GOVERNMENT OF THE RUSSIAN FEDERATION

RESOLUTION

No. 1517 of December 30, 2015

MOSCOW

On Governmental Regulation of Prices for Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens

Pursuant to Article 80 of the Federal Law *On the Fundamentals of Public Healthcare in the Russian Federation*, the Government of the Russian Federation **hereby resolves**:

1. To approve the enclosed:

Rules for State Registration of Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens;

Rules for Maintaining the State Register of Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens;

Procedure for Setting Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens, and Ceiling Wholesale

Markups on Actual Producer-set Prices for Said Medical Devices.

2. For the Federal Service for Supervision of Healthcare, within:

(a) 20 business days from the effective date of this resolution — to send requests to producers of medical devices on the list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free medical care for citizens (approved by Russian Government Resolution No. 2762-r of December 29, 2014 (hereinafter "medical devices")) or to their authorized representatives for information (to be provided within one month of receiving the requests) needed for purposes of calculating the weighted average producer-set prices for medical devices of the types corresponding to the nomenclature classification of medical devices using the form provided in the annex to the procedure approved by this resolution;

(b) 4 months from the effective date of this resolution — to submit to the Federal Antimonopoly Service for approval the weighted average producer-set prices for medical devices of the types corresponding to the nomenclature classification of medical devices, which have been calculated by the Federal Service for Supervision of Healthcare, along with copies of calculations of the ceiling producer-set prices for medical devices presented by producers of medical devices (or by their authorized representatives) in hardcopy and in electronic form via the Internet;

(c) 10 business days from the date of approval by the Federal Antimonopoly Service of the calculations of weighted average producer-set prices for medical devices of the types corresponding to the nomenclature classification of medical devices — to publish information about said prices on its official website on the Internet.

3. For the Federal Antimonopoly Service — within 2 months of receiving from the Federal Service for Supervision of Healthcare the calculations of weighted average producer-set prices for medical devices of the types corresponding to the nomenclature classification of medical devices — to verify the calculations of weighted average producer-set prices for medical devices of the types

corresponding to the nomenclature classification of medical devices and send to the Federal Service for Supervision of Healthcare a decision approving or denying approval of said calculations (and explaining the reasons why approval has been denied).

4. For producers of medical devices (or their authorized representatives) to send — by July 15, 2016 — to the Federal Service for Supervision of Healthcare for purposes of state registration of ceiling producer-set prices for medical devices the documents listed in Section 4 of the Rules for State Registration of Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens, which have been approved by this resolution.

5. The starting (ceiling) prices of contracts for procurement of medical devices shall not exceed the registered ceiling producer-set prices for medical devices, taking into account the established ceiling wholesale markups and value added tax (for medical devices on which value added tax is assessed).

6. To recommend that executive authorities of the constituent entities of the Russian Federation establish — by September 1, 2016 — the ceiling wholesale markups on the actual producer-set prices for medical devices in accordance with the procedure approved by this resolution.

7. For the Ministry of Health of the Russian Federation to offer clarifications on using the procedure approved by this resolution.

8. For the Ministry of Health of the Russian Federation jointly with the Ministry of Economic Development of the Russian Federation, the Ministry of Finance of the Russian Federation, the Ministry of Industry and Trade of the Russian Federation, the Federal Antimonopoly Service, and the Federal Service for Supervision of Healthcare — based on analysis of the practice of state registration of ceiling producer-set prices for

medical devices — to present by October 1, 2016, their approved proposals regarding the process of renewal of registration of ceiling producer-set prices for medical devices in the prescribed manner to the Government of the Russian Federation.

Prime Minister
of the Russian Federation

Dmitry Medvedev

APPROVED
by Russian Government Resolution
No. 1517 of December 30, 2015

RULES

for State Registration of Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens

1. These Rules establish the process of performing state registration of ceiling producer-set prices for medical devices originating in countries that are member states of the Eurasian Economic Union and foreign-made medical devices (hereinafter "producers"), which have been put on the Russian Government-approved list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free medical care for citizens (hereinafter "the list" and "medical devices", respectively).

2. State registration of ceiling producer-set prices for medical devices shall be performed by the Federal Service for Supervision of Healthcare (hereinafter "the registering authority").

3. The ceiling producer-set price proposed for state registration shall not exceed the weighted average producer-set price for the relevant type of medical device that is calculated by the registering authority according to the procedure for setting ceiling producer-set prices for medical devices on the list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free

medical care for citizens, and ceiling wholesale markups on actual producer-set prices for said medical devices, which has been approved by Russian Government Resolution No. 1517 of December 30, 2015, *On Governmental Regulation of Prices for Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens* (hereinafter "the Procedure").

4. For purposes of state registration of the ceiling producer-set price for a medical device, the applicant — the medical device producer or its authorized representative — shall submit the following to the registering authority:

(a) an application for state registration of a ceiling producer-set price for medical devices on the list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free medical care for citizens (hereinafter "the application") prepared using the form provided in the annex in hardcopy or in the form of an electronic document signed with a qualified advanced electronic signature;

(b) a document evidencing the authority of the authorized representative of the medical device producer.

5. The registering authority shall verify the documents mentioned in Section 4 of these Rules and the completeness and veracity of information contained in them by comparing them with data in the registration dossier of the medical device and the state register of medical devices and organizations (individual entrepreneurs) that manufacture and produce medical devices.

6. If the documents mentioned in Section 4 of these Rules contained incomplete and/or false information or are incorrectly prepared or if the ceiling producer-set price for the medical device proposed for state registration exceeds the weighted average price for the type of medical device, the registering authority shall notify the applicant within 10 business days of receiving the application via registered mail (with proof of service) and via an electronic document

signed with a qualified advanced electronic signature or in electronic form via the Internet information and telecommunications network (hereinafter “the Internet”) about the need to rectify any discovered violations within 20 business days of receiving the notice.

7. If the documents mentioned in Section 4 of these Rules have been properly prepared and if the discovered violations have been rectified within the time frame indicated in Section 6 of these Rules, the registering authority shall do the following within 5 business days of receiving the application or of the date when the violations have been rectified:

(a) make a decision to approve state registration of the ceiling producer-set price for a medical device while issuing a relevant order and including information about the registered price in the state register of ceiling producer-set prices for medical devices;

(b) in respect of a new type of medical device per the nomenclature classification of medical devices — submit to the Federal Antimonopoly Service for approval the registering authority's calculation of the weighted average producer-set price for the medical device of the types corresponding to the nomenclature classification of medical devices along with a copy of calculations of the ceiling producer-set price for the medical devices presented by the applicant in hardcopy and in electronic form via the Internet.

8. Within 20 business days of receiving the documents indicated in Subsection (b) of Section 7 of these Rules, the Federal Antimonopoly Service shall make a decision approving or denying approval (and explaining the reasons why approval has been denied) of the calculation of the weighted average producer-set price for the new medical device of the type corresponding to the nomenclature classification of medical devices, and shall send the relevant decision to the registering authority.

9. Within 10 business days of receiving from the Federal Antimonopoly Service the decision approving or denying approval of the calculation of the weighted average producer-set price for the new medical device of the type corresponding to the nomenclature classification of medical devices, the registering authority shall make a decision to perform state registration of the ceiling producer-set price for the medical device and issue a relevant order and include information about the registered price

in the state register of ceiling producer-set prices for medical devices or a decision to deny state registration of the ceiling producer-set price for the medical device (and explain the reasons why approval has been denied).

10. Grounds on which the registering authority may deny state registration of the ceiling producer-set price for a medical device shall be:

(a) submission of false information;

(b) incomplete submission of documents indicated in Section 4 of these Rules and/or incomplete information contained in them;

(c) failure to rectify any discovered violations within the time frame indicated in Section 6 of these Rules;

(d) the ceiling producer-set price proposed for state registration exceeds the weighted average producer-set price for the relevant type of medical device;

(e) absence of the medical device in the list.

11. Within 5 business days of making the decision, the registering authority shall send to the applicant:

(a) an excerpt from the order approving state registration of the ceiling producer-set price for the medical device, in hardcopy or in the form of an electronic document signed with a qualified advanced electronic signature;

(b) a notice about a decision denying approval of state registration of the ceiling producer-set price for the medical device, in hardcopy or in the form of an electronic document signed with a qualified advanced electronic signature (and explaining the reasons why approval has been denied).

12. The decision denying approval of state registration of the ceiling producer-set price for the medical device may be appealed in court.

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ANNEX
to Rules for State Registration of Ceiling
Producer-set Prices
for Medical Devices on the List of Medical Devices
Implantable into the Human Body as Part of Medical Aid
Provided to Citizens under the Program of State
Guarantees of Free Medical Care for Citizens

(Form)

APPLICATION

for State Registration of a Ceiling Producer-set Price for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens

_____
(name of the applicant organization)

Type of medical device per the nomenclature classification	Description of medical device	Details of the registration certificate (number and date of issuance)	Ceiling producer-set price for a medical device
1	2	3	4

Manager of organization
that produced the medical device _____ _____
(Signature) (Full name)

Place of seal

Typed by _____ _____
(Signature) (Full name and phone number)

APPROVED
by Russian Government Resolution
No. 1517 of December 30, 2015

RULES

for Maintaining the State Register of Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens

1. These Rules establish the process of maintaining the state register of registered ceiling producer-set prices for medical devices included in the Russian Government-approved list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free medical care for citizens (hereinafter "the register" and "medical devices", respectively).

2. The register is a federal information system containing information about state registration of ceiling producer-set prices for medical devices.

3. The register shall be maintained by the Federal Service for Supervision of Healthcare (hereinafter "the registering authority") in electronic format with the use of an automated system by making registration entries in the register.

4. A registration entry shall include the following information:

(a) name of the medical device producer; (b) description of

the medical device;

(c) type of medical device per the nomenclature classification of medical devices;

(d) registration number of the medical device;

(e) registered ceiling producer-set price for the medical device in roubles;

(f) date of state registration of the ceiling producer-set price for the medical device.

5. The registering authority shall include a registration entry in the register within 3 business days of making a decision approving state registration of the ceiling producer-set price for a medical device.

6. The details of state registration of the ceiling producer-set price for a medical device shall be excluded from the register within 3 business days from the date of the decision to exclude them from the register in the following cases:

(a) the producer (or authorized representative of the producer) of the medical device has submitted a request for exclusion of the details of state registration of the ceiling producer-set price for a medical device from the register;

(b) the medical device has been excluded from the state register of medical devices and organizations (individual entrepreneurs) that manufacture and produce medical devices;

(c) the medical device has been excluded from the list indicated in Section 1 of these Rules;

(d) the registering authority or the Federal Antimonopoly Service have found out that the producer (or the authorized representative of the producer) of the medical device has submitted false information upon state registration of ceiling producer-set prices for medical devices, which has caused the registered ceiling producer-set price for the medical device to be overstated.

7. If the registering authority has made a decision to exclude the details of state registration of the ceiling producer-set price for a medical device pursuant to Subsections (b) to (d) of Section 6 of these Rules, within 2 business days of this decision the producer shall be sent a relevant notice by registered mail (with proof of service) or in the form of an electronic document signed with a qualified advanced electronic signature.

8. Changes to a registration entry without changing the latest registered price for a medical device shall be made by the registering authority based on an application from the producer (or authorized representative of the producer) of the medical device without requiring the approval of the Federal Antimonopoly Service if such changes have been necessitated by a change of the name of the medical device producer or a change of the medical device name (as long as the properties and characteristics vital to the quality, efficacy, and safety of the medical device have not changed).

9. Details contained in the register shall be publicly available and published on the official website of the registering authority on the Internet.

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APPROVED
by Russian Government Resolution
No. 1517 of December 30, 2015

PROCEDURE

for Setting Ceiling Producer-set Prices for Medical Devices on the List of Medical Devices Implantable into the Human Body as Part of Medical Aid Provided to Citizens under the Program of State Guarantees of Free Medical Care for Citizens, and Ceiling Wholesale Markups on Actual Producer-set Prices for Said Medical Devices

1. This procedure establishes the process of determining the ceiling producer-set prices for medical devices included in the Russian Government-approved list of medical devices implantable into the human body as part of medical aid provided to citizens under the program of state guarantees of free medical care for citizens, and ceiling wholesale markups on actual producer-set prices for said medical devices (hereinafter "the medical device").

2. The weighted average producer-set price for the relevant type of medical device per the nomenclature classification of medical devices, which is procured in the Russian Federation, shall be determined on the basis of information submitted by producers of medical devices or their authorized representatives using the form presented in the Annex by the Federal Service for Supervision of Healthcare using the formula:

$$\text{price T} = \frac{(\text{WtdAvgPr-1 price} \times \text{Qty-1}) + (\text{WtdAvgPr-2 price} \times \text{Qty-2}) + \ldots + (\text{WtdAvgPr-n price} \times \text{Qty-n})}{\text{Total Qty}}$$

Where: price T – the weighted average producer-set price for the relevant type of medical device (roubles);

WtdAvgPr-1 price, WtdAvgPr-2 price, ... WtdAvgPr-n price – the weighted average producer-set price for the medical device (roubles);

Qty-1 (Qty-2, ... Qty-n) – the quantity of medical devices of the producer (in terms of the name as it appears in the registration certificate for the medical device and the type of nomenclature classification of medical devices) sold in the previous 12 months or a shorter period since the market circulation of the medical device began (units);

Total Qty – the quantity of medical devices of a given type sold by all producers in the reporting period (units).

3. Information about weighted average producer-set prices for medical devices by type per the nomenclature classification of medical devices shall be published on the official website of the Federal Service for Supervision of Healthcare on the Internet.

4. The ceiling wholesale markups on the actual producer-set prices for medical devices shall be set by executive authorities of the constituent entities of the Russian Federation.

5. The ceiling wholesale markups on the actual producer-set prices for medical devices shall be set using a differentiated approach depending on the ceiling producer-set price for a medical device and taking into account the medical device sales costs whose economic substantiation shall be performed in the manner prescribed by laws of the Russian Federation.

6. Medical device sales costs are subdivided into the following groups:

(a) Transportation costs. Transportation costs shall be calculated taking into account contracts for transportation services with third parties or actual expenses for deliveries using own vehicles, including vehicle upkeep and maintenance costs;

(b) Expenses for wages with the relevant disbursements as required by laws of the Russian Federation;

(c) Expenses for the upkeep and operation of buildings, structures, premises, and equipment;

(d) Amortization (depreciation) deductions;

(e) Expenses for storage and pre-sales preparation of goods. In calculating expenses for storage and pre-sales preparation of goods, account shall be taken of the cost of materials used in pre-sales preparation and expenses for third-party services involving storage of medical devices;

(f) Expenses for utility services. In calculating expenses for utility services, account shall be take of electricity, water supply and wastewater removal, gas and heat supply costs;

(g) Miscellaneous expenses (to be calculated according to the Tax Code of the Russian Federation).

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ANNEX
to the Procedure for Setting Ceiling Producer-set Prices
for Medical Devices on the List of Medical Devices
Implantable
into the Human Body as Part of Medical Aid Provided
to Citizens under the Program of State Guarantees of
Free Medical Care for Citizens, and Ceiling Wholesale
Markups on Actual Producer-set Prices for Said
Medical Devices

(Form)

INFORMATION

for Calculating Weighted Average Sales Prices for Medical Devices by Type per the Nomenclature Classification of Medical Devices

_____ __, 20__

Medical device producer or authorized representative of the medical device producer: name and place of business of the organization producing the medical device or last name, first name,
and (if any) patronymic and address of residence of the individual entrepreneur who manufactures the medical device, email address: ;

person of authority, job title, contact phone numbers: .

Item No.	Type of medical device per the nomenclature classification	Description of medical device	Details of the registration certificate (number, date of issuance)	Quantity of manufactured (in case of domestically produced) or imported (in case of foreign made) medical devices in the previous 12 months or a shorter period since the market circulation of the medical device began	
				units	thousands of roubles
	1	2	3	4	5

In addition, information shall be submitted in electronic form about the volumes of sales of implantable medical devices as part of each shipment in unit and money terms.

Manager of the applicant organization _____ _____
(Signature) (Full name)

Place of seal

Typed by _____ _____
(Signature) (Full name and phone number)