



# Legal Regulation of Control (Supervision) over Quality and Safety of Medical Activities in Transport Industry



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## ABSTRACT

The relevance of the study is determined by important social functions of the transport infrastructure in the life of modern society and the need for medical care for transport employees, which ensures continuity of provision of transport services, safety, and security of citizens.

The subject of this study is the current regulatory legal framework and the features of control (supervision) over quality and safety of medical activities in transport sector in the Russian Federation. The study consistently considers the legal framework

for implementation of control (supervision) in the field of transport, analyses the system of bodies exercising it, their rights, powers, and visualize the features of inspections, overviews the rights of organisations in respect of which control (supervision) of quality and safety of medical activities is carried out.

The article studies the theoretical and regulatory legal aspects related to implementation of the control function of the state in transport sector, formulates proposals for improving the legal support for control over implementation of medical activities in transport field.

**Keywords:** transport, medical care, medical activities, control (supervision), transport safety, prosecution authorities.

*For citation:* Leonov, T. M., Zemlina, O. M. Legal Regulation of Control (Supervision) over Quality and Safety of Medical Activities in Transport Industry. World of Transport and Transportation, 2023, Vol. 21, Iss. 2 (105), pp. 237–242. DOI: <https://doi.org/10.30932/1992-3252-2023-21-2-11>.

**The text of the article originally written in Russian is published in the first part of the issue.**  
**Текст статьи на русском языке публикуется в первой части данного выпуска.**

## INTRODUCTION

The results of historical and legal analysis indicate that the special importance of transport for economy, national security, socio-economic development of the state, combined with obvious technical complexity of vehicles, transport infrastructure facilities, has always predetermined the need to establish regulatory rules and requirements for their implementation [1, P. 267], ensuring their compliance with the use of legal means [2, pp. 250–251].

It is reasonably noted that this problem is no less significant at the present time, thus determining the need for special attention to the issues of systemic and full legal support of transport relations [3, P. 4971; 4, P. 238], the formation of the legal culture of transport specialists [5, P. 4961].

In connection with the complication of the transport safety and security system, objectively determined by digitalisation of the economy and transport logistics, there is an increasing need for imperative regulation of relations related to the activities of the transport sector, which can be carried out exclusively using public law means [6, P. 67].

Today, more than ever, important social functions in the life of modern society are performed by the transport infrastructure, providing unlimited access to which for various categories of people, including the disabled persons and people with limited mobility, acquires not even a socio-economic, but a socio-political character [7, P. 147; 8, P. 14].

Activities in the field of transport are carried out and provided by various categories of officials, including medical employees. Medical care for transport employees, in turn, is a condition for ensuring the continuity of provision of transport services and safety of citizens.

An analysis of domestic and foreign scientific literature shows that under the conditions of temporary restrictions on the degree of accessibility of transport services in the context of introduction of legal regimes to counteract the spread of infectious diseases, firstly, the degree of awareness of the population in their personal significance for them of the possibility of unhindered use of transport increases [9, P. 27; 10–16], and on the other hand, there is an

increasing understanding of the problems of ensuring quality and safety of medical activities in transport [17, pp. 18–21; 18, P. 17; 19, P. 16].

Medical activity in transport is complex, designed to fulfil many mandatory requirements, and has its own organisational and legal foundations. It is no coincidence that legal norms are developed by society so that they are effectively implemented in practice, so that the goals that the legislator was counting on are achieved [20, P. 84].

One of the trends that characterise the current state of legislation is the impact on lawmaking of various mechanisms of law enforcement [21, P. 144].

Mandatory for formal certainty of law is the legislative discretion of the duties and missions of officials performing state-significant, i. e., public functions [22, pp. 78–79; 23, P. 31].

The *objective* of the study is to reveal and scientifically substantiate the essence, content, and structure of the legal regulation of this control (supervision). Solution of research problems of a comprehensive knowledge based on a systematic legal approach, used *methods* of formal dogmatic and comparative legal analysis of the current system of legal regulation, establishing the features of organisation and the procedure for monitoring (supervision) over quality and safety of medical activities in transport sector.

## RESULTS

### Foundations of Legal Regulation of Medical Activities in Transport Sector

Medical activity in the Russian Federation is a special, licensed type of activity, the legal regulation of which is based on the norms of the Constitution of the Russian Federation, Federal Laws «On the Fundamentals of Protecting the Health of Citizens in the Russian Federation», «On the Circulation of Medicines», «On Licensing Certain Types of Activities», «On the immunoprophylaxis of infectious diseases», «On the sanitary and epidemiological well-being of the population», Decree of the Government of the Russian Federation dated June 1, 2021, No. 852 «On licensing medical activities (with the exception of the specified activities carried out by medical organisations and other organisations that are part of a private

health care system, on the territory of Skolkovo innovation centre) and invalidation of certain acts of the Government of the Russian Federation» and other regulatory legal acts that are sometimes contradictory and gap-filled, which requires the use of special knowledge when carrying out medical and complex examinations [24, pp. 31–32; 25, pp. 283–265].

Medical care (except for medical care provided within the framework of clinical testing) is organised and provided in accordance with the regulation on organisation of medical care by type of medical care, which is approved by the authorised federal executive body; in accordance with the procedures for provision of medical care, approved by the authorised federal executive body and binding on the territory of Russia by all medical organisations; based on clinical guidelines; taking into account the standards of medical care approved by the Russian Ministry of Health. This norm is established by Part 1 of Article 37 of the Federal Law «On the Fundamentals of Protecting the Health of Citizens in the Russian Federation» [26].

Medical activity in transport is also regulated by the Federal Laws «On Railway Transport in the Russian Federation», «On Highways and Road Activities in the Russian Federation and on Amendments to Certain Legislative Acts of the Russian Federation», «Charter of Road Transport and Urban Surface Electric Transport», «Charter of Railway Transport of the Russian Federation», the Labour Code and other regulatory legal acts of the Russian Federation.

### **Legal Regulations of Control (Supervision) in the field of Health Care**

The Federal Law «On the Fundamentals of Protecting the Health of Citizens in the Russian Federation», in addition to the basics of providing medical care to citizens and the procedure for carrying out medical activities, regulates issues of control (supervision) in the field of health protection. This control (supervision) is carried out, in particular, through federal state control (supervision) of quality and safety of medical activities, departmental quality control and safety of medical activities, internal quality control and safety of medical activities. These requirements are normatively enshrined

in Article 85 of the said law.

It is important to pay attention to the fact that the authorised authorities exercising state control (supervision) in the field of health protection have the right to issue binding orders in case of violations of the law; hold a person accountable for violation of legislation in the field of health protection, legislation on circulation of medicines; draw up protocols on administrative offenses, consider cases on administrative offenses; send materials to the authorised bodies to resolve issues of initiating criminal cases on the grounds of crimes; apply to the court with claims, statements about violations of the law and others. Consequently, when monitoring (supervising) quality and safety of medical activities, in case of committed and detected violations, adverse consequences may occur in relation to medical organisations (officials) associated with administrative, civil, or criminal prosecution.

Federal state control (supervision) of quality and safety of medical activities is carried out by Roszdravnadzor [Federal Service for Surveillance in Healthcare]. The subject of federal state control (supervision) of quality and safety of medical activities covers:

1) Compliance by medical organisations (including medical employees), pharmaceutical organisations (including pharmaceutical employees), state extra-budgetary funds, individual entrepreneurs engaged in medical activities, and individual entrepreneurs engaged in pharmaceutical activities, with mandatory requirements in the field of health protection, requirements to objects used in implementation of activities in the field of health protection.

2) Compliance with licensing requirements for implementation of medical activities.

The regulation on federal state control (supervision) of quality and safety of medical activities was approved by Decree of the Government of the Russian Federation of June 29, 2021, No. 1048. This document regulates the procedure for organising and implementing federal state control (supervision) of quality and safety of medical activities carried out by Roszdravnadzor. Roszdravnadzor Order No. 5974 dated July 10, 2020, approved the Administrative Regulations on implementation of state control over quality and safety of



medical activities, which establishes the procedure, timing and sequence of administrative procedures during inspections.

Officials of Roszdravnadzor (of its territorial bodies) in the exercise of state control have the right to:

1) Request from legal entities and receive information necessary to make a decision on issues within their competence.

2) Get acquainted with the documents related to the goals, objectives, and subject of the on-site inspection, if the on-site inspection was not preceded by a documentary inspection.

3) Freely obtain access to the territory of inspected legal entities.

4) Carry out, with the execution of appropriate protocols, sampling of materials and organise the conduct of the necessary studies, tests, examinations, analyses, and assessments.

5) Make copies of the documents necessary for carrying out state control, as well as, if necessary, take photographs and proceed with filming, video recording during inspection and examination.

6) Apply measures of a restrictive and preventive nature provided for by law, aimed at preventing and (or) eliminating the consequences of violation of mandatory requirements.

7) Provide legal entities and individuals with clarifications on issues within the competence of Roszdravnadzor.

Roszdravnadzor Order No. 973 dated February 11, 2022, approved forms of checklists (lists of checklists, the answers to which indicate compliance or non-compliance by the controlled person with mandatory requirements) used by Roszdravnadzor and its territorial bodies for implementation of federal state control (supervision) of quality and safety medical activities. This is an important document in terms of what issues will be assessed during the audit.

As for the legal regulation of other types of state control (supervision) of quality and safety of medical activities, the Procedure for organising and conducting departmental quality control and safety of medical activities is normatively approved by order of the Ministry of Health of Russia dated July 31, 2020 No. 787n, and the Requirements for organising and conducting internal quality control and safety of medical activities approved by order of the

Ministry of Health of Russia dated July 31, 2020, No. 785n.

In accordance with Decree of the Government of Russia dated April 28, 2015 No. 415 «On the Rules for Formation and Maintenance of a Single Register of Inspections», the register of inspections, as well as information about the bodies involved in their conduct, is posted on the Internet information and telecommunication network.

It should be noted that the rights of a medical organisation in respect of which control (supervision) of the quality and safety of medical activities is carried out are stipulated by Article 21 of the Federal Law «On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Implementation of State Control (Supervision) and Municipal Control». According to this article, the head of a legal entity (another official or authorised representative), during an audit, has the right to:

1) Be directly present during the audit, give explanations on issues related to the subject of the audit.

2) Receive from the state control (supervision) body, their officials information that relates to the subject of inspection.

2.1) Get acquainted with the documents and (or) information received by the state control (supervision) bodies.

2.2) Submit documents and (or) information requested to the state control (supervision) body on their own initiative.

3) Get acquainted with the results of the inspection and indicate in the act of inspection about their familiarisation with the results of the inspection, agreement or disagreement with them, as well as with certain actions of officials of the state control (supervision) body.

4) Appeal against the actions (inaction) of officials of the state control (supervision) body, which entailed a violation of the rights of a legal entity, during an audit, in an administrative and (or) judicial manner in accordance with the law.

### **Features of Legal Regulation of Medical Activity and Control (Supervision) over it in Transport Sector**

When carrying out medical activities in transport, special attention should be paid to



the following regulatory legal acts: Order of the Ministry of Health of Russia dated December 15, 2014, No. 835n «On approval of the Procedure for conducting pre-shift, pre-trip and post-shift, post-trip medical examinations»; Order of the Ministry of Transport of Russia dated January 12, 2021 No. 4 «On approval of the Procedure for conducting mandatory pre-trip or pre-shift medical examinations in railway transport»; order of the Ministry of Transport of Russia dated February 2, 2021 No. 26 «On approval of the List of professions of railway workers engaged in production activities directly related to the movement of trains and shunting work, who undergo mandatory pre-trip or pre-shift medical examinations, as well as, at the request of employers, a medical examination for state of intoxication (alcoholic, narcotic or other toxic intoxication)»; order of the Ministry of Transport of Russia dated October 19, 2020, No. 428 «On approval of the Procedure for conducting mandatory preliminary (when applying for a job) and periodic (during employment) medical examinations in railway transport» and other regulatory legal acts.

Also, in accordance with the Federal Law of January 17, 1992, No. 2202–1 «On the Prosecutor’s Office of the Russian Federation» (Articles 1, 21, 22, 26, 27), the relevant prosecutor has the right to participate (conduct) in implementation of measures to control (supervise) quality and safety of medical activities in transport.

**BRIEF CONCLUSIONS**

Taken together, measures to control (supervise) quality and safety of medical activities in transport make it possible to reliably establish compliance by medical organisations and medical employees with mandatory (including licensing) requirements. This makes it possible to ensure timely diagnosis of diseases, save the health of transport employees and ensure provision of due and perfect medical care to them. The current direction of further research concerns optimising administrative procedures in the field of control (supervision) of medical activities in transport, identifying duplicate or

outdated rules of law while simultaneously increasing the efficiency of control (supervisory) activities.

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Article received 06.10.2022, approved 27.02.2023, accepted 24.04.2023.