#### MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

# ORDER dated December 20, 2012, No. 1181n

# ON APPROVAL OF THE PROCEDURE FOR PRESCRIBING AND ADMINISTERING MEDICAL PRODUCTS AS WELL AS OF PRESCRIPTION TEMPLATES FOR MEDICAL PRODUCTS AND THE PROCEDURE FOR ISSUE, ACCOUNTING FOR AND STORAGE OF THESE FORMS

Pursuant to Article 14, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Articles 3442, 3446) and Section 5.2.185 of the Regulations on the Ministry of Health of the Russian Federation, as approved by Resolution of the Russian Federation Government dated June 19, 2012, No. 608 (Collection of Laws of the Russian Federation, 2012, No. 26, Article 3526), I order:

1. To approve:

The Procedure for Prescribing and Administering Medical Products, according to Appendix 1;

Form No. 1-MI, Prescription Form for Medical Products, according to Appendix 2;

Form No. 2-MI, Prescription Form (Corrective Glasses), according to Appendix 3;

Form No. 3-MI, Prescription Form for Contact Lenses, according to Appendix 4;

Procedure for Issue of, Accounting for and Storage of Prescription Forms for Medical Products, according to Appendix 5.

2. This Order shall inure on July 1, 2013.

Minister V. SKVORTSOVA

Appendix 1

#### PROCEDURE FOR PRESCRIBING AND ADMINISTERING MEDICAL PRODUCTS

1. This Procedure governs prescribing and administering of medical products (except for rehabilitation equipment <1>) in provision of medical services, except for first aid, including specialized first aid, in healthcare institutions. For the purposes of this Procedure, a healthcare institution means the healthcare institution defined in Article 2, Federal Law *On Fundamentals of Public Health Protection in the Russian Federation* <2> (hereinafter the 'medical institution').

<1> The Resolution of the Russian Federation Government dated April 7, 2008, No. 240, On the Procedure for Rehabilitation Equipment Procurement for the Disabled and for Prosthetic (except for Dental Prosthesis) and Orthopedic Appliance Procurement for Certain Population Categories Out of Veterans (Collection of Laws of the Russian Federation, 2008, No. 15, Article 1550; 2011, No. 16, Article 2294; 2012, No. 17, Article 199; No. 37, Article 5002).

<2> Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Article 3442, 3446.

2. Medical products shall be administered and prescribed by: A physician in charge of a medical institution;

A paramedical, an obstetrician, if they are vested with powers of the physician in the established manner <1> (hereinafter the 'medical professionals').

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<1> Order of the Ministry of Health and Social Development of the Russian Federation dated March 23, 2012, No. 252n, On Approval of the Procedure for Vesting a Paramedical or an Obstetrician with Certain Primary Care and First Aid Functions of a Physician by the Medical Institution Director to Provide Direct Care of the Patient in Observation and Treatment, Including Prescription and Application of Drugs, Narcotic and Psychoactive Medicines in Particular (registered by the Ministry of Justice of the Russian Federation on April 28, 2012, No. 23971).

- 3. Information on the prescribed and administered medical product (the medical product name, the quantity of the medical product units, the estimated course duration, substantiation of the medical product prescription) shall be specified in a patient's medical record.
  - 4. It shall be prohibited to medical professionals to write prescriptions:

in the absence of medical indications;

for medical products not registered in the Russian Federation.

5. Prescriptions for medical products shall be in Prescription Forms 1-MI, 2-MI, 3-MI in accordance with the requirements envisaged in the Procedure for Issue, Accounting for and Storage of Prescription Forms for Medical Products, as approved by Order of the Ministry of Health of the Russian Federation dated December 20, 2012, No. 1181n.

It shall be prohibited to abbreviate the medical product name so that it prevents from establishing what particular medical product is prescribed.

- 6. If there is a need in urgent or immediate dispense of a medical product to a patient, the notions of "cito" (urgently) or "statim" (immediately) shall be written in the upper part of the prescription.
- 7. The validity period of a medical product prescription shall be one month from the prescription date. If prescriptions are written for individuals in the retirement age, for Group 1 disabled persons and disabled children, the prescription validity period shall be three months from the prescription date.
- 8. For diagnosis and treatment of chronic diseases, medical products prescriptions shall be written for the treatment and diagnosis course of up to 3 months.

When prescribing a medical product for an up-to-three-months treatment or diagnosis course, the medical professional shall make a prescription form note 'For a Chronically III Patient', indicate the prescription validity period and the medical product dispense frequency for the pharmacy (weekly, monthly etc.), certify this indication with his/her signature and personal seal as well as the medical institution seal For Prescriptions.

- 9. When prescribing a medical product for chronically ill persons, medical professionals shall establish the prescription validity period of up to one year.
- 10. When prescribing a medical product for certain categories of individuals as envisaged in Russian law and entitled to receive medical products for free, the medical professional shall make the prescription form note Free of Charge.
- 11. The prescription for a medical product, which is written in violation of the requirements established in Order of the Ministry of Health of the Russian Federation dated December 20, 2012, No. 1181n, On Approval of the Procedure for Prescribing and Administering Medical Products as well as of Prescription Templates for Medical Products and the Procedure for Issue of, Accounting for and Storage of these Forms, or which contains a wrong medical product name shall be deemed invalid.
- 12. A prescription for a medical product shall be written in the name of the patient, for whom the medical product is prescribed.

A prescription for a medical product may be received by a patient or his/her authorized representative <1>. Actual writing of a medical product prescription for an authorized representative shall be confirmed with the patient's medical record entry.

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<sup>&</sup>lt;1> With respect to a person indicated in Part 2, Article 20, Federal Law dated November 21, 2011, No. 323-FZ, On Fundamentals of Public Health Protection in the Russian Federation (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Articles 3442, 3446).

Form No. 1-MI

#### PRESCRIPTION FORM FOR MEDICAL PRODUCTS

Medical institution name:
Stamp:
MSRN

Source of funding in case of drug procurement for reimbursement (please underline as appropriate):  1) federal budget 2) budget of the Russian Federation constituent	Patient's payment percentage: 1) 100% 2) free of charge	The prescript valid up to indicate the period):	(please
PRESCRIPTION series	No	Issue date:	, 20
For a chronically ill pa	atient		
Patient's full name			
Date of birth: Medical insurance policy numb	per:		
Patient's medical record numb	per		
Medical professional's full m	name		
Medical professional's teleph	none number		
Medical product name			
Number of units			
Medical professional's signat	ture		
Medical professional's person	nal seal	S.S.	
(to be filled-	in by a pharmacy wo	rker)	-
Dispensed under a prescription Dispense date: Medical product name:	on: - ——		
Quantity (units) For the total of			
	- (detach here)		
Prescription coupon series _ Medical product name	No	Issue date:	_, 20
Quantity (units)			

Form 2-MI

## PRESCRIPTION FORM (corrective glasses)

Medical product name: Stamp MSRN

MONN						
of drug pr reimburser underline 1) federal 2) budget	funding in rocurement : ment (please as approprial budget of the Russaconstitues	for p 1 iate): 2	atient's payme ercentage: ) 100% ) free of char		valid up	ription is to (please the validity
	ION series <sub>-</sub> full name	No		Issue da	te:	, 20
Date of back	irth:	licy number				
Patient's	medical red	cord number	2			
Medical p	rofessional	's full nam	ne			
Medical p	rofessional	's telephor	ne number			
Medical p	roduct name					
Number of	units					
		Sphere	Cylinder	Axle	Prism	Base
Right	Тор					
- C.	Bottom					
Left	Top Bottom					
7 00	D : la +		1,			
ADD Notes: AD	Right DD - <mark>addidat</mark>	ion (for b	iphocal and pr	Left rogressi	ve spectaci	le lens)
(	Figure not provide	d)				gure covided)
Interpupil	llary dista	г nce L		I	Right	Left
			erline):			

Special coverage	
Special marks	
Medical professional's signature	
Medical professional's personal seal	S.S.
(to be filled-in by a pharmacy worker)	
Dispensed under the prescription: Dispense date:, Medical product name:	
Quantity (units)	
For the total of:	
(detach here)	
Prescription coupon series No Issue d Medical product name	late:, 20
Quantity (units)	

Form 3-MI

#### PRESCRIPTION FORM FOR CONTACT LENSES

Medical institution name:
Stamp:
MSRN

of drug preimburser underline 1) federa 2) budget	funding in c rocurement fo ment (please as appropria l budget of the Russi n constituent	te):	Patient' percenta 1) 100% 2) free	ge:		valid	up to	otion is (please e validity
	ION series full name	No	·		Issue da	ate:		20
Date of b	irth:							
Medical in	nsurance poli	cy numbe	er					
Patient's	medical reco	rd numbe	er					
Medical p	rofessional's	full na	ame					
Medical p	rofessional's	telepho	one numbe	er				
Medical p	roduct name							
Number of	units							
		Con	tact len	ses pa	arameter	`S		
Right	Name of contact lenses	Radius (R)	Diamete r (D)	Colo r	Sphere (Sph)	Cylinde r (Cyl)	Axle (Ax)	Adidation (Ad)
eye (OD)								
Left eye (OS)								
		Appl	ication	recomm	nendatio	ns		
Wear mode Contact le	enses replace	ment fre	equency					
Contact le	enses care an							
Medical p	rofessional's	signatı	ıre:					
Medical p	rofessional's	persona	al seal			S.S.		
	(to be f	illed-ir	n by a ph	narmac	y worke:	r)		

Medical p	roduct name				
Quantity	(units)				
For the t	otal of				 
		(detach	n here)		 
-	ion coupon series . roduct name	No.	·	Issue date:	 , 20_

# PROFEDURE FOR ISSUE OF, ACCOUNTING FOR AND STORAGE OF PRESCRIPTION FORMS FOR MEDICAL PRODUCTS

## I. General Provisions

- 1. The stamp of a medical institution, indicating its name, address and telephone, shall be placed on prescription forms 1-MI, Prescription Form for Medical Products, 2-MI, Prescription Form for Corrective Glasses, and 3-MI, Prescription Form for Contact Lenses (hereinafter 'Prescription Forms', 'Forms 1-MI', '2-MI', '3-MI', respectively), in the upper left-hand corner.
- 2. The location address, license number and date, name of the governmental authority that has issued the license, shall be indicated in the prescriptions issued by individual businessmen holding a medical license, typographically or by placing a stamp in the upper left-hand corner.
- 3. Prescription forms shall be filled in by a medical professional legibly, clearly, in blue, purple or black ink or ball pen.
  - 4. It shall be allowed to fill in all of the prescription form details using computer technologies.
  - 5. Issue of prescription forms shall include digital encoding:-
- (a) medical institution code, according to the Main State Registration Number (MSRN), placed when prescription forms are drafted;
- (b) note of the source of funding (federal budget [1], budget of the Russian Federation constituent [2], and the patient's share in the prescription payment (100% [1], free-of-charge [2]).
  - 6. In prescription forms:-

The Patient's Full Name column specifies a patient's full name;

The Date of Birth column indicates a patient's date of birth (dd/mm/yyyy);

The Statutory Medical Insurance Policy Number specifies a citizen's personal insurance account number with the Pension Fund of the Russian Federation (SNILS) and a statutory medical insurance policy number;

The Patient's Medical Record (Child's Development History) Number column specifies a patient's medical record (child's development history) number;

The Medical Professional's Full Name column specifies a full name of the medical professional entitled to administer and prescribe medical products;

The Medical Product Name column indicates a medical product name, in accordance with the name specified in the national register of medical products and medical product manufacturers/makers; when Form 2-MI is filled-in, 'corrective glasses' is written; when Form 3-MI is filled-in, 'contact lenses' is indicated;

The Quantity of Units column specifies the precise quantity and the measurement unit.

- 7. A prescription issued on a prescription form shall be signed by the medical professional, certified with his/her personal seal as well as the medical institution's seal 'For prescriptions'.
  - 8. One medical product name shall be allowed to be prescribed on one prescription form.
- 9. To correct errors, it shall be necessary to strike through a wrong value, to write the correct value and to have the medical professional's signature placed under the correction with indication of the correction date. All corrections shall be certified with the seal of the physician in charge. Error correction using a corrective or another device shall not be allowed.
- 10. Upon dispense from a pharmacy of a medical product prescribed to certain categories of individuals envisaged in Russian law and entitled to receive the same free-of-charge, the prescription shall be kept in the pharmacy; the prescription coupon shall be provided to the patient (the patient's representative) with the mark of the medical product name and the dispensed unit quantity.

In other cases, the prescription shall be returned to the patient (the patient's representative).

### II. Prescription Form Accounting

11. All prescription forms for medical products shall be subject to accounting.

Prescription forms shall be accounted in registers numbered, sewn and bearing the Medical

Director's signature and the medical institution's seal or the signature of the individual businessman holding a medical license.

- 12. The prescription form register shall contain the following columns:-
- (a) sequence number;
- (b) in the Incoming section:-

Receipt voucher registration date;

Receipt voucher number and date; the supplier's name;

Total quantity of received prescription forms;

Full name and signature of the responsible medical professional that has received prescription forms from the supplier;

(c) in the Outgoing section:-

Prescription form issue date;

Quantity of issued prescription forms;

Full name of the responsible medical professional that has received the prescription forms;

Signature of the responsible medical professional that has received the prescription forms;

- (d) full name and signature of the responsible medical professional that has issued prescription forms;
  - e) balance of prescription forms.

#### III. Prescription Form Storage

- 13. Prescription forms for medical products written to certain categories of individuals envisaged in Russian law and entitled to receive medical products for free shall only be subject to storage.
  - 14. The prescription form reserve in medical institutions shall not exceed 6-month needs.
- 15. The person responsible for receipt, storage of, accounting for and issue of all prescription forms shall be appointed in each medical institution by the Medical Director's order.
- 16. Prescription forms shall be kept by the responsible person appointed by the medical institution Director in a locked metallic cabinet (safe deposit box) or in a metallic case.
- 17. An individual businessman holding a license for medical activities shall keep prescription forms in a locked metallic cabinet (safe deposit box) or in a metallic case.
- 18. A standing commission established in a medical institution shall inspect the state of storage of, accounting for, actual availability and consumption of prescription forms once a quarter.
- If a book balance of prescription forms does not meet their actual availability, the person responsible for receipt, storage of, accounting for and issue of prescription forms, shall be liable according to Russian law.
- 19. The prescription forms that satisfy two-week needs shall be given to medical professionals by the order of the Medical Director or his/her deputy.