

Legal Regulation of Digital Transformation of Technologies in Healthcare in Russia and Abroad Under the Influence of the COVID-19 Pandemic

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Abstract: Currently, in the context of the COVID-19 pandemic and periodically introduced lockdowns for the Russian healthcare system, an important goal is to create conditions for the provision of medical care to all citizens, despite the territorial location and the possibility of physical visits to a hospital or polyclinic. In modern conditions of digitalization of life, an effective way to solve this problem is the development of information tools in the field of healthcare through the creation of a unified medical information space. The progressive development of technologies (medical and infocommunication) launches the process of digital transformation and the development of telemedicine. With all the above, it is fair to note that there is currently no formulated idea of what telemedicine includes, and there are also no fully formed norms for telemedicine services. A number of problems specific to telemedicine, but requiring solutions, for example, the question of who and what responsibility should be borne for the consultation provided, the problem of proper protection of personal data and compliance with medical secrecy, need to be resolved in the near future, which will make it more accessible and widespread to provide remote medical care using digital technologies.

1 INTRODUCTION


To date, in the context of the COVID-19 pandemic, an increasing number of countries have accelerated the development of projects for the modernization and implementation of telemedicine technologies in classical medicine. The World Health Organization plans to create a global telecommunications network in the field of medicine. That is, to create a single network through which it will be possible to carry out centralized transmission of medical data, to organize an electronic document management system for medical documents and a system for storing and searching medical information, as well as to use it for remote discussions, meetings, consultations (Inshakova et al., 2021).


Experts of the American Association of Telemedicine believe that the direction of telemedicine suggests that medical data can be transmitted over different distances between a doctor

and a patient, doctors, various medical organizations. The use of telemedicine technologies implies the active use of infocommunication technologies and services to ensure communication between medical professionals and medical organizations, with patients located at a distance, for the purposes of therapeutic procedures, consultations, diagnostics and training."

According to the organization Health On the Net ("Health on the Net"), in most of Western Europe, telemedicine is an additional technology for providing medical care. According to M.S. Varyushin (Varyushin, 2018), the legal framework of telemedicine can be divided into 2 categories:

1. Legislation that regulates relations between medical organizations and patients. Refers to the regulatory framework on healthcare. It defines the standards of medical care with the use of telemedicine services, regulates the licensing procedure, regulates document flow and logging, focuses on protecting the

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rights of the patient, and also defines the area of responsibility of the medical organization and its employees;

2. The second category includes legal relations arising between a medical organization, technical staff and a patient, which are based on telemedicine technologies. For example, the transfer of patient data occurs through third parties (provider, technical staff), which may entail a violation of medical confidentiality, or disclosure of personal data.

2 MATERIALS AND METHODS

In the course of the research, general scientific methods used, including formal-logical, dialectical, system-structural, and critical cognition. Methods of synthesis, classification, and generalization used to interpret the results of the study. Private scientific methods also used in the work: formal-legal, the principle of assessing legal processes, the method of comparative analysis, etc.

3 RESULTS AND DISCUSSION

Unlike the Russian Federation, the experience and practice of foreign countries have allowed the European Union to create a single legal framework regulating the provision of telemedicine services. In addition, EU countries (for example, Belgium, Germany, the Netherlands, etc.) have their own internal legislation that complements generally accepted standards. These are standards regulating the provision of medical care with the use of telemedicine technologies, on the transfer of personal data of participants in telemedicine sessions, on the provision of information services by medical personnel. These include:

- Directive 95/46/EC of the European Parliament and of the Council of the European Union of October 24, 1995 "On the protection of the rights of individuals with regard to the processing of personal data and on the free movement of such data (repealed from May 25, 2018);
- Directive 98/34/EC of the European Parliament and of the Council of the European Union of June 22, 1998 "On the procedure for the dissemination of information on technical standards and regulations";
- Directive 2000/31/EC of the European Parliament and of the Council of the European

Union of June 08, 2000 "On certain legal aspects of the provision of information services to the public, in particular e-commerce, in the domestic market" (Kuznetsov and Syryamkin, 2019).

In addition, Directive 2011/24/EC of the European Parliament and of the Council of March 9, 2011 "On the rights of patients in cross-border medical care" was considered.

Of all the countries in which telemedicine technologies are used, the country with the most active development of legislation in this area can be called the United States of America, in which legislation is common at the state level and its own for each state. The main reason for such dynamically developing legislation in the field of telemedicine is the need to coordinate laws within the state. Due to the fact that telemedicine involves the use of infocommunication technologies in healthcare, difficulties arise caused by restrictions on medical activities on the part of national jurisdictions (Bogdanovskaya, 2007).

Modern legislation provides support for programs that are aimed at the process of forming medical services, taking into account the use of telemedicine technologies. For example, in 1997, a bill was formed in Alaska that regulates the official project for the development of telemedicine, including defining a plan for its financing. In the state of Oklahoma, the telemedicine Law states the following: "in programs aimed at healthcare, nothing can be a factor that restricts the right to provide medical services using audio, video or infocommunication technologies." This makes it possible to more actively use telecommunication technologies for consultations, diagnostic measures, as well as to transmit medical information in this way, which can be considered a stimulating factor in the development of telemedicine.

Medical services in American law could initially be provided only if the patient made a face-to-face visit to a doctor, but over time this requirement was changed. For example, the law in Colorado allows the use of telemedicine technologies to diagnose, identify, prevent diseases, pains, ailments, as well as painful conditions, both mental and physical, allowing the use of images, including photographs. According to the law of the State of Indiana, since 1996 medical practice includes the provision of medical care and diagnostic measures using infocommunication technologies, based on oral or written consent to the provision of medical care (Abashidze et al., 2021).

The law restricts the technologies that can be used in telemedicine. For example, legislators in some states specify that telemedicine services cannot be provided by telephone and fax. In 1999, a law was passed in Minnesota, which refers interactive video to the technical means of communication used for remote consultations.

One of the projects aimed at creating and developing a global medical infocommunication system is "Satellite". This project will allow the participating countries to create a unified system that promotes the exchange and accumulation of medical knowledge, and allows simplifying the process of training and advanced training of medical workers.

Another project, "Planet Here" was developed by the World Health Organization. The main goal of this project is to create a global medical telecommunications system, but aimed at scientific activity and acting as a management tool. WHO proposes to use this system as the main one through which other systems and networks will be managed, through which international scientific telecommunications will be conducted, and which will also be used for international examinations.

4 DISCUSSION OF THE RESULTS

The worldwide interest in the introduction of telemedicine technologies in the context of the COVID-19 pandemic contributes to the fact that a large number of international-scale projects have been funded and developed in Europe for several years.

These projects cover a wide range of areas and methods where telemedicine can be applied: from the development of systems that simplify and speed up the provision of medical care, especially ambulance (an example of such a project is HECTOR), to the ability to carry out treatment when a patient is at home (for example, the HOMER-D project). The main goal of telemedicine projects is the integration of information technologies into the medical infrastructure, for the development of methods of processing and standardization of medical information, whether it is its registration, transmission or reception. There are processes of development and testing of algorithms for effective compression of information, standard forms that simplify the exchange of various types of data, both in the form of source data, that is, images, electrical or electromagnetic signals, etc., and in the form of a generated patient's medical record. Automated workplaces are also being developed, taking into

account the specifics of various medical and diagnostic specialties.

The regulatory framework of informatization in the field of healthcare in Russia includes: state legislative acts that affect the use of telemedicine technologies; standards and protocols for medical care; standards for building telecommunication networks, including international ones; documents developed by the World Health Organization (Inshakova et al., 2021).

Since 2001, legal regulation of issues related to the provision of medical services using telemedicine technologies has been carried out in the legislation of the Russian Federation. The Order of the Ministry of Health of the Russian Federation No. 344 and RAMS No. 76 dated August 27, 2001 "On approval of the concept of development of telemedicine technologies in the Russian Federation and its implementation plan" was issued. The purpose of this document is to optimize activities related to the use of telemedicine technologies. The need for advanced telemedicine technologies is caused by the problem of shortage of qualified medical personnel in remote regions and the territorial peculiarity of the Russian Federation.

Today in Russia, the use of telemedicine technologies is regulated by the Federal Law "On the Basics of protecting the Health of Citizens of the Russian Federation", as well as by-laws, for example, the Order of the Ministry of Health of the Russian Federation No. 965n "On approval of the procedure for organizing and providing medical care using telemedicine technologies", Decree of the Government of the Russian Federation No. 1006 "On approval of the Rules for the provision of paid medical services by medical organizations", etc.

Paragraph 22 of Article 2 of Law No. 323-FZ defines telemedicine technologies as "information technologies that provide remote interaction of medical workers with each other, with patients and (or) their legal representatives, identification and authentication of these persons, documentation of their actions during consultations, consultations, remote medical monitoring of the patient's health."

Regulation of telemedicine in the legal field begins only in 2017, when Federal Law No. 242-FZ of April 29, 2017 "On Amendments to Certain Legislative Acts of the Russian Federation on the use of information technologies in the field of health protection" was adopted.

A legislative act and by-laws regulating the use of IT technologies in the field of medicine are needed (Matytsin et al., 2021). We also need resources, both organizational and technical, for the full implementation of modern technologies throughout

the country. This need is due to the territorial features of our state. The development of information technologies enables a wider range of people to take advantage of the constitutional right to health protection and affordable medical care, including in conditions of limited access to public places and movement with the introduction of restrictive measures to limit the spread of COVID-19.

Based on Parts 2 and 4 of Article 36.2 of Law No. 242-FZ, medical services using telemedicine technologies can be provided in the format of consultations and remote monitoring of the patient online, that is, in real time, while the interaction of participants in this format, recorded in the protocol of medical opinion or consultation of doctors, or in other available documents, must be stored in the form of audio recordings, video recordings and text messages.

Another important format in the context of the COVID-19 pandemic is the use of telemedicine technologies - an online consultation, for example, of the attending physician with a doctor or a consultation of doctors to clarify the diagnosis or exchange experience. If a medical opinion is issued by a medical council, it will be stored only in the form of text messages. This will allow you to receive timely medical care and advice in lockdown conditions, as well as persons over 65 years of age who are advised to refrain from visiting public places.

Both formats assume that the consultation can be of the type "medical worker or a consultation of doctors - attending physician" or "doctor - patient" (Sokolenko and Bagnyuk, 2017).

Telemedicine consultations are conducted so that the attending physician can analyze the previously prescribed treatment, its effectiveness, including for collecting anamnesis and new patient complaints, for monitoring the patient's condition as a whole. And already based on the collected data, the doctor decides whether the patient needs to apply to a medical organization for a full-time appointment.

The use of telemedicine technologies in the age of digital development is a new stage in the improvement of the field of healthcare, especially in demand in the context of the COVID-19 pandemic. This becomes possible thanks to the consulting centers implemented on the basis of medical institutions located in the central cities of Russia, but providing medical services online for all residents of the country.

In Russia, the use of telecommunication technologies in the field of healthcare is less developed than in foreign countries.

In progressive countries, digitalization in the field of healthcare is also aimed at achieving basic

standards for providing medical care and its accessibility to the population who live in rural areas or in places with an insufficient number of doctors.

The global digitalization of healthcare in Australia led to the formation of a governing body in 2016 - the Australian Digital Health Agency. The example of Australia shows that the purpose of telemedicine services is being transformed. Previously, the use of telemedicine technologies was supposed to provide affordable medical care in hard-to-reach areas, but today the tasks are changing somewhat. Now such goals as: to reduce or eliminate negative adverse reactions caused by prescribed treatment or medications are put at the forefront in telemedicine; to reduce the number of hospitalizations by preventing possible changes in the patient's health status; the possibility of achieving more effective coordination in providing medical care to people in an emergency situation; the possibility of correcting treatment for remote patients.

According to foreign scientists, innovative components in telemedicine should be: new technologies (including virtual reality, robots with remote control, 3D printing, etc.), personalized mini-devices, sensors for remote monitoring.

5 CONCLUSIONS

The use of telemedicine technologies gives the patient the opportunity to get a doctor's opinion from any city or even country, as well as for people who are quarantined by COVID-19. Thanks to them, the geographical location of the patient is not a decisive factor in the availability and quality of medical care.

Russian legislation in the field of application of telemedicine technologies has a number of problems, including:

- there is no legalized definition of "telemedicine" as an independent direction in medicine;
- problems in the field of licensing activities with the use of telemedicine and information technologies;
- problems of introduction of telemedicine services in medical insurance;
- determination of participants in legal relations in the field of telemedicine, establishment of their rights and obligations, conditions of liability.

When conducting a consultation using telemedicine technologies, its participants are: a doctor (consultant), a patient (consulted), support

staff. But the process of informatization expands this list with new subjects of legal relations: providers, manufacturers of computer devices, site administrators, pharmaceutical companies, payment systems, cloud service operators, etc. It follows from this that the protection of private information should also extend to new entities.

According to paragraph 9 of Order No. 965n of the Ministry of Health of the Russian Federation, the legal responsibility falls entirely on the consultant doctor for the recommendations given by him in the framework of the medical report. At the same time, there is no responsibility of the attending physician who diagnoses the patient;

In accordance with paragraph 7 of Article 20 of the Federal Law "On the Basics of protecting the health of citizens in the Russian Federation", the patient has the right to receive medical care using telemedicine technologies only after submitting a signed application with an electronic digital signature (EDS). And obtaining an enhanced qualified EDS is a difficult process;

- the doctor is not able to make a diagnosis remotely when using telemedicine services;
- in accordance with paragraph 47 of the Order of the Ministry of Health of the Russian Federation No. 965n "On approval of the procedure for the organization and provision of medical care using telemedicine technologies", during consultations with the attending physician, prescriptions for medicines can be formed in the form of an electronic document, subject to the appointment of treatment to the patient in person. In this case, the electronic prescription must be certified by an enhanced qualified EDS of a medical professional. But the receipt of EDS by medical professionals is not regulated in any way. In addition, there is no set list of requirements according to which pharmacies could accept electronic prescriptions, each entity should organize this independently in 2021;
- there are a number of conditions for providing medical care using telemedicine technologies: a medical worker must be registered in the Federal Register of Medical Workers, and a medical organization must be entered in the Federal Register of Medical Organizations of the Unified State Information System in the Field of Healthcare. These conditions also apply to non-governmental organizations and private practitioners. They, in turn, also place information in the registers mentioned above. This raises the question of protecting the data being entered.

There remains the problem of forming an electronic patient's medical history, which includes the results of tests, medical examinations reflecting the course of the patient's illness.

- the complexity of providing medical care using telemedicine technologies at the global level;

If the patient - the consumer of medical services is located in one country, and the doctor (the performer of medical services) is in another, then the question arises which state legislation will be applied. There is no answer to this problem these days.

- another urgent problem is the guarantee of medical secrecy.

In the classic doctor-patient relationship, confidentiality has always been a problem, so the possibility of ensuring secrecy in telemedicine is questioned. This is also due to the fact that technical workers who support the system participate in the process between the consultant and the person being consulted.

In the Russian Federation, a number of regulatory legal acts should be adopted to ensure compliance with medical secrecy. But the problem is that in our country, on the contrary, there are legal acts that oblige providers to save user visit histories, call records, etc. on their servers. This is done to combat terrorism, but, in turn, may lead to information leakage.

The above problems show the urgency of prompt amendments and additions to the existing Russian legislation in the field of application of telemedicine technologies in the context of the COVID-19 pandemic. When forming proposals, it is necessary to rely, among other things, on the experience of foreign countries, their practice of implementing legal norms in the field of telemedicine.

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