

EXTENDED FIRST AID: PERSPECTIVES AND CHALLENGES OF REGULATORY AND LEGAL FRAMEWORK

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Abstract. In order to improve quantitative and qualitative characteristics of first aid, an urgent need arose to increase its authorised volume for certain categories of first aid providers in accidents, disasters, natural calamities, epidemics, terrorist acts and armed conflicts and under other special conditions.

In accordance with Order No. 3155-r of the Government of the Russian Federation of 28 November 2020, legislative mechanisms should be developed by December 2021 to expand the scope of first aid. Introduction of changes and additions into Art. 31 of Federal Law No. 323-FZ of 21 November 2011 "On Fundamentals of Public Health Protection in the Russian Federation" will make it possible to update current legislation by amending a number of acts and by adopting new documents.

The authors suggest the development of draft amendments to the federal law "On Medical Drugs Circulation", to draft normative legal acts of the Government of the Russian Federation and of federal executive bodies which will be necessary for implementation of norms of the federal law "On Amendments to Art. 31 of the federal law "On Fundamentals of Public Health Protection in the Russian Federation".

Key words: *extended first aid, first aid, normative-legal regulation, scope of first aid*

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РАСШИРЕННАЯ ПЕРВАЯ ПОМОЩЬ: ПЕРСПЕКТИВЫ И ПРОБЛЕМЫ НОРМАТИВНО-ПРАВОВОГО РЕГУЛИРОВАНИЯ

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Резюме. Отмечено, что для повышения количественных и качественных характеристик оказания первой помощи насущной потребностью является увеличение объема ее оказания для отдельных категорий лиц, оказывающих первую помощь при авариях, катастрофах, стихийных бедствиях, эпидемиях, террористических актах, в вооруженных конфликтах и в других особых условиях.

В соответствии с Распоряжением Правительства Российской Федерации от 28.11.2020 г. №3155-р к декабрю 2021 г. должны быть разработаны законодательные механизмы, направленные на расширение объема оказания первой помощи. Внесение изменений и дополнений в ст.31 Федерального закона «Об основах охраны здоровья граждан в Российской Федерации» от 21.11.2011 г. №323-ФЗ даст возможность актуализировать действующее законодательство путем внесения изменений в целый ряд актов и принятия новых документов.

Авторами представлены предложения по разработке проектов внесения изменений в Федеральный закон «Об обращении лекарственных средств», в проекты нормативных правовых актов Правительства Российской Федерации и федеральных органов исполнительной власти, которые будут необходимы для реализации норм Федерального закона «О внесении изменений в ст. 31 Федерального закона «Об основах охраны здоровья граждан в Российской Федерации».

Ключевые слова: *нормативно-правовое регулирование, объем оказания первой помощи, первая помощь, расширенная первая помощь*

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Introduction

For some participants in the provision of first aid, the expansion of its volume is an urgent social need [1]. The need to expand the volume of first aid is due to the fact that some groups of people may be exposed to specific risk factors — potent chemicals, local armed conflicts, terrorist attacks, barotrauma, ionizing radiation, hazardous production, etc. In addition, some groups of persons may face impossibility of timely provision of medical assistance in case of disasters and accidents requiring emergency rescue operations, and in case of natural disasters; when they are in remote areas of the taiga and the Far North, at Roshydromet stations, on ships and aircrafts, in mines, etc.

In the above situations, in order to save lives and to preserve people's health, it is necessary to take such measures as medical triage of victims, inhalation of oxygen, immobilization, transportation, and also — in some cases — anesthesia, blood loss replacement, use of antidotes, etc. Without taking these measures, under conditions when the first aid measures approved by the order of the Ministry of Health and Social Development of Russia dated May 4, 2012 No. 477n¹ will not be enough to save the victim's life, and the provision of medical assistance is impossible or delayed, the person may die or his health may be severely, sometimes irreparably, damaged.

However, at present, these measures are not included in the scope of first aid, approved by the above order.

In this regard, in order to further improve the provision of first aid, it is necessary to differentiate its volume, which is possible through the adoption of appropriate regulatory legal acts. This approach is consistent with international experience.

Abroad, most of the systems for the provision of prehospital medical care include several levels that differ from each other in volume and quality of medical care.

In many countries, the first level of prehospital medical care — First Aid — is provided by people without medical education. They are called First Responders — literally, first aid provider [2]. There are 2 groups within this level.

The first group includes First Responders, who provide basic first aid — First aid. These are people from various social or professional groups (taxi and truck drivers, soldiers, students, workers with no medical education). They are trained in voluntary or compulsory programs to recognize the critical condition of the victim, to call for medical assistance and to provide basic first aid until trained rescuers arrive. The same level of help can be provided by ordinary citizens — witnesses of the event. To learn First Aid skills a course of study that uses simple materials and brochures, which is usually a few hours long [3], is enough.

The second group consists of persons providing Advanced First Aid — extended first aid. This group includes people ad-

ditionally trained in the first aid. These people, during their daily work, are more likely than ordinary citizens to be exposed to casualties with severe or life-threatening injuries or conditions.

Depending on the circumstances and on the level of need for their involvement in the provision of the first aid, people trained to provide extended first aid work either on a voluntary basis or are paid. They learn the principles of rescuing and retrieving victims from vehicles or rubble, of first aid, of preparation and of safe transport of patients to hospitals. In addition, they are equipped with a small set of equipment and with means for first aid [4].

First Responder training for extended first aid varies from country to country in terms of duration and extent of its provision and of the range of procedures permitted.

For example, in Australia, First Responder is a person trained in advanced first aid skills, including the use of an automatic defibrillator. In rural or other remote areas, he/she is the first to come to aid the victim and to begin to provide the first aid while the ambulance is on the way [5].

In the United States, first aid participants can be of two levels: first responder and certified first responder. The first level of the first aid is provided by ordinary people, including those who have no training or who have completed a short (usually eight hours) course. Certified first responder has an officially issued certificate of completion of courses lasting 40-60 hours and can perform a broader scope of activities [6].

The second level of care is called Basic Life Support (BLS). It is performed by: Emergency Medical Technician (EMT) — Basic; Intermediate Ambulance Techniques — EMT-Intermediate; ambulance technicians - paramedics — EMT-Paramedic [3].

The third — more complex — type of prehospital care is called "Advanced Life Support" — Advanced Life Support (ALS) and includes the implementation of complex interventions to save the life of the victim. It is performed by paramedics and doctors in the prehospital and hospital periods. The World Health Organization (WHO) believes that the decision to provide this level of care should not prejudice the simpler, basic elements of prehospital care [4].

Despite the high cost of advanced life support, WHO does not have sufficient evidence to suggest that this type of care benefits more than just a limited number of patients or victims who are most critically ill. In contrast, a significant improvement in first aid outcomes was recorded after primary trauma care providers were trained in the provision of the first aid [7]. In view of this, WHO recommends that caution is taken in deciding whether to use ALS and that decisions are based on a clear understanding of the relationship between costs and expected treatment outcomes when using these methods [4].

On November 28, 2020, the Government of the Russian Federation approved an action plan for the implementation of the Healthcare Development Strategy in the

¹ Order of the Ministry of Health and Social Development of Russia "On approval of the list of conditions in which first aid is provided, and the list of measures for first aid" dated May 4, 2012 No. 477n

Russian Federation for the period up to 2025², clause 7 of which provides for the development and implementation by December 2021 of legislative mechanisms aimed at expanding the volume of first aid, including its provision to victims of road accidents. For these purposes, the Government of the Russian Federation instructed the Ministry of Health, the Ministry of Industry and Trade, the Ministry of Internal Affairs of Russia and interested federal executive bodies to develop a corresponding draft law.

The State Duma has already passed the first reading of the draft Federal Law No. 466977-7 "On Amendments to Art. 31 of the Federal Law "On the Fundamentals of Health Protection of Citizens in the Russian Federation (in terms of providing first aid using automatic external defibrillators)" — hereinafter bill No. 466977-7. This bill should cite the provisions of Art. 31 of the Federal Law "On the Fundamentals of Health Protection of Citizens in the Russian Federation" dated November 21, 2011 No. 323-FZ in accordance with the current needs of the development of legal regulation of first aid and to differentiate first aid into 2 types: basic first aid and extended first aid.

After the adoption of this bill, in order to introduce expanded volumes of first aid, it will be necessary to adopt a number of regulatory legal acts, which is the subject of this article.

The purpose of the study is to provide a systematic comprehensive analysis of the problems and to determine the prospects for the legal regulation of the provision of extended first aid in the Russian Federation.

Research objectives: to assess the compliance of regulatory legal acts with the needs of expanding the volume of first aid, to identify problems and gaps in the regulatory legal framework, to develop proposals for improving the regulatory legal framework in order to expand the volume of first aid.

Materials and research methods. The methodological basis of the research was: general scientific — dialectical analysis and synthesis — and private — the method of legal hermeneutics, formal legal, systemic structural, historical legal, comparative legal and sociological — methods of scientific knowledge. Their use made it possible to carry out a comprehensive and complex analysis of the subject of research, to make theoretical generalizations, practical recommendations, and to formulate conclusions.

The normative and empirical base of scientific research is analytical material on the organization of extended first aid, contained in the works of Russian and foreign scientists. A study of federal laws and by-laws regulating the management of first aid activities, the organization of first aid and equipping of various categories of participants in first aid with first aid kits for its provision was carried out.

Research results and their analysis. Order of the Ministry of Health and Social Development of Russia dated May 4, 2012 No. 477n, providing for an equal volume of first aid for all participants in its provision, can be considered as basic.

Appendix No. 2 to the order contains the following list of first aid measures: measures to assess the situation and to ensure safe conditions for first aid; calling an ambulance, other special services, whose employees are required to provide first aid in accordance with federal law or a special rule;

determination of the presence of consciousness in the victim; measures to restore airway patency and determine the signs of life in the victim; arrangements for cardiopulmonary resuscitation before signs of life appear; measures to maintain airway patency; measures for a body check of the victim and for a temporary stop of external bleeding; measures for a detailed examination of the victim in order to identify signs of injuries, poisoning and other conditions that threaten his/her life and health, and to provide first aid if these conditions are detected; giving the victim's body an optimal position; monitoring the condition of the victim (consciousness, breathing, blood circulation) and providing him/her with psychological support; transfer of the injured to an ambulance brigade or to other special services, whose employees are required to provide first aid in accordance with federal law or with a special rule.

This list of measures does not include the use of drugs and invasive techniques, which can be an urgent need for a number of participants in the provision of the first aid under specific risk factors and / or in remoteness from medical care.

The normative limitation of the volume of first aid was of great importance at the stage of formation of the institute of first aid, since it allowed for the first time to normatively delimit the activities of this type of aid from all other types of public health protection. However, to further improve the provision of first aid, it is necessary to normatively differentiate its volume.

Differentiation of first aid into basic and extended will require the adoption of a number of new by-laws, as well as amendments and additions to the current legislation.

At the first stage, it will be necessary to determine which federal executive authorities are interested in expanding the volume of first aid for the subjects controlled by them. To do this, it is necessary to form a circle of persons who will have the authority to provide extended first aid.

Next, it is necessary to determine the scope of provision of extended first aid for each category of persons based on the presence or absence of specific risk factors, on the availability of medical care, of legal authority to provide first aid and on many other factors — to develop lists of conditions in which the corresponding type of extended first aid is provided, and lists of measures to provide the appropriate type of extended first aid. It is necessary to authorize a relevant federal executive body to approve the specified lists, for which it will be necessary to make changes and additions to the Regulations on it.

All participants in the provision of extended first aid will have to undergo training in its provision. This will require exemplary programs of the training course, subject and discipline "Providing extended first aid". Such programs should be developed by interested federal executive bodies in conjunction with the Ministry of Health of Russia and should be approved in the prescribed manner.

For each contingent of participants in the provision of extended first aid, it will be necessary to develop and to approve requirements for the composition of first aid kits. After the approval of these requirements, the interested federal executive bodies, in our opinion, will need to develop their own rules for their supply, as well as the rules for storage, disposal and the procedure for allocating financing for their purchase, as well as for appointing a responsible unit. Lack of these requirements can make it extremely difficult to equip extended first aid participants with first aid kits.

² Order of the Government of the Russian Federation of November 28, 2020 No. 3155-r

In our opinion, the most effective from an organizational and legal point of view will be the development and adoption of a single package of the above departmental regulatory legal acts in the context of interagency cooperation. It seems appropriate to carry out work on draft regulatory legal acts within the framework of the Specialized Commission of the Ministry of Health of Russia on First Aid, which includes an expert council for the development of draft bylaws that determine the provision of extended first aid.

Consideration will also need to be given to the regulatory option of including drugs in the equipment of participants in extended first aid. Medicines may be required to provide extended first aid in case of poisoning with potent chemicals (introduction of antidotes), to replenish blood loss in conditions of impossibility of rapid medical care, etc. To realize this opportunity, the following should be prescribed normatively: the procedure for approving requirements for the composition of first-aid kits for basic and advanced first aid, including drugs; the procedure for the purchase, supply, storage and the procedure for the disposal of these medicinal products. Let us consider in more detail the changes and additions, which should be made to the regulatory legal framework.

The Regulation of the Ministry of Health of the Russian Federation — approved by the Decree of the Government of the Russian Federation dated June 19, 2012 No. 608 — empowers this body to approve “requirements for the complete set of medical products for first aid kits” (clause 5.2.12.). Thus, in order to complete the first aid kits not only with medical products, but also with medicines, it is necessary to expand the powers of the Ministry of Health of Russia. To do this, we propose to formulate clause 5.2.12 of the said Regulation in a new edition, which will provide for the vesting of the Ministry of Health of Russia with the authority to approve the requirements for the packaging of medicines and / or medical products for first aid kits.

As for the legal prospects for the procurement, acceptance for supply, storage and disposal of medicines for the provision of extended first aid, it should be noted that in the Federal Law "On the Circulation of Medicines" dated April 12, 2010 No. 61-FZ in Art. 53, 58 are presented: an exhaustive list of entities to which pharmaceutical wholesalers can sell or transfer medicines, as well as an exhaustive list of entities entitled to store medicines. These lists do not include institutions and organizations whose employees will provide extended first aid, since these institutions and organizations are not licensed for pharmaceutical activities. Thus, individuals, for example, tourists, who are not subject to this law, can purchase medicines necessary for the provision of extended first aid at retail from a pharmacy organization, while legal entities in which the performers of extended first aid work, are not allowed to procure and to store medicines unless they are licensed to conduct pharmaceutical activities.

In this regard, it is proposed to supplement Art. 53 of the Federal Law "On the Circulation of Medicines" with a provision providing for the possibility of purchasing medicines for the provision of extended first aid by institutions and organizations that are not licensed to conduct pharmaceutical activities, whose employees are required and / or entitled to provide extended first aid. And also to supplement Art. 58 of this Federal Law by the provision allowing the storage of medicines for the provision of extended first aid in institutions and organizations that are not licensed to conduct pharmaceutical activities.

Art. 58.1 of the Federal Law "On Circulation of Medicines" establishes the procedure for maintaining subject-quantitative records of medicines. The list of medicines for medical use subject to quantitative accounting was approved by order of the Ministry of Health of Russia dated April 22, 2014 No. 183n³. In the case of the inclusion of drugs from this list to the composition of first aid kits for providing extended first aid, legal entities purchasing them will need to keep records in accordance with Art. 58.1 of the Federal Law "On the Circulation of Medicines", which will be quite problematic from an organizational and legal point of view. In our opinion, possible ways out of this situation may be: not to include drugs from this list in the equipment for first aid, or, if necessary, to make changes and additions to Art. 58.1, allowing not to keep records of medicines for the provision of extended first aid.

Conclusion

An urgent need to improve the quantitative and qualitative characteristics of first aid is to expand the volume of first aid for certain categories of participants in its provision.

The planned amendments and additions to Art. 31 of the Federal Law "On the Fundamentals of Health Protection of Citizens in the Russian Federation" dated November 21, 2011 No. 323-FZ will make it necessary to update the current legislation by amending a number of regulatory legal acts and by adopting new documents.

1. It will be necessary to develop and to approve the following documents by departmental regulatory legal acts:

- lists of conditions in which extended first aid is provided, and lists of measures for providing extended first aid for each category of participants in its provision;

- preliminary programs of the training course, subject, discipline for providing extended first aid for each category of participants in its provision;

- requirements for the complete set of medical devices and / or drugs of first aid kits for the provision of extended first aid;

- rules of acceptance for supply, storage, and disposal, as well as a procedure for the allocation of finance; responsible unit for each federal executive body, which will be subordinate to the participants in the provision of extended first aid.

2. The above documents must be approved by the relevant federal executive bodies, for which it will be necessary to make changes and additions to their functionality in accordance with the Regulations on them.

3. To provide institutions and organizations whose employees will provide extended first aid, with the powers in the procurement and storage of medical products, it will be necessary to make changes and additions to Art. Art. 53, 58 of the Federal Law "On the Circulation of Medicines", allowing the specified institutions and organizations to purchase and to store them without having a license for pharmaceutical activities.

4. In the event that medicines from the list of medicines for medical use subject to quantitative accounting are included in the requirements for the complete set of medical devices and / or medicines, it will be necessary to make changes and additions in Art: 58.1 of the Federal Law "On the Circulation of Medicines", which allows not to keep records of medicines for the provision of extended first aid.

³ Order of the Ministry of Health of Russia "On approval of the list of medicines for medical use subject to quantitative accounting" dated April 22, 2014 No. 183n

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