r*-Pearson 0.90 in 2018-2019); from the number of beneficiaries who retained the right to MA under the SIMP program (*r*-Pearson 0.99 in 2018-2019); from the number of prescriptions (*r*-Pearson 0.73 in 2018, 0.71 in 2019) and from the average cost of one prescription (*r*-Pearson 0.58 in 2018, 0.69 in 2019) (all *p* < 0.05).

The medians of actual costs in the studied constituent entities of the Russian Federation (10th and 90th percentiles) amounted to 1,723.0 rubles (10th and 90th percentiles of 1,101.5 and 2,235.6 rubles, respectively) in 2018 and 1,526.8 (1,144.6 and 2,118.0 rubles, respectively) in 2019. In general, in 2019, the actual costs per one beneficiary who appealed for MA (in relation to 2018), changed insignificantly (-1.2±4.4%). The largest relative increase in actual costs (≥15%) was reported in the Republic of Tatarstan, Chelyabinsk and Tula regions, the largest cost reductions (≥15%) – in the Republic of Sakha / Yakutia, Sakhalin region, Chuvash Republic, Republic of Karelia.

In the analyzed constituent entities of the Russian Federation in 2018–2019, more than 18 million prescriptions were issued annually under the SIMP program (Table 4).

According to the data presented in Table 4, for one federal beneficiary who appealed for MA (taking into account the proportion of the persons who retained the MA right under the SIMP program, and the appealability), an average of 18 prescriptions are issued per year (the range of 6–37 prescriptions and 5–31 prescriptions for one beneficiary who appealed for MA in 2018 and 2019, respectively). The largest decrease in the number

of prescriptions in 2019 compared to 2018, was reported in Moscow (-35.2%), Sakhalin Oblast (-19.8%) and the Republic of Sakha / Yakutia (-19.0%). The largest relative increase in the number of prescriptions was recorded in the Tula region (+ 34.4%) and the Krasnodar Territory (+ 20.1%).

Based on the data in Table 4, it was determined that the average cost of one prescription (± root-mean-square error) under the SIMP program in 20 constituent entities of the Russian Federation, was 1,107.2 (±150.4) rubles in 2018 and 1,297.2 (± 144.2) rubles in 2019.

In 2018, the average cost of one prescription ranged from 527.1 rubles up to 2,099.2 rubles, in 2019 – from 597.8 up to 2,258.0 rubles. In general, there was a significant increase in the cost of one prescription in most constituent entities of the Russian Federation by 10.0 ± 2.9% on average, while the maximum increase was reported in the Chelyabinsk Region (by 42.7%), in Moscow (by 22.6%) and in the Chuvashskaya Republic (by 21.2%).

The indicators "Number of prescriptions" and "Average cost of one prescription" correlated with the total amount of funding for the program and the number of beneficiaries who retained the MA right under the SIMP program (*p* < 0.05).

DISCUSSION

In the Russian Federation, as in many other developed countries of the world, there is a tendency towards centralized controlled prescription of drugs with the active use of digital technologies. The MA programs adopted here, are aimed at improving the quality of healthcare and ensuring control over the costs of drugs [3, 7–9]. At the same time, in foreign countries, the mechanisms for MA programs implementing, have specific features and differences of their own.

For example, in the USA there is no public health system [10, 11]. In this regard, people who do not have health insurance, cannot receive elective care, or they are unable to buy prescribed drugs [12, 13]. At the same time, there are fully funded and government-run health care programs in the United States. In the MA systems, the patients, healthcare providers, large medical groups and integrated supply systems are payers themselves. Some of the oldest government welfare programs are those created in 1965, to fund medical care for the poor (Medicaid) and elderly Americans over 65 (Medicare). Medicare also includes the disabled and the people with certain chronic diseases, such as those on dialysis for chronic kidney disease, and those who have become disabled due to other diseases, such as cancer. Medicare and Medicaid are a form of social security. They are funded from a set of taxes collected by the federal government but administered by the states. Therefore, the eligibility criteria and the amount of aid funded in these programs, may differ from state to state. Medicare is the closest thing to a community system that includes several components (inpatient care, outpatient care, private

insurance), but all Medicare components have copayments, and those copayments exceed those of health plans in other countries [10, 13].

In Canada, prescription drugs provision is regulated at the government level of each province and territory, in accordance with a list of prescription drugs, which includes drugs for the provision of outpatient health care to selected categories of citizens (for example, the elderly and other benefit categories), as well as at the federal level (the government provides reimbursement of the cost of medicines to privileged categories of citizens belonging to aboriginal peoples and Inuit inhabitants). Despite the creation of the National Pharmaceuticals Strategy and the 10-Year Plan to Strengthen Health Care, adopted at the 2004 ministerial meeting, the efforts made were insufficient to develop an *All-Canadian* program of the population coverage with drugs in case of catastrophic medical expenses [14, 15].

In Great Britain, the established system of public health care and social security, was formally brought into action in 1948 [13, 16]. The main principle of the system was medical care on free-of-charge basis for all people living in the country. The system is funded from the state budget. The citizens pay for medications without a prescription from their own funds. As for prescription drugs, medical devices and services, England has a fixed co-payment; Wales, Scotland and Northern Ireland have no co-payment. More than 90% of medicines are available free of charge: for the citizens over 60 years old, children under 16 years old (or up to 19 years old if they are full-time students), patients with certain categories of diseases (type II diabetes mellitus, hypoparathyroidism, severe hypothyroidism, oncological diseases, epilepsy, myasthenia gravis, etc.), people with low incomes, pregnant women and those who gave birth in the previous 12 months, the disabled. The medicines used in hospitals, day hospitals, and medicines prescribed for the treatment of tuberculosis and sexually transmitted diseases do not require co-payment. For expensive medicines and technologies, the National Institute for Health and Clinical Excellence (NICE) conducts a cost-benefit pharmacoeconomic analysis. The more an intervention can save Quality Adjusted Life Years (QALYs), the more likely it is that NICE will make a positive recommendation on the preferential introduction of this technology into the national health system. This scheme does not allow solving the problem of high costs for expensive technologies [17].

One of the oldest systems for providing state social guarantees, is the German health care system [13]. The system is based on the existence of health insurance funds, which were formed on an industrial or regional basis. The health insurance funds are non-profit organizations that insure the risks associated with the diseases, and negotiate with doctors (or their associations) and drug manufacturers / suppliers regarding the cost of their services / goods. In Germany, social insurance

does not include the citizens whose income exceeds certain thresholds. More than 70% of health care costs in Germany, are spent from social insurance funds. To reduce the growth in health care costs, a number of measures had been taken to reduce the cost of care and the demand for it. A negative non-refundable list had been created, and maximum covered prices had been introduced. In Germany, since 2006, there are also copayments in the amount of 10% of the cost of the drug, if the costs are at least 5 euros, but not more than 10 euros. When spending on medicines exceeds 1% of the total household income for patients with chronic forms of the disease and 2% of the total household income for patients without chronic forms of disease, patients are exempted from co-payments [12].

In the Scandinavian countries, the health care system is characterized by tax (non-insurance) coverage of medical expenses and decentralization [16, 18]. In Finland, health care is financed from the municipalities' general tax revenues and from the social insurance system through the organization responsible for social insurance. In Finland, reimbursement of the drugs costs, is carried out under several schemes. If a drug was referred to the basic category (the drugs which had been planned to be paid for from public funds), then the patient's copayments will be 58% with a fixed component. Two other categories of drugs are special, and to be referred to these categories, it is necessary that they be used to treat certain diseases and have proven effectiveness. Patients' co-payments for the purchase of medicines referred to the first special category (used to treat bronchial asthma, arterial hypertension), are 28%. The medicines referred to the second special category (used to treat severe and / or life-threatening conditions such as malignant neoplasms and diabetes mellitus), are fully covered by the social insurance organization, but a patient has to pay a fixed fee (3 euros per purchase). The complexity of the system is the possibility of having a drug in more than one list [18].

In the People's Republic of China, it is currently planned to implement a program to co-finance the costs of drugs for the treatment of arterial hypertension, diabetes mellitus and some other diseases at the expense of health insurance funds, the share of reimbursable costs can reach 50% [19].

A system of multi-stage assessment of the cost-effectiveness of drugs, has been adopted by European countries. This allows the EU countries to include drugs with proven effectiveness for each therapeutic area and disease in the drug reimbursement systems, in contrast to the United States, where the cost of any purchased drugs can be reimbursed, which, along with lack of a reference price, can be a heavy burden for taxpayers [12, 13, 20, 21]. According to 2015 data, 64% of drugs costs in the United States, were paid directly by consumers or through private insurance. The level of the cost coverage in the EU countries is much higher, for example, in

Germany: at least 80% of the costs are paid by the state [12, 22].

In the Commonwealth of Independent States, there is a rather low level of economic accessibility of medicines for the population, in particular, in privileged categories, which is due to the extremely low level of financing of health care systems, a low solvent level of the population and the prevalence of the population expenditures in the structure of total financing of medicines, as well as irrational spending of funds in the existing systems of privileged drug provision [13, 23].

The experience of the Russian Federation in the implementation of federal MA programs, differs from the experience of foreign countries. The main feature is that in our country federal beneficiaries are not co-payers of their own drug provision, since the costs of drugs under the SIMP program, are fully reimbursed from the federal budget. Another characteristic feature is that in the Russian Federation, the amount of funding for SIMP program depends on the number of federal beneficiaries, while the program budget is formed on the basis of the principle of equal per capita funding [1–3, 23].

The results obtained in the course of the study, indicate a significant variation in the values of the indicative indicators of the SIMP program implementation, as well as their dynamics in various constituent entities of the Russian Federation. However, there is a number of universal objective laws.

The amount of funding for the program, is calculated according to the same criteria, based on the standard of monthly financial costs for each federal beneficiary. In this regard, it is logical that a linear correlation between the amount of funding for the program and the number of beneficiaries in the constituent entity of the Russian Federation, has been obtained. The correlation with the population size in a constituent entity of the Russian Federation, can be also explained by the relatively comparable (in most constituent entities of the Russian Federation) proportion of citizens eligible for privileged drug provision (from 1.9 to 4.1%).

The indicators "Actual costs for beneficiary per month" and "Average cost of one prescription" in the constituent entities of the Russian Federation vary, which may be due to differences in the contingent of beneficiaries, in the structure of their morbidity, as well as in the structure of the assortment of prescribed drugs. At the same time, it should be notified that the amount of actual costs for one beneficiary per month who appealed for MA in the surveyed constituent entities of the Russian Federation (which are to some extent a representative sample for assessing the SIMP program implementation in the Russian Federation as a whole), exceeded the standards of financial costs for one citizen receiving the government social assistance (GSA) in the form of a set of social services (SSS), per month. It should be also notified that this Regulation was established by the RF Government. After the recalculation, the average

amount of actual costs per one citizen eligible for GSA in the form of SSS, amounted to 1119.7±90.2 rubles in 2018 and 1081.5±80.5 rubles in 2019, compared to the standards of 823.30 rubles and 861.80, respectively.

The results of the analysis confirm the previously identified problems in the field of medicine assistance (MA), caused by the massive refusal of federal beneficiaries to receive the government social assistance (GSA) in the form of set of social services (SSS). Since the majority of federal beneficiaries (about 80%) prefer to receive monetary compensation, the principle of social insurance is really violated. As a result, patients with severe illnesses, who also need expensive drugs, remain in the SIMP program predominantly [1, 14, 24]. Despite the fact that in this study, there are no obtained statistically significant relationships between the average cost of one prescription, actual costs, and the proportion of the citizens who retained the right for GSA in the form of SSS, this may mean the presence of a more complex relationship between these indicators (taking into account socio-economic and demographic features of the constituent entities of the Russian Federation). The revealed discrepancy between the standard and actual costs, can be also an indirect confirmation of the insufficient funds in the federal program to fully cover the need for drugs and the need to reorganize the existing system for the elimination of the imbalance in financing these social assistance measures [24, 25].

CONCLUSION

Thus, the experience of the Russian Federation in federal MA programs implementation, differs from the experience of foreign countries. The main feature is that in our country, federal beneficiaries are not co-payers of their own drug provision, since the costs of purchasing drugs under the SIMP program, are fully reimbursed from the federal budget. Another characteristic feature is that in the Russian Federation, the amount of funding for the SIMP program depends on the number of federal beneficiaries, while the program budget is formed on the basis of the principle of equal per capita funding.

On the example of 20 constituent entities of the Russian Federation from 7 federal districts, the differences in the indicative indicators of the SIMP program implementation in 2018-2019, have been revealed. It has been notified that the average actual costs per citizen eligible for government social assistance (GSA) in the form of set of social services (SSS), exceeded the standards established by the Regulations established by the RF Government.

Based on the analysis carried out, it can be concluded that the federal MA program for federal beneficiaries, needs further improvement. According to the authors' opinions, when implementing this program, it is advisable to use the lost insurance principle: the patients who need medical care, should be provided with drugs under the total budget of the medical material program.

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AUTHORS' CONTRIBUTION

All authors have equally contributed to the research work.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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