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## ADMISSION OF EMPLOYEES TO THE CIRCULATION OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

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When organizing the work on the circulation of narcotic drugs and psychotropic substances (ND and PS), one of the conditions for the implementation of the activity is the registration of the admission of employees to work with ND and PS. For the past three years, this subject has become relevant in terms of the frequency of registration of one of the main documents such as a Certificate of absence of drug addiction, substance abuse and chronic alcoholism. Unfortunately, up to date, the validity period of this document has not been clarified by the regulatory authorities and is not regulated by law. When conducting control and supervisory activities, there is no unified and clear understanding of the specified requirements. In the practical activities of medical and pharmacy organizations, when meeting the requirements for annual registration of the certificate, additional financial and organizational difficulties arise, which

can lead to a limitation in the number of employees engaged in activities with ND and PS, and thereby, to decrease in the availability of pain – relieving medical care to the population.

**Keywords:** narcotic drugs, psychotropic substances, medical examination, medical clearance

When organizing the work on the circulation of narcotic and psychotropic drugs in medical and pharmacy organizations, one of the conditions for the implementation of activities is the registration of the admission of employees to work with narcotic drugs and psychotropic substances.

The procedure for obtaining the admission for employees to work with ND and PS is closely related to Article 10 of the Federal Law No. 3 dated 8.01.1998 "On Narcotic Drugs and Psychotropic

Substances" [1], which specifies the special requirements for the conditions for carrying out activities related to the circulation of ND and PS and their precursors included in List I, and the cultivation of narcotic-containing plants. Sub-paragraphs 4 and 5 of paragraph 3 of this Article provide for the mandatory availability of the following documents for legal entities:

- Certificates of absence of drug addiction, substance abuse and chronic alcoholism issued by the medical institutions of the public health system or municipal health system in the manner prescribed by the Federal Executive authority responsible for formulation and implementation of state policy and normative-legal regulation in the sphere of health, in coordination with the Federal Executive authority in the sphere of internal affairs, to the employees, who in accordance with their work responsibilities should have access to the ND and PS, List I precursors or cultivated drug-containing plants;
- the reports of conclusion of the Internal Affairs Bodies that the employees, who in accordance with their duties shall have access to ND and PS, List I precursors or cultivated drug-containing plants, have no unexpunged or unspent conviction for misdemeanor, serious crime, very serious crime or illegal trafficking of the ND and PS, their precursors or illicit cultivation of narcotic-containing plants, including the crime committed outside the Russian Federation.

According to the requirements of p. 4 of the Decree of the Government of the Russian Federation dated 06.08.1998 No. 892 "On approval of the Rules for admission of persons to work with the narcotic drugs and psychotropic substances as well as to activities connected with circulation of precursors of narcotic drugs and psychotropic substances", [2], the presence of the above certificates and conclusion reports is a prerequisite for registration of admission of employees to work with ND and PS: "The persons under 18 years

of age, and the persons, who have no certificates and conclusions provided for in sub-paragraphs 4 and 5 of paragraph 3 of Article 10, respectively, are not admitted to work with the narcotic drugs and psychotropic substances, as well as activities related to circulation of precursors."

In accordance with p. 6 of abovementioned Decree, the head of the organization issues to the person to be hired to work with the ND and PS, as well as for the implementation of activities related to circulation of precursors, the referrals to healthcare organizations for preliminary (periodic) **medical examination** and mandatory psychiatric **evaluation** in a prescribed manner for **obtaining certificates** stipulated in pp. 4, p. 3 of Article 10 of the Federal Law № 3-FZ. This paragraph, according to some lawyers, indicates the relationship between medical examinations and psychiatric examinations to obtain a certificate of absence of drug addiction, substance abuse and chronic alcoholism [3].

Previously (until 2017), the form of the certificate and the procedure for obtaining it were not specified, the absence of drug addiction, substance abuse and chronic alcoholism was confirmed only by the absence of information from the drug treatment and (or) psychiatric dispensary on employees (that are not registered), issued in any form by the relevant organizations, as well as by the medical conclusion of a professional pathologist on the state of health of the employee (after a preliminary or periodic examination), which indirectly confirmed the absence of these diseases. The validity period of such certificates was not specified, it was enough to issue (receive) them to the employee once when the employee obtained admission to work with the ND and PS.

However, since February 2017, the Order of the Ministry of Health of the Russian Federation No. 988H dated 22.12.2016 "On the procedure for issuing a certificate of absence of drug addiction, substance abuse, and chronic alcoholism to employees who, in accordance with their employment duties, must have access to ND

and PS included in List I and Table I of List IV of NDs and PSs and their precursors subject to control in the Russian Federation, precursors or cultivated narcotic-containing plants" [4], which regulates the procedure for obtaining such a certificate and does not provide for the need to undergo a preliminary (periodic) medical examination and a mandatory psychiatric examination in accordance with the specified procedure.

The specified procedure for issuing a certificate applies to all employees whose activities are related to the circulation of **narcotic drugs and psychotropic substances subject to control in the Russian Federation**, including in medical and pharmacy organizations, which is directly regulated by sub-paragraph 4 of paragraph 3 of Article 10 of the Federal Law "On Narcotic Drugs and Psychotropic Substances", while the Decree of the Government of the Russian Federation No. 892 dated 06.08.1998 reminds that "the persons in respect of whom there are no certificates" are not allowed to work with Narcotic Drugs (ND) and Psychotropic Substances (PS). The Order of the Ministry of Health of the Russian Federation dated 22.12.2016 No. 988H, regulating the procedure for obtaining a certificate of absence of drug addiction, substance abuse, and chronic alcoholism, is closely related to the normative legal acts specifying the rules for admission to work with ND and PS.

Taking into account the current regulatory legal acts, to obtain an admission for each employee of a medical or pharmacy organization whose activities are related to the treatment of ND and PS, it is necessary have the following documents (see Table).

On the basis of the documents received for each employee, the HR department prepares an order on admission for the head of the organization.

It should be noted that, in accordance with paragraphs 7 and 9 of the Decree of the RF Government dated 06.08.1998 No. 892 it was specified that the validity of the admission is limited

to the duration of the employment contract. Also, the admission of a person to work with ND and PS, to activities related to the circulation of precursors, is terminated when circumstances are identified that prevent the issuance of relevant certificates and conclusions provided for in sub-paragraphs 4 and 5 of paragraph 3 of Article 10.

The main documents required for registration of admission are a Criminal record certificate and a Certificate on the absence of drug addiction, substance abuse and chronic alcoholism.

A special feature of a Criminal record certificate for an employee whose activities are related to the circulation of ND and PS (see Table) is that it is issued for the organization where the employee works, and is valid for the period of performance of his duties related to the circulation of ND and PS.

The second mandatory document for registration of admission is a Certificate of absence of drug addiction, substance abuse and chronic alcoholism (hereinafter referred to as the Certificate). Ministry of Health Order No. 988H allocated a **separate medical examination** for obtaining the Certificate of absence of drug addiction, substance abuse and chronic alcoholism, which includes the following steps:

- examination by an addiction psychiatrist;
- determination of the presence of psychoactive substances in the urine;
- qualitative and quantitative determination of carbohydrate-deficient transferrin (CDT) in blood serum by capillary electrophoresis;
- analysis of the information contained in the employee's medical records (if available).

This examination is more accurate and indicative for detection of drug addiction, substance abuse and chronic alcoholism, but it becomes an independent procedure, regardless of the preliminary (periodic) examination and psychiatric evaluations of employees, which are also provided by the RF Government Decree No. 892 and binding in the organization.

### LIST OF DOCUMENTS REQUIRED TO OBTAIN ADMISSION TO THE ND AND PS

Normative legal act regulating the availability of the document	Document	Validity period of a document
<p>1. Paragraph 3 of Article 10 of the Federal Law "On Narcotic Drugs and Psychotropic Substances"</p> <p>2. Paragraphs 4, 6 and 9 of Decree of the RF Government dated 06.08.1998 No. 892 "On approval of the Admission Rules..."</p> <p>3. Paragraph 7 "d" of Decree of the RF Government dated 22.12.2011 No. 1085 "About licensing activities..." [5]</p> <p>4. Order of Ministry of Internal Affairs of the Russian Federation dated 17.07.2017 No. 470 "On the approval of the Administrative Regulations..." [6]</p>	<p>The report of conclusion of the Internal Affairs Bodies that the employees, who in accordance with their duties shall have access to ND and PS, List I precursors or cultivated drug-containing plants, have no unexpunged or unspent conviction for misdemeanor, serious crime, very serious crime or illegal trafficking of the ND and PS, their precursors or illicit cultivation of narcotic-containing plants, including the crime committed outside the Russian Federation.</p>	<p>NA</p> <p>An employee may be excluded from the conclusion at the request of the organization in cas of:</p> <ul style="list-style-type: none"> <li>• changes in the employee's work obligations,</li> <li>• employee termination;</li> <li>• availability of information about the new criminal record. The deadline for submitting an application for the exclusion of an employee from the conclusion report is not specified.</li> </ul>
<p>1. Paragraph 3 of Article 10 of the Federal Law "On Narcotic Drugs and Psychotropic Substances"</p> <p>2. Paragraphs 4, 6 and 9 of Decree of the RF Government dated 06.08.1998 No. 892 "On approval of the Admission Rules..."</p> <p>3. Paragraph 7 "d" of Decree of the RF Government dated 22.12.2011 No. 1085 "About licensing activities..."</p> <p>4. Order of the Ministry of Health of the Russian Federation dated 22.12.2016 No. 988H "On the procedure of issuing the Certificate of absence of drug addiction, substance abuse, and chronic alcoholism..."</p>	<p>Certificates of absence of drug addiction, substance abuse, and chronic alcoholism issued to employees who, in accordance with their employment duties, must have access to ND and PS, precursors included in List I or cultivated narcotic-containing plants.</p>	<p>Not applicable</p>

*End of the table*

Normative legal act regulating the availability of the document	Document	Validity period of a document
<p>1. Paragraphs 6 of Decree of the RF Government dated 06.08.1998 No. 892 "On approval of the Admission Rules..."</p> <p>2. Order of MHSD dated 12.04.2011 No. 302H "On the approval of the lists of harmful and (or) dangerous production factors and works for performing of which the mandatory preliminary and periodic medical examinations are provided, and the Procedure for conducting the mandatory preliminary and periodic medical examinations of employees engaged in heavy work and work with harmful and (or) dangerous working conditions" [7]</p>	<p>Medical conclusion according to the results of a preliminary (periodic) examination of employees.</p>	<p>1 year</p>
<p>1. Paragraphs 6 of Decree of the RF Government dated 06.08.1998 No. 892 "On approval of the Admission Rules..."</p> <p>2. Article 6 of the Law of the Russian Federation dated 02.07.1992 No. 3185-1 "On psychiatric care and guarantees of the rights of citizens in delivery of such care" [8]</p> <p>3. Decree of the RF Government dated 28.04.1993 No. 377 "On the implementation of the Law of the Russian Federation "On psychiatric care and guarantees of the rights of citizens in delivery of such care"[9]</p> <p>4. Decree of the RF Government dated 23.09.2002 No. 695 "On the mandatory psychiatric evaluation of employees who carry out certain types of activities, including activities related to sources of increased risk (with the influence of harmful substances and unfavorable production factors), as well as who work in conditions of increased risk" [10]</p>	<p>The decision of the medical commission (in writing) that conducted the psychiatric examination.</p>	<p>5 years</p>

Unfortunately, the regulatory document **does not specify the frequency** of receipt of this Certificate. In other documents regulating the need to obtain a Certificate (see Table), there is also no data on the period of its validity.

An important factor affecting the execution of a Certificate of absence of drug addiction, substance abuse and chronic alcoholism is the difficulty of obtaining it [11], because the required studies are carried out using the special equipment, which is only available in large clinics, as well as due to the duration of the tests and the high cost. All of that create significant difficulties not only for medical and pharmacy organizations located in rural areas, but also for large multidisciplinary medical organizations, where hundreds of employees are allowed to work with ND and PS. At the same time, the financial expenses of these studies are borne by the employer.

The following two documents – the Conclusion Report on the results of the preliminary (periodic) medical examination of employees and the Decision of the medical commission that conducted the psychiatric evaluation – do not directly affect the admission of employees to the ND and PS. According to the RF Government Decree No. 892, their execution is required only to “obtain the certificates provided under p. 3 of Article 10,” but in the Order of the Ministry of Health of the Russian Federation No. 988H they are not required.

Some experts refer to the direct dependence of the Order of the MHSD of Russia dated 12.04.2011 №302H and Order Ministry of Health of Russia dated 22.12.2016 №988H [12]. However, from the point of view of the health care organizers, there is no hierarchy of these documents in circulation of the ND and the PS.

Let’s consider the procedure of execution of the Order of the MHSD of Russia dated 12.04.2011 No. 302H in relation to the circulation of ND and PS. The Conclusion Report on the results of preliminary (periodic) medical

examination shall be executed in accordance with Order No. 302H, according to which the **use of the ND and PS** in medical activities is not harmful and (or) dangerous production factor, as well as the activity for circulation of ND and PS is not specified in the list of works, for performing of which the mandatory preliminary and periodic medical examinations of employees shall be conducted. The order provides for mandatory preliminary and annual periodic examination only **in the production of ND and PS** (p. 1.3.9.6 of Appendix No. 1), as well as for employees of medical and pharmacy organizations in accordance with paragraphs 17 and 24 of Appendix No. 2, regardless of whether their activities are related to the circulation of ND and PS or not. When conducting a medical examination of these categories of employees, the laboratory and functional studies do not provide for mandatory tests (toxicology screening, CDT) required to obtain a Certificate of absence of drug addiction, substance abuse and chronic alcoholism, but when conducting PME (periodic medical examinations), the participation of a psychiatrist and a narcologist is always mandatory, who, in accordance with paragraph 38 of Order No. 302H, must **in case of identification** of persons with suspected medical contraindications (drug addiction, substance abuse, alcoholism) send them “for examination by the medical commission authorized by the health body”.

Definitions and types of “**medical evaluation**” and “**medical examination**” are specified in Federal Law No. 323 dated 21.11.2011 “On the Basics of Public Health Protection in the Russian Federation” [13]. In accordance with p. 1 of Article 46 of this law, “a medical examination is a complex of medical interventions aimed at identifying pathological conditions, diseases and risk factors for their development.” In accordance with p. 1 of Article 65 of this law, a medical evaluation of a person is a set of methods of medical examination and medical investigation aimed at

confirming such health status of a person that results in the legal implications.

From these definitions, it can be concluded that only **the evaluation of the patient, carried out in case of suspected** medical contraindications, involves an in-depth study of health parameters (including the urine psychoactive substances tests and determination of the carbohydrate-deficient transferrin in the blood serum) with obtaining a certificate of the absence of drug addiction, substance abuse, chronic alcoholism.

Psychiatric evaluation is an independent procedure, which is regulated by the Law of the Russian Federation dated 02.07.1992 No. 3185-1 "On psychiatric care and guarantees of the rights of citizens in its provision". Thus, according to the Decree of the RF Government dated 28.04.1993 No. 377, the activities for circulation of ND and PS is included in the List of medical psychiatric contraindications for the implementation of certain types of professional activities related to the source of increased danger. The frequency and timing of psychiatric evaluation of employees are regulated, the procedure is available in many medical organizations that have the appropriate license, which does not cause difficulties and disagreements when obtaining the decision of the medical commission that conducted the psychiatric evaluation.

## CONCLUSIONS

In relation to circulation of ND and PS, it is necessary to clearly separate the concepts of **"medical examination"** and **"medical evaluation"**, in accordance with Federal Law No. 323-FZ dated 21.11.2011. Based on the comparison, it can be concluded that the annual evaluation should be carried out **only in case of suspected** medical contraindications, which involves an in-depth study of health parameters (including the urine psychoactive substances tests and determina-

tion of the carbohydrate-deficient transferrin in the blood serum) with obtaining a Certificate of the absence of drug addiction, substance abuse, chronic alcoholism.

It should be noted that the Certificate under discussion is only an integral part of the materials issued to persons whose activities are related to the circulation of ND and PS.

To obtain the Certificate in question, the head of the organization issues referrals to medical organizations to the person being hired in order to undergo a preliminary (periodic) medical examination and a mandatory psychiatric evaluation (once every 5 years) [14].

Thus, as a result of the **medical examination**, it is necessary to evaluate not the general mental health of the candidate, but to determine whether he can engage in a specific activity – participation in the handling of ND and PS.

The employee applies to a medical organization and undergoes a medical examination, which includes:

- examination by an addiction psychiatrist;
- determination of the presence of psychoactive substances in the urine;
- qualitative and quantitative determination of carbohydrate-deficient transferrin (CDT) in blood serum by capillary electrophoresis;
- analysis of the information contained in the employee's medical records (if available).

If an employee doesn't suffer from drug addiction, substance abuse and chronic alcoholism, a corresponding Certificate is issued. The term of its validity is not specified by legal acts, there is only a requirement to have such a Certificate when applying for a job.

***Taking into account the above, the validity period of a person's admission to work with narcotic drugs, psychotropic substances, as well as to activities related to the circulation of precursors, is limited by the validity period of the employment contract.***

There is an opinion of some lawyers that as part of the mandatory annual periodic

medical examinations of employees, it is necessary to receive a new Certificate each time. We believe that this opinion should be considered critically, since, as mentioned above, the Certificate is only an integral part of the materials for admission to work with ND and PS, as well as to activities related to the circulation of precursors. In accordance with part 2 of Art. 213 of the Labor code [15], the employees, including medical organizations, undergo regular medical examinations in order to protect public health, prevent the occurrence and spread of diseases, and therefore, the employers or medical institutions have no legal grounds to send annually the employee for a medical evaluation to obtain a new Certificate about the absence of drug addiction, substance abuse, chronic alcoholism.

Currently, the Ministry of Health of the Russian Federation is actively working to improve the legal regulation of medical care. The amendments are aimed at increasing the availability of pain-relieving therapy and ensuring the necessary control over the circulation of ND and PS. However, in the practical work of medical and pharmacy organizations, sometimes there is a different understanding of the specified requirements, which needs additional explanations from the federal executive authorities.

## REFERENCES

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2. Decree of the Government of the Russian Federation dated 06.08.1998 No. 892 "On Approval of the Rules for the admission of persons to work with narcotic drugs and psychotropic substances, as well as to activities related to the circulation of precursors of narcotic drugs and psychotropic substances".
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4. Order of the Ministry of Health of the Russian Federation dated 22.12.2016 No. 988H "On the procedure for issuing a Certificate of absence of drug addiction, substance abuse, chronic alcoholism to the employees who, in accordance with their work duties, must have access to ND and PS included in List I and Table I of List IV of ND and PS and their precursors subject to control in the Russian Federation, precursors or cultivated narcotic-containing plants".
5. Decree of the Government of the Russian Federation No. 1085 dated 22.12.2011 (as amended on 04.04.2020) "On Licensing Activities for the Circulation of Narcotic Drugs, Psychotropic Substances and their Precursors, Cultivation of narcotic-containing plants" (together with the "Regulations on Licensing Activities for the Circulation of Narcotic Drugs, Psychotropic Substances and Their Precursors, Cultivation of Narcotic-containing Plants").
6. Order of the Ministry of Internal Affairs of Russia dated 17.07.2017 №470 "On approval of Administrative Regulations of the Ministry of Internal Affairs of the Russian Federation on provision of the state service for issuance of the conclusion reports on the absence of unpunished or unspent conviction for misdemeanor, serious crime, very serious crime or illegal trafficking of the ND and PS, their precursors or illicit cultivation of narcotic-containing plants, to employees, who in accordance with their duties shall have access to ND and PS, List I precursors or cultivated drug-containing plants...".
7. Order of MHSD dated 12.04.2011 No. 302H "On the approval of the lists of harmful and (or) dangerous production factors and works for performing of which the mandatory preliminary and periodic medical examinations are provided, and the Procedure for conducting the mandatory preliminary and periodic medical examinations of employees engaged



- in heavy work and work with harmful and (or) dangerous working conditions"*
8. Law of the Russian Federation dated 02.07.1992 No. 3185-1 "On psychiatric care and guarantees of the rights of citizens in delivery of such care".
  9. Decree of the RF Government dated 28.04.1993 No. 377 "On the implementation of the Law of the Russian Federation "On psychiatric care and guarantees of the rights of citizens in delivery of such care"
  10. Decree of the RF Government dated 23.09.2002 No. 695 "On the mandatory psychiatric evaluation of employees who carry out certain types of activities, including activities related to sources of increased risk (with the influence of harmful substances and unfavorable production factors), as well as who work in conditions of increased risk"
  11. The Order of the MHSD of Russia dated January 27, 2006, No. 40 "On organization of Toxicology screening with analytical diagnosis of the presence of alcohol, narcotic drugs, psychotropic and other toxic substances in the human body".
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