

## Problems of legal regulation of medical waste disposal

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The article is devoted to an urgent problem in the field of environmental safety – legal regulation of medical waste management at the level of federal legislation, as well as trends in the normative consolidation of the medical waste disposal system being created. The selected legislative mechanism for special regulation in the field of medical waste disposal is the most optimal model of legal regulation. Exemption of the specified category from the scope of Federal Law No.89-FZ “On Production and Consumption Waste” of June 24, 1998 contributes to the environmental safety on issues of medical waste disposal. On the other hand, a serious problem of legal regulation has been identified. The result of the study is a recommendation on the need for special legal regulation of the medical waste management system at the level of the law. The normative model of special regulation on the example of the draft law “On conducting experiments on the organization and centralized management of medical and biological waste in the Moscow region and on amendments to certain legislative acts of the Russian Federation” is assessed by the authors positively in terms of differentiating the concepts of “medical waste” and “biological waste”, but the idea of introducing a regional operator and the principles of public-private partnership (by analogy with the model of solid waste disposal) is criticized.

**Keywords:** medical waste, regulation, liability in the field of medical waste circulation, legal regulation model.

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## Проблемы правового регулирования утилизации медицинских отходов

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Статья посвящена актуальной проблеме в сфере экологической безопасности – правовому регулированию обращения с медицинскими отходами на уровне федерального законодательства, а также тенденциям в сфере нормативного закрепления создаваемой системы утилизации медицинских отходов. Выбранный законодателем способ специального нормативного регулирования в сфере утилизации медицинских отходов является наиболее оптимальной моделью правового регулирования. Изъятие указанной категории из сферы действия Федерального закона от 24.06.1998 № 89-ФЗ «Об отходах производства и потребления» способствует обеспечению экологической безопасности в вопросах утилизации медицинских отходов. С другой стороны, выявлена серьёзная проблема правового регулирования: на уровне федерального законодательства определяется лишь понятие и классификация медицинских отходов, ключевые вопросы действия системы устанавливаются на уровне подзаконных нормативных актов (санитарных норм и правил), что является причиной возможного ухода от ответственности. Результатом исследования являются рекомендации о необходимости специального правового регулирования системы обращения с медицинскими отходами на уровне федерального закона. Нормативная модель специального регулирования на примере законопроекта «О проведении эксперимента по организации и осуществлению централизованного обращения с медицинскими и биологическими отходами в Московской области и о внесении изменений в отдельные законодательные акты Российской Федерации» оценивается авторами положительно в

части разграничения понятий «медицинские отходы» и «биологические отходы», но критике подвергается идея внедрения регионального оператора и принципов государственно-частного партнёрства (по аналогии с моделью утилизации твёрдых бытовых отходов).

**Ключевые слова:** медицинские отходы, нормативное регулирование, ответственность в сфере оборота медицинских отходов, модель правового регулирования.

The accumulation of waste, as an “inevitable” consequence of human development, turns into a global environmental problem, becomes a direct threat to the environment and public health in most countries of the world [1]. Annually in the period before the pandemic in Russia, statistical data confirmed the presence of up to 2 million tons of medical waste [2]. In the last two years, the pandemic has been adding 10 million used masks, respirators, gloves, protective glasses every day [3], which confidently allows us to conclude that the volume of medical waste in the country is growing at a high rate [4]. Currently, only on the territory of the Moscow region, the annual volume of medical waste is more than 100 thousand tons, and taking into account Moscow’s waste entering the territory of the region for disposal and recycling, it is estimated at more than 300 thousand tons [5]. In early May 2020, near Kirov, a resident of the city found more than 300 kg of used syringes and test tubes in the water protection zone of the Vyatka River [2]. Tariff regulation of this activity has not been carried out. As a result, there is no source of investment to create a modern high-tech and safe industry for the disposal of medical and biological waste. In this regard, there are environmental and epidemiological risks in the places of their disposal and placement. Violations of the rules for handling medical and biological waste are systemic in nature. There are cases of contamination of land plots, dumping of medical and biological waste into household garbage containers with subsequent removal to landfills for burial, disposal and destruction of biological waste without the conclusion of a veterinary specialist, placement of residues from medical waste at landfills.

Due to the inadequacies in the current legal regulation, a paradoxical situation has developed when the legal regime of medical waste is much softer than the rules established for ordinary municipal waste [6]. Thus, the problem of medical waste disposal is closely related to issues of legal regulation both at the level of federal legislation and subordinate regulatory legal acts.

Scientists have repeatedly addressed the problem of legal regulation of medical waste disposal in their works. In particular, the works [7–10] and others are devoted to this. However,

the pandemic of a new coronavirus infection (COVID-19) forces us to revisit this problem, taking into account the newly appeared aspects that need to be studied.

The purpose of this study is to identify the problems of legal regulation in the field of medical waste disposal, to analyze the trends of legal regulation in this area and their legal assessment, as well as to analyze existing liability measures in the treatment of medical waste.

### Objects and methods of research

The object of the study is public relations in the field of legal regulation of medical waste management of the Russian Federation legislation. The subject of the study is a set of legal norms in the field of medical waste management in the Russian Federation. At the same time, the authors argued for the application of special regulatory regulation to the establishment of rules for the disposal of this type of waste, identified gaps in the legal regulation of medical waste management based on the analysis of current legislation, as well as the draft federal law “On conducting an experiment of organizing and implementing centralized management of medical and biological waste in the Moscow region and on amendments to certain legislative acts of the Russian Federation”. The methodological tools of the research include general scientific methods, such as dialectical and logical, as well as specific scientific methods: legal interpretation, systemic, structural and comparative legal methods. When writing the article, in order to select material for analyzing the state of medical waste disposal legal regulation, the authors used the Legal Reference system “Consultant Plus”, as well as the search engines Google scholar, Social Science Research Network, Scopus, Web of Science, scientific electronic library databases Elibrary.ru according to the words and phrases that are key to this article. The period from 2007 to the present has been covered.

### The problem of medical waste legal regulation

The main problem that gives rise to shortcomings of legal regulation in the field of medical

waste disposal is that, in accordance with Article 2 of Federal Law No. 89-FZ of 24.06.1998 "On Production and Consumption Waste" (hereinafter referred to as the Federal Law "On Production and Consumption Waste"), the said law and its requirements do not apply to medical waste. Moreover, licensing of activities for the disposal of medical waste is not carried out [11], state control over the treatment of such waste is not actually provided for by the current legislation.

At the same time, formally, issues related to medical waste are not in a state of legal gap, since they are placed in a special regulatory sphere. Thus, Article 49 of Federal Law No. 323-FZ of 21.11.2011 (as amended on 02.07.2021) "On the Basics of protecting the health of citizens in the Russian Federation" (hereinafter referred to as the Federal Law "On the Basics of protecting the Health of Citizens in the Russian Federation") defines medical waste, and their classification is established at the level of a subordinate regulatory act. Special attention should be paid to Class B medical waste.

Firstly, a sharp increase in volumes is observed in this very segment. In accordance with the information of the Ministry of Health of the Russian Federation [12], due to the current epidemiological situation, the treatment of waste generated during the implementation of medical measures for the treatment of a new coronavirus infection (COVID-19) is carried out in accordance with the sanitary and epidemiological requirements for the treatment of class B medical waste. At the same time, any types of class B waste disposal which differ from those specified in the document are unacceptable.

Secondly, medical waste of other hazard classes after neutralization, according to law enforcement agencies, can acquire a legal regime of production and consumption waste [13].

As part of a comparative analysis of the legal regulation systems for solid household and medical waste management, it should be noted that the Federal Law "On Production and Consumption Waste", within the framework of separate regulations for the management of solid household waste at the legislative level, defines the following: the procedure for licensing activities for collection, transportation, processing, disposal, neutralization, waste disposal, requirements for waste disposal facilities, requirements for the federal waste management scheme, fundamentals of the federal state information system for the accounting of municipal solid waste, requirements for the transportation of waste, etc. However, there are serious problems

with solving similar issues related to medical waste. In fact, the legal regulation of the medical waste treatment is carried out at the level of SanPiN 2.1.7.2790-10, there is no regulatory consolidation at the legislative level. At the same time, due to the direct instructions of the legislator, the legal regulation of the medical waste treatment is carried out exclusively at the level of federal legislation, whereas the treatment of production and consumption waste is regulated by legislative and other regulatory legal acts of the federal, regional and municipal levels.

The introduction of medical waste into the special regulatory sphere presupposes the existence of a separate system for the medical waste treatment, which is stated at the level of a separate federal law. The actual absence of such a system makes its normative consolidation impossible. It should be noted that the sharp increase in the volume of medical waste during the pandemic has significantly actualized the problem of creating a unified system of medical waste management and its further regulatory consolidation.

### **Responsibility for violating medical waste disposal rules**

In order to ensure compliance with the standards for the disposal of medical waste, authorized representatives of Rospotrebnadzor may conduct laboratory and instrumental control during routine inspections and inspections on epidemiological indicators. In this case, samples of environmental and industrial environment objects can be taken to carry out their measurements. The selection is made in the presence of the head or an authorized representative of the organization and is formalized by a protocol.

In addition to routine inspections, an administrative investigation may be conducted if information about an offense being committed is received. If sufficient evidence that an offence has been committed is found during the administrative audit, a definition is made out and an administrative case is initiated. At the end of the preliminary investigation, either a resolution is issued to terminate the case of an administrative offense (in the absence of a *corpus delicti*), or a protocol on an administrative offense is drawn up and a presentation is made on the elimination of the causes and conditions that have contributed to an administrative offense (if there is a *corpus delicti*). Responsibility for non-compliance with the requirements in the field of environmental protection during the collection, accumulation,

transportation, processing, disposal or neutralization of production and consumption waste is stated in art. 8.2 of the Code of Administrative Offences of the Russian Federation. For officials, the maximum fine will be 30 thousand rubles, for legal entities – 250 thousand rubles. For example, according to the above-mentioned norm, administrative responsibility for violating the requirements of the SanPiN when handling medical waste (mixing of waste of different classes, lack of instruction and handling schemes, lack of labeling of containers, etc.) is imposed by the decree of the Chief Sanitary Doctor for the Southern Administrative District of the City on The Federal State Budgetary Scientific Institution “Scientific Research Institute of Human Morphology” and it was fined 200 thousand rubles [14].

In judicial practice, there are also cases of criminal liability under Article 247 of the Criminal Code of the Russian Federation for violating the rules of handling environmentally hazardous substances and waste. It should be noted that this norm applies only to the handling of prohibited types of hazardous waste, radioactive, bacteriological and chemical substances and waste. At the same time, hazardous waste is understood, including those that contain pathogens of infectious diseases [15]. WHO classified medical waste as hazardous as far back as in 1979 [16]. The committed acts must pose a threat of causing significant harm to human health or the environment, the consequences of causing harm to human health, the environment, mass death of animals, human death or mass illness of people are indicated as a mandatory feature in the qualified elements of the crime.

It is also necessary to consider that, from the subjective side, the crime is characterized by an intentional form of guilt (in the case of an administrative offense, guilt is possible both in the form of intent and in the form of negligence). For example, according to the results of the inspection of the Volgograd Interdistrict Environmental Prosecutor’s Office, a criminal case had been initiated under Paragraph 1 of Article 247 of the Criminal Code of the Russian Federation. The commercial organization signed a contract with two medical institutions, but the obligations for disposal were not fulfilled, medical waste was taken out into the open ground and stored at 6 pieces of land. The convict was sentenced to a fine of 20 thousand rubles [17].

Thus, the main criterion for distinguishing between administrative and criminal offenses are the consequences of the perpetrator’s act or

the threat of their occurrence. And although, according to the Criminal Code of the Russian Federation, the maximum penalty provided for in the article is imprisonment up to 2 years, most often the courts are limited to fines, and in an amount smaller than when qualifying the act as an administrative offense, despite the increased public danger.

### **Regulatory consolidation of the experiment on medical waste management in the Moscow Region as a model of special legal regulation**

Focus separately on draft law No. 1006365-7, submitted for consideration by the State Duma, which provides for the regulatory consolidation of the medical waste management system, which will be piloted at the regional level for further introduction nationwide.

The medical waste control system in the Moscow region and the existing methods for determining the standards for the formation of medical waste, as well as the problem of disposal of harmful substances of various hazard classes formed as a result of medical activity, have been analyzed and reflected in scientific research [18].

Both the chosen model for building a medical waste control system and the features of codify are of particular interest. According to the Deputy Chairman of the State Duma O.V. Timofeeva, the regions “will not stand another “garbage” reform as a simple duplication of standards for medical waste. It is necessary to pay more attention to the convergence of legislation in these two areas. Unfortunately, there are still 2 waste classifications in operation, and we have not received a single government initiative on this issue” [18].

Conducting an experiment on the organization and implementation of centralized management of medical and biological waste in the Moscow region is aimed at comprehensive legal regulation of the issue of medical and biological waste management, creating conditions for the use of public-private partnership mechanisms to modernize existing and create new processing infrastructure, as well as the introduction of rationing and tariffication of the services in this industry and their licensing.

The draft law introduces a phased experiment (4 stages until December 31, 2035 inclusive) and a new conceptual apparatus: “medical waste”, “biological waste”, “territorial scheme of medical and biological waste management in the Moscow region”, “regional operator for

medical and biological waste management”, “centralized management of medical and biological waste”. The basic requirements for the treatment of medical and biological waste during the experiment are established, and an institute of a regional operator for the treatment of medical waste is being introduced.

The concept of “medical waste” has been corrected in the draft law. First of all, the concept of biological waste is excluded from it, it is regulated separately. Secondly, the list of activities that result in medical waste is basically maintained. Thirdly, medical products that have lost their properties or whose intended use is prohibited, including due to the current shelf life, are directly classified as medical waste.

Within the framework of the draft law, it is planned to create a system of a similar model of solid household waste management, providing for licensing, the definition of a regional operator and the establishment of the foundations of public-private partnership.

The proposed legal regime for the treatment of medical waste involves regulation at the level of legal norms of federal and regional legislation and regulatory legal acts of the supreme executive body of the subject of the Russian Federation, ensuring the creation of conditions for special regulation of activities for the treatment of medical and biological waste.

The UN International Center for Environmental Technologies has developed a systematic procedure by which the proposed technological intervention is evaluated in terms of its potential impact on the environment, consequences for sustainable development and possible cultural and socio-economic consequences. Further improvements in the qualitative approach to life assessment from the point of view of environmental technologies have led to the emergence of a new methodology known as sustainable assessment of technology (SAT). This methodology evaluates both the process itself and its result. It is this SAT methodology, according to the UN International Center for Environmental Technologies, that is applicable to medical waste treatment technologies. The methodology uses a progressive evaluation process, including initial selection, determination of the scope of work and detailed analysis. It is important to note that the methodology uses a systematic approach and focuses on information expertise and stakeholder participation [19]. The authors believe that the SAT methodology should be applied to evaluate the medical waste management system in the Moscow region.

## Conclusion

So, the issues related to the treatment of medical waste have been brought into the special regulatory sphere, which assumes its own system of such treatment. In fact, the issues are resolved at the SanPiN (sanitary rules and norms) level, there is no separate federal law, which, in the conditions of increasing medical waste against the background of a pandemic, creates an immediate threat to environmental safety.

Using the example of the planned experiment in the Moscow region and the procedure for its regulatory consolidation, the following trends in the legal regulation of medical waste disposal issues can be noted:

- the legislator will continue to follow the special regulatory position in this area, which should be evaluated positively;

- the attribution of issues of medical and biological waste disposal to issues of joint responsibility, including issues of legal regulation, should be criticized if the issues raised in the draft law remain in the sphere of rule-making of the subjects of the Russian Federation. The best option is a special regulation of medical and biological waste at the level of federal law with the consolidation of key positions: the procedure for licensing activities for collection, transportation, processing, disposal, neutralization, disposal of waste, requirements for waste disposal facilities, requirements for the federal waste management scheme, etc.;

- the implementation of a system for the disposal of medical and biological waste on the basis of public-private partnership can lead to negative consequences. The most optimal option is the use of a single federal operator system [19].

It is also necessary to evaluate the system, which is being introduced at the moment, from the perspective of the SAT methodology: countries, cities and institutions that have used this handbook and developed an existing waste control system are much better able to cope with sharp swings in the volume of medical waste associated with disasters, including the ongoing pandemic [19].

Currently, the Russian Federation provides for administrative and criminal liability for violating the rules of waste management, including medical waste. At the same time, according to the practice of application, the assigned criminal punishment is several times less than administrative sanctions, which does not correspond to the degree of public danger of the acts committed.

## References

1. Gordeeva Y.M. Waste management law and policy: global trends and European Union experience // *Theoretical and Applied Ecology*. 2020. No. 4. P. 237–241 (in Russian). doi: 10.25750/1995-4304-2020-4-237-241
2. Sokolova M. Materials of an interview with the head of the State Duma Committee on Ecology and Environmental Protection It is proposed to issue a license for the disposal of masks and syringes // *Parliamentary newspaper*. 08.06.2020 [Internet resource] <https://www.pnp.ru/politics/na-utilizaciyu-masok-i-shpricev-predlagayut-vydat-licenziyu.html> (Accessed: 06.10.2021) (in Russian).
3. Zvyagina Zh. They want to give medical waste operators the right to work in the framework of a public-private partnership. *Parliamentary newspaper*. 24.09.2020 [Internet resource] <https://www.pnp.ru/economics/predpriyatiyam-poutilizacii-medotkhodov-khotyat-dat-pravo-rabotat-v-ramkakh-gosudarstvenno-chastnogo-partnerstva.html> (Accessed: 06.10.2021) (in Russian).
4. Akimkin V.G., Timofeeva T.V., Mamontova L.S., Zudinova E.A. Modern features of the dynamics of the volume of education and structure medical waste in large cities of the Russian Federation // *Public health and habitat*. 2015. No. 9. P. 9–14 (in Russian).
5. Explanatory note to the draft Federal Law “On the Experiment on the organization and implementation of centralized circulation with medical and biological waste in the Moscow region and on amendments to certain legislative acts Russian Federation” [Internet resource] <https://sozd.duma.gov.ru/bill/1006365-7> (Accessed: 06.10.2021) (in Russian).
6. Ponomarev M.V., Tsomartova F.V. Legal regime of medical waste // *Journal of Russian Law*. 2019. No. 9. P. 145–158 (in Russian).
7. Alekseeva N.A. Legal aspects of environmental safety in the field of medical waste management in the context of the pandemic // *RUDN Journal of Law*. 2021. V. 25. No. 3. P. 586–601.
8. Borodina I.M. Medical waste as an object of civil rights // *Bulletin of the Volgograd State University. Series 5. Jurisprudence*. 2014. No. 2 (23). P. 92–95 (in Russian).
9. Ponomarev M.V. Legal problems of application of administrative responsibility for offenses in the field of medical waste management // *Constitutional and legal foundations of responsibility in the field of ecology. Collection of materials of International scientific conferences. Moskva*, 2019. P. 352–358 (in Russian).
10. Gromova G.A. Some problems of legal regulation of medical waste management and bringing to administrative responsibility for violations in medical waste management // *Administrative and Municipal Law*. 2014. No. 10. P. 1031–1038 (in Russian).
11. Shamshurina N.G., Prisyazhnaya N.V., Pavlova Yu.V., Shulyatev S.V. Legal and economic problems of the control system of the medical waste // *Hygiene and Sanitation*. 2020. No. 99 (7). P. 656–662 (in Russian).
12. The Ministry of Health of Russia on the procedure for handling medical waste in connection with the spread of coronavirus infection [Internet resource] <https://www.rosminzdrav.ru> (Accessed: 06.10.2021) (in Russian).
13. Letter from the Ministry of Natural Resources of Russia 12.02.2015 No. 12-50/1025-OG “About consideration of the appeal” [Internet resource] [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_177092/](http://www.consultant.ru/document/cons_doc_LAW_177092/) (Accessed: 06.10.2021) (in Russian).
14. Decision of the Moscow City Court in the case No. 7-8933/18 26.07.2018 [Internet resource] <https://www.mos-gorsud.ru/mgs/cases/docs/content/d6ab577a-9268-41a8-b4b2-786df19b6e0c> (Accessed: 06.10.2021) (in Russian).
15. Commentary on the criminal code of the Russian Federation (itemized) / Ed. A.I. Chuchaev. Moskva: KONTRAKT, 2012. 356 p. (in Russian).
16. Osipova T.V., Kolpashchikova I.F., Smirenskaya L.Yu., Budnikova M.V., Shtraykher A.S. Medical waste – handling problems // *Hygiene and Sanitation*. 2007. No. 2. P. 15 (in Russian).
17. The verdict of the Gorodnischensky District Court of the Volgograd Region in the case No. 1-203-/2011 [Internet resource] <https://sudact.ru/regular/doc/abRj-63C5E4ob/> (Accessed: 06.10.2021) (in Russian).
18. Timofeeva O. It is necessary to take into account the risks of “garbage” reform when handling medical waste // *Materials from the official website of the State Duma Committee on Ecology and Protection of the State Environment* 18.12.2020 [Internet resource] <http://www.komitet2-21.km.duma.gov.ru/Novosti-Komiteta/item/24726918/> (Accessed: 06.10.2021) (in Russian).
19. Compendium of Technologies for Treatment / Destruction of Healthcare Waste [Internet resource] [https://wedocs.unep.org/bitstream/handle/20.500.11822/8628/IETC\\_Compndium\\_Technologies\\_Treatment\\_Destruction\\_Healthcare\\_Waste.pdf?sequence=3&isAllowed=y](https://wedocs.unep.org/bitstream/handle/20.500.11822/8628/IETC_Compndium_Technologies_Treatment_Destruction_Healthcare_Waste.pdf?sequence=3&isAllowed=y) (Accessed: 06.10.2021).
20. Rostec offered to appoint him as operator of medical waste collection. *Materials* 18.08.2020 [Internet resource] <https://www.rbc.ru/business/18/08/2020/5f36a5989a794779f41cd131> (Accessed: 06.10.2021) (in Russian).