BRACE
Law Firm

November 2018

# DIGEST
# of regulation of pharmaceutical industry

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

## Brief news

For the member states of the Eurasian Economic Union, criteria were made for the procedure for classifying products as medical product products, which are planned to be applied from 2019.

Substantial changes have been made to the procedure for rendering medical aid to adults in the “anesthesiology and resuscitation” profile.

New standards for providing primary health care to adults with illness caused by human immunodeficiency virus have been approved.

Requirements for the conditions of admission of medicines included in the list of vital and essential medicines originating from foreign countries have been supplemented.

The regulations on licensing medical activities in terms of bringing them in line with the nomenclature of positions of medical and pharmaceutical workers, as well as the Regulations on monitoring the activities of health insurance organizations and medical organizations in the field of compulsory medical insurance can be changed by territorial compulsory medical insurance funds.

A draft law has been proposed permitting the provision of palliative care in outpatient settings and at home, as well as in day hospitals by medical workers who have been trained in providing such assistance.

The Supreme Court concluded that it was illegal to charge penalties for late performance. Since the delay was insignificant and the contract did not provide for the calculation of the fine for the delay. A penalty was imposed for breach of contract. For the member states of the Eurasian Economic Union, criteria were made for the procedure for classifying products as medical products, which are planned to be applied from 2019.

Substantial changes have been made to the procedure for rendering medical aid to adults in the “anesthesiology and resuscitation” profile.

New standards for providing primary health care to adults with illness caused by human immunodeficiency virus have been approved.

Requirements for the conditions of admission of medicines included in the list of vital and essential medicines originating from foreign countries have been supplemented.

The regulations on licensing medical activities in terms of bringing them in line with the nomenclature of positions of medical and pharmaceutical workers, as well as the Regulations on monitoring the activities of health insurance organizations and medical organizations in the field of compulsory medical insurance can be changed by territorial compulsory medical insurance funds.

A draft law has been proposed permitting the provision of palliative care in outpatient settings and at home, as well as in day hospitals by medical workers who have been trained in providing such assistance.

The Supreme Court concluded that it was illegal to charge penalties for late performance. Since the delay was insignificant and the contract did not provide for the calculation of the fine for the delay. A penalty was imposed for breach of contract.

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

## 1. Laws, by-laws, legal news

**1.1. The Board of the Eurasian Economic Commission recommends applying the criteria from May 16, 2019. The collegium of the Eurasian Economic Commission of the Eurasian Economic Union established criteria determining the procedure for classifying products as medical product.**

*Recommendation of the Board of the Eurasian Economic Commission of November 12, 2018 N 25*

This recommendation specified that the appointment of a medical product is one of the main criteria for the classification of products to medical products. It must be single or primary.

These criteria allow to attribute the product to medical product for each of the following, determined by the recommendations of groups of goods:

- perfumery and cosmetic products and personal care products;
- disinfectants and equipment;
- general purpose products;
- products for adaptation and rehabilitation of people with disabilities;
- products for sports and physical therapy;
- personal protective equipment;
- software;
- packaging and equipment for storage of medical products and other products;
- physiotherapy equipment and household products;
- furniture;
- medical products containing medicines;
- products for in vitro diagnostics.

The Board of the Eurasian Economic Commission recommends applying the criteria from May 16, 2019.

**1.2. The board of the Eurasian Economic Commission of the Eurasian Economic Union launched the process of forming and maintaining a single register of pharmaceutical inspectors of the Eurasian Economic Union.**

*Order of the Board of the Eurasian Economic Commission of the Eurasian Economic Union of November 12, 2018 N 175*

Pursuant to the requirements of the Procedure for joining the general process "Formation, maintenance and use of a unified register of pharmaceutical inspectors of the Eurasian Economic Union", approved by the Decision of the Board of the Eurasian Economic Commission N 127 dated November 25, 2016, it was adopted to establish this process. The order established that the accession of new participants to the overall process, put into action, is carried out by performing the procedure of accession in the prescribed Procedure.

**1.3. The Ministry of Health approved amendments to the Procedure for rendering medical aid to adults in the “anesthesiology and resuscitation” profile.**

*Order of the Ministry of Health of the Russian Federation “On Approval of the Procedure for Providing Medical Care to the Adult Population in the Anesthesiology and Resuscitation Profile” of November 15, 2012 N 919n*

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

The Order of the Ministry of Health and Social Development of the Russian Federation of April 13, 2011 N 315n "On approval of the provision of anesthesia and resuscitation care to the adult population" was declared null and void.

A new procedure has established that medical care in the "anesthesiology and resuscitation" profile can be provided in the following conditions:

• outside the medical organization (at the place where the ambulance brigade is called, as well as in vehicles during medical evacuation);

• on an outpatient basis (in conditions that do not provide for round-the-clock medical observation and treatment);

• in the day hospital (in conditions that provide for medical observation and treatment in the daytime, which do not require round-the-clock medical observation and treatment);

• in-patient facility (in conditions that provide round-the-clock medical observation and treatment).

At the same time, it was established that ambulance, including emergency specialized, medical care for this profile is provided in emergency and emergency form outside the medical organization, as well as in outpatient and inpatient settings.

The recommended distribution of the working time of the anesthesiologist-resuscitator for anesthesia is 70% of the time for anesthesia and 30% of the time for examinations and counseling patients in outpatient and inpatient settings.

To increase the effectiveness of the management system for providing medical care to the adult population in an emergency form through information interaction, including the organization of consultations and (or) participation in the consultation of doctors using telemedicine technologies with remote interaction of medical workers among themselves, a remote Consultative Center for Anesthesiology-Resuscitation.

**1.4. The Order of the Ministry of Health entered into force, canceling a previously existing order on measures to provide palliative care for patients with the immunodeficiency virus. A number of standards of primary health care for adults have been adopted for diseases caused by the human immunodeficiency virus.**

*Order of the Russian Ministry of Health dated October 22, 2018 N 719 "On recognition of the order of the Ministry of Health and Social Development of the Russian Federation dated September 17, 2007 N 610" On measures to organize the provision of palliative care for patients with the immunodeficiency virus". Order of the Ministry of Health of the Russian Federation dated November 20, 2018 N 802n "On the approval of the standard of primary health care for adults with illness caused by the human immunodeficiency virus (third-line antiretroviral therapy)". Order of the Ministry of Health of the Russian Federation dated November 20, 2018 N 798n "On the approval of the standard of primary health care for adults with a disease caused by the human immunodeficiency virus (alternative first-line antiretroviral therapy)". Order of the Ministry of Health of the Russian Federation dated November 20, 2018 N 799n "On the approval of the standard of primary health care for adults with a disease caused by the human immunodeficiency virus (special cases of first-line antiretroviral therapy)"*

November 15, 2018 was registered with the Ministry of Justice of the Russian Federation, which invalidated the order "On measures to organize the provision of palliative care for patients with the immunodeficiency virus."

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

The adopted standards abolish the order of the Ministry of Health of Russia dated December 24, 2012 N 1511n "On approving the standard of primary health care for diseases caused by the human immunodeficiency virus" and establishes a list of services for diagnosing a disease and treating a disease, as well as a list of necessary medicines doses.

**1.5. The requirements for admission conditions for medicines included in the list of vital and essential medicines originating from foreign countries have been added.**

*Order of the Ministry of Finance of Russia dated June 4, 2018 N 126n "On the conditions for admission of goods originating from a foreign state or group of foreign states for the purpose of procuring goods for state and municipal needs"*

As a general rule, for the procurement of a medicinal product included in the list of essential and essential medicinal products for state and municipal needs, which is the subject of a single contract, the customer rejects all applications containing proposals for the supply of medicinal products originating from foreign countries, provided that at least 2 applications were submitted for participation in the determination of the supplier, which meet the requirements of the notice of the implementation of the procurement and (or) documentation on procurement and who simultaneously:

• contain proposals for the supply of medicines whose country of origin is a member state of the Eurasian Economic Union;

• do not contain proposals for the supply of medicines from the same manufacturer or manufacturers belonging to the same group of persons.

The said order established that in the event of rejection of applications for the above reason, the contract is concluded with the procurement participant at the proposed contract price with a combination of the following conditions:

• the application of such a procurement participant contains a proposal for the supply of medicines, all stages of production of which, including the synthesis of the active substance molecule in the production of pharmaceutical substances, are carried out in the territories of the member states of the Eurasian Economic Union, and information about such pharmaceutical substances is included in the state medicines registry;

• the application of such a procurement participant complies with the requirements of the procurement documentation;

• such procurement participant has been offered the contract price, which is the lowest among the procurement participants whose bids are not rejected;

• such a procurement participant has been offered a contract price that does not exceed by more than 25 percent the smallest offer on the price of a contract if it is submitted by the procurement participant whose application has not been rejected.

These provisions do not apply in the absence of the procurement participant whose application meets the specified conditions.

## 2. Drafts of legal acts

**2.1. Proposals have been made to amend a number of provisions regarding the control over the activities of health insurance organizations and medical organizations in the field of compulsory health insurance.**

*Draft order of the Federal Mandatory Medical Insurance Fund "On Amendments to Appendices N 1 and N 2 to the Order of the Federal Mandatory Medical Insurance Fund dated April 16, 2012 N 73 "On Approval of Regulations on Control over the Activities of Insurance Medical Organizations and*

*Medical Organizations in the Field of Mandatory medical insurance by territorial funds of compulsory medical insurance"*

It has been established that the subjects of the audit of the organization and conduct of control over the volumes, terms, quality and conditions of the provision of medical care for compulsory health insurance by an insurance medical organization are:

• observance of the timing of the monitoring of volumes, terms, quality and conditions of the provision of medical care, established by the Procedure for organizing and conducting monitoring;

• fulfillment of volumes of medical and economic control, medical and economic expertise and examination of the quality of medical care, established by the Procedure for organizing and conducting control;

• compliance of experts-experts of the medical insurance organization conducting medical and economic expertise, and experts in the quality of medical care, carrying out expert evaluation of the quality of medical care, with the requirements of the Procedure for organizing and conducting monitoring;

• reliability and timeliness of submission of reports on the results of monitoring the volume, timing, quality and conditions of the provision of medical care.

In addition, it is indicated that in the event that a medical organization carries out activities in the field of compulsory health insurance outside the subject of the Russian Federation in which it is located, it is possible to conduct a territorial fund at the place of medical activity.

**2.2. Ministry of Health proposes to change the list of medical works and services subject to licensing.**

*Draft Resolution of the Government of the Russian Federation "On Amendments to the Regulations on the Licensing of Medical Activities (with the exception of these activities carried out by medical organizations and other organizations within the private health care system in the territory of the Skolkovo Innovation Center)"*

The project proposes to separate the concepts of work (services) in physical therapy and sports medicine, which can have a positive effect on reducing the costs of license applicants

The project provides for the addition of works (services) for forensic examination:

• on forensic examination and examination of victims, the accused and other persons and on the basis of the case materials;

• forensic examination and examination of the corpse and on the materials of the cases.

A large number of activities are proposed to be excluded from the list of works (services) subject to licensing. Such additions are due in the first place to bring the list in compliance with the current legislation, including the nomenclature of posts of medical and pharmaceutical workers. For example, it is proposed to exclude works (services):

• on aviation and space medicine. With the division of this type into such types as: work of medical certification of aviation personnel and work on medical certification and medical support of astronauts;

• diabetology, clinical mycology, laboratory mycology, laboratory work, genetics, resuscitation, abdominal surgery;

• bacteriology and virology, disinfectology, narcology and operations;

• emergency medical care. The explanatory note to the project states that such services are provided by different specialists, therefore licensing is supposed to be carried out for work (service), which corresponds to the specialty of a doctor or health worker with secondary medical education;

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

• general practice. As for the nurse of the general practitioner (family doctor), secondary vocational education is required in one of the specialties: “Medicine”, “Obstetrics”, “Nursing” and professional retraining in the specialty “General Practice”;

• general dentistry. Since the nomenclature of posts of medical and pharmaceutical workers does not provide for a post of general practitioner, therefore, work (services) in general dentistry is not required to be licensed separately, etc.

**2.3. Palliative medical care will be allowed to be provided in hospitals.**

*The draft law “On Amendments to the Federal Law“ On the Basics of the Protection of Citizens' Health in the Russian Federation ”on the provision of palliative medical care”*

The draft law proposes to allow the provision of palliative care in outpatient settings, including at home, in day hospital and inpatient settings by medical workers who have been trained to provide such assistance, in collaboration with employees of social service organizations and other persons. Presumably, the adoption of such changes may have a positive impact on the promptness of receiving palliative care by patients in need of appropriate assistance.

**2.4. The Ministry of Finance of Russia proposed to give the Ministry of Health of the Russian Federation the authority to determine the price of a contract when purchasing medical products.**

*Draft Resolution of the Government of the Russian Federation “On the federal executive body authorized to establish the procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, performer) when purchasing medical products”*

According to part 22 of article 22 of the Law on the Contract System, the Government of the Russian Federation has the right to determine areas of activity in which, when making procurements, a procedure is established for determining the initial (maximum) price of a contract and federal executive bodies authorized to establish such a procedure.

Provision is made for the Ministry of Health of the Russian Federation to be empowered to establish a procedure for determining the initial (maximum) contract price, as well as the price of a contract concluded with a single supplier (contractor, performer) when purchasing medical products.

## 3. Judicial and other law enforcement practice

**3.1. The Supreme Court of the Russian Federation sent for a new trial a case of refusal by lower courts to write off an accrued penalty at the expense of compulsory medical insurance.**

*Resolution of the Arbitration Court of the West-Siberian District of November, 08 2018 in case N A81-10941/2017*

The inspection body concluded that it was illegal to use money to pay off taxes and fees at the expense of compulsory health insurance. The Arbitration Court of the West Siberian District came to different conclusions.

In this case, the implementation of such actions by a branch of a medical organization (hereinafter referred to as the branch) is due to the fact that the court imposed a ban on managing the funds in the applicant's accounts with banks and other credit organizations, as well as direct tax writing off the tax authority of the applicant the ability to transfer money from your account, in particular, to pay for consumables and medical supplies. The medical organization has fulfilled all the

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

conditions of the tariff agreement. She acted in good faith, and her branch continued to provide medical care, despite blocking his special account.

The Foundation could not prove that the Medical Organization had abused the right. The court did not even convince him the following arguments.

**3.2. The Supreme Court referred to the Judicial Board on Economic Disputes a case concerning the recovery of a fine in case of violation of the terms of fulfillment of obligations by a supplier under a state contract.**

*Determination of the Supreme Court of the Russian Federation dated November 11, 2018 N 310-ES18-13489 in case N A08-2558 / 2017*

From the circumstances of the case it follows that due to the delay in the medical organization of supplies, a fine was charged. At the same time, the lower courts, meeting the requirements for collecting a fine, proceeded from the possibility of collecting both a fine and a penalty, since in this case there is a violation of the terms of the contract as a whole, and a violation of the terms of performance of obligations.

However, the Supreme Court concluded that the courts violated the norms of substantive law, referring to the violation of Article 34 of the Law on the contract system and clause 6.7 of the contract, since if the deadlines for the fulfillment of obligations are violated, the penalty is excluded. In addition, the delay is two days, while the amount of the fine is equal to 10 percent of the amount of the contract.

**3.3. The Omsk Department of the Federal Antimonopoly Service of Russia ruled the procurement participant's complaint to be justified, since the customer violated the requirements of the Law on the contract system and the application of the procurement participant was wrongfully inconsistent with the requirements established by the documentation on the electronic auction.**

*The decision of the Omsk Department of the Federal Antimonopoly Service of Russia of November 6, 2018 N 03-08/93-2018*

During the consideration of the case, it was established that the Commission considering applications was misled in connection with the numbering of registration certificates and inconsistencies between the name of medical devices in the first parts of the participant's application and registration certificate. As a result, when considering the second parts of applications for participation in an electronic auction, the auction commission erroneously decided that the application with the serial number 226 did not comply, stating in the minutes that the positions N 43, 44, 47, 48, 52, 53, 57 , 58, 61 - 65, 69, 70, 72 - 75 there is no copy of the registration certificate for the medical device.

The Commission, after analyzing the information contained in the first part of the application of the sole procurement participant, as well as the copies of registration certificates for medical products presented to them in the second part of the application, concluded that the content of the second part of the application met the requirements established by the electronic auction documentation.

This practice cannot be uniform and the question of the compliance of applications is subject to individual consideration in each specific case. In this regard, it is extremely important to correctly fill out applications for participation in procurement, while avoiding any contradictions and inaccuracies.