

PEDTR 2019**18th International Scientific Conference “Problems of Enterprise Development:
Theory and Practice”****LEGAL REGULATION OF HEALTHCARE DIGITALIZATION IN
RUSSIA AND THE USA**

S. N. Revina (a)*, A. V. Sidorova (b), S. V. Blinov (c)

*Corresponding author

(a) Samara State University of Economics, 443090, Soviet Army Str., 141, Samara, Russia, 29.revina@mail.ru

(b) Samara State University of Economics, 443090, Soviet Army Str., 141, Samara, Russia, an.sido@bk.ru

(c) Medical University «Reaviz», 443030, Chkalov Str., 100, Samara, Russia, sekretar@dkb63.ru

Abstract

The end of XX century and the beginning of XXI century are marked by digitalization of all life spheres. The healthcare is no exception. Nowadays, special attention is paid to the development of telemedicine. The development of telemedicine in Russia and abroad increases the availability and quality of medical care and dispensary supervision for patients, including residents of remote areas. Telemedicine in Russia is just beginning to develop as a public medical practice, which is facilitated by changes in the domestic legislation, huge distances, and the socio-economic importance of the application of telemedicine technologies. Remote counseling for the purpose of providing medical care and information dates back to the times when information about epidemics was transmitted by special couriers, but the development of telemedicine is timed to the emergence of new means of communication, primarily the telegraph. The official appearance of the term "telemedicine" is considered to be the beginning of the twentieth century. But even today, the facts once again confirm the complexity, ambiguity and versatility of the concept of "telemedicine". A unified approach to the definition of this term content in Russian and foreign science has not yet been formed, and boundaries of medical services are not clearly defined. In Russia, the provision of medical services using telemedicine technologies is limited by national standards. The development of "telemedicine" would be facilitated by the unification of legislation and qualification requirements at the interstate level.

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1. Introduction

In recent years, information and communication technologies have led to a revolution in almost all life spheres of our society. Modern innovative technologies have also caused significant changes in the field of health care. This has made telemedicine one of the ways that has changed the quality of medical services.

2. Problem Statement

The authors of this study set the following research tasks:

- To analyze the national and foreign legislation regulating the telemedicine scope;
- To identify common views on digital technologies in medicine;
- To determine differences in the legal regulation in this sphere.

3. Research Questions

In the framework of this research the authors tried to find answers to the following questions:

- What is common in the legal regulation of telemedicine in Russia and the United States?
- What are differences in the legal regulation of telemedicine in Russia and the United States?

4. Purpose of the Study

The purpose of this research is to study the legislation regulating telemedicine in Russia and foreign countries, identify differences in the legal regulation of telemedicine in different countries, and form proposals for reforming Russian legislation in this area.

5. Research Methods

The authors applied philosophical and general scientific methods. In addition, specific scientific methods were used: historical-legal and comparative-legal. These methods were used to form a real picture of the sphere of legal regulation of the digitalization process in health care in Russia and foreign countries.

6. Findings

In 2006, the Draft Federal law No. 308883-4 "On information and communication technologies in medicine", regulating legal relations for the provision of medical services with the use of information technologies, was submitted to the Russian State Duma. The project was received critically. The official review dated 15.11.2006 stated: "the regulation subject of the submitted project is not clearly defined. Based on the draft content, the subject of its regulation is not relations in the field of information and communication technologies, but medical services provided using these technologies" (Komissarov, Kravts, Karmeev, Reznik, & Nastashevskiy, 2006). It was this part of the review that indicated the main obstacle – the lack of an unambiguous understanding of the content of the terms "telemedicine" and "telemedicine technology", etc. The development of legislative consolidation of the terms "telemedicine"

and "telemedicine technologies" in Russia returned in 2016. The new bill, firstly, did not imply the adoption of an independent legal act on telemedicine, proposing changes in the Basis of health protection, and secondly, was significantly different in its approach to the concept of telemedicine. If in the 2006 bill, the focus was on medical services with the use of technologies and communications, the Draft Federal law N 1085466-6 "On amendments to the Federal law "On the basis of health protection of citizens in the Russian Federation" and article 10 of the Federal Law "On Personal Data" dated 07.27.2006 N 152-FZ in the original version were based on the technological component and defined telemedicine technologies as "a system of technical, organizational, and other measures used by providing medical services to patients through procedures, means and methods of data transmission through communication channels (lines)" (Federal Law "On Personal Data" dated 07.27.2006 N 152-FZ), providing reliable identification of participants of information exchange – the medical worker and the patient or his legal representative.

It was also not approved and was replaced by a new one, where the concept of telemedicine technologies actually gained its present form. Despite minor comments on the definition of "telemedicine technologies", the State Duma Committee on Health Protection, the Legal Department and other persons authorized to comment on the bill officially, agreed with the concept of telemedicine as a technological and information complex used for the provision of medical services. In 2010, the Model Law on Telemedicine Services in the CIS Member States Adopted at the thirty-fifth plenary meeting of the Interparliamentary Assembly of the CIS Member States by Decree No. 35-7 of October 28, 2010 was adopted where telemedicine is defined as a set of organizational, technological and financial measures that ensure the operation of the system of providing remote consulting and diagnostic medical services, in which the patient or the doctor directly conducting the examination or treatment of the patient receive a remote consultation of a specialist – medical worker, using modern information and communication technologies. Under telemedicine services it was proposed to understand delayed consultations, real-time consultations, remote control of the physiological parameters of the patient's body, remote diagnostic and therapeutic manipulations, medical videoconferences, teleconferences, teleseminars, telelections and other medical services provided using modern information and communication technologies. On January 01, 2018, in the Russian Federation for the first time, Art. 36.2 and paragraph 22 of Art. 2 of the Federal law of 21.11.2011 No. 323-FZ "On the basic of health protection of citizens in the Russian Federation" (2011), established the possibility of obtaining medical care provided with the use of telemedicine technologies, and gave a legal definition of telemedicine technologies as information technologies providing distant interaction of medical specialists with each other and with patients and (or) their legal representatives. This technology also allows the identification and authentication of these persons, documenting their actions at consultations, remote medical monitoring of the patient's health.

Analyzing the experience of legal regulation of telemedicine in the United States, we consider it necessary to draw attention to the fact that in accordance with the tenth amendment and the eighth paragraph of article 1 of the Constitution of the United States (1787) medical law belongs to the jurisdiction of the states. Thus, each state has its own separate legislation in the field of medicine. Currently, the legal regulation of telemedicine differs in all 50 U.S. states, despite some similarities in the terms used. For example, in some states, telemedicine services are included in the state law on general medicine, while in others, telemedicine is addressed through the federal Medicaid program – a joint federal-state program that helps pay for medical services provided to some citizens with limited income and resources. The American

health insurance Association describes Medicaid as a government insurance program for people of all ages whose income and resources are insufficient to pay for health care (Medicaid, 2019). In the context of Medicaid, telemedicine is seen as a cost-effective alternative to the more traditional individual method of medical care (such as face-to-face consultations or examinations). At the same time, the federal law on the Medicaid program does not consider telemedicine (telehealth/telemonitoring) as a separate service. Such an approach is analogous to that used in the Russian Federation and described in the Federal law of the Russian Federation of 21 November 2011. No. 323-FZ "On basis of health protection of citizens in the Russian Federation" (Federal law of 21.11.2011 No. 323-FZ) and the Order of the Ministry of Health Care of the Russian Federation from 30.11.2017 No. 965n "On approval of the procedure of organizing and providing medical care with application of telemedical technologies". According to the conceptual framework adopted by Medicaid, telehealth (or telemonitoring) means the use of communications and information tools to provide access to health assessment, counselling, diagnosis, intervention, surveillance at a distance (The United States Government, 2019).

Paragraph 410.78 of the Code of Laws of the United States (Office of the Law Revision Counsel, 2019) enshrines the basic concepts and principles of telemedicine services: a doctor or medical professional must have a license to provide appropriate medical services in accordance with state law; services are provided to the patient at the location of the medical organization (doctor), that is, receiving services while the patient is, for example, at home is not possible; receiving a service by a patient using telemedicine technologies is possible only if there is no possibility of receiving such a service in person at the location of the patient. For example, if there is no allergist at the place of residence of the patient, the service can be obtained through telemedicine technologies, otherwise there are no grounds for obtaining telemedicine services. The medical organization must be a member of the relevant system of tele-health protection. The examination of patients should be carried out only under the direct supervision of a doctor or a medical professional providing telemedicine services.

The provision of telemedicine (tele-health/telemonitoring) services via Medicaid is possible in two forms. First, by means of an interactive telecommunications system: multimedia communication equipment including at least audio and video equipment allowing real-time two-way interactive communication between the health care provider and the patient. The definition of an interactive telecommunications system doesn't cover telephones, fax machines and e-mail systems. Second, by using asynchronous storage and forwarding technologies, which means transferring a patient's medical information to a healthcare professional. In this case, the medical professional can review the medical case without online communication with the patient. Regarding the second method, in Medicaid it is noted that asynchronous or "saved and forwarded" applications cannot be considered as a direct case of telemedicine, but can be used to provide medical services. As an example of asynchronous technologies, the transfer of photos from a patient to a medical professional is given. Several conclusions can be drawn from the above. Patient consultation in the U.S.A. can only be carried out using special interactive telecommunications equipment, which includes, at least audio and video equipment, which does not include telephone, fax or e-mail. Telemedicine is recognized as an only two-way interactive communication in real time between the patient and the health care provider. Operators (providers) of the telemedicine system are required to have the appropriate license (permission) to provide such services. Each state issues a separate license for the

provision of communication services, so for the technical provision of telemedicine services between the states, the operator (provider) must have two licenses – at the location of the medical worker and at the location of the patient.

As another example, let's consider the order of telemedicine services in Colorado, which does not use telemedicine through Medicaid. According to the local legislation, telemedicine (tele-health/telemonitoring) is the provision of certain medical services, any consultation, diagnosis, treatment, transmission of medical data or education related to medical services using interactive audio, interactive video or interactive data transmission instead of face-to-face contact. According to the guidelines for payments in sphere of telemedicine services, a telephone communication is not considered as telemedicine. The provision of telemedicine services should take place in the presence of a medical professional license for the appropriate type of medical care and under the condition of special equipment usage. The list of medical services that can be obtained using telemedicine technologies is quite limited. In contrast to Medicaid telemedicine, Colorado law implies that some medical services can be provided directly to the patient while the patient is at home, for example, if the patient has special equipment.

The health care professional may also determine other requirements for the patient's location, such as adequate lighting and noise levels. The provision of telemedicine services in Colorado is subject to mandatory confidentiality requirements. Where services are provided by Medicaid-connected health care professionals, they are required to use existing protocols ensuring the service quality and privacy guidelines for participants involved in the process of telemedicine services provision. As basic principles of providing telemedicine in Medicaid, the following can be designated: data transmission should be carried out on dedicated secure lines or using an adequate encryption method sufficient to protect the confidentiality and integrity of the transmission; data transmission must apply adequate procedures for identification and authentication of both the contractor and the recipient of medical services; for each user of the system, unique identifiers or passwords should be used; the system should provide a permanent record of electronic medical information.

In the case of other systems, the confidentiality requirements are determined by state law, the insurer, etc. Currently in the United States there are several types of telemedicine systems – national, regional, non-profit organizations that perform auxiliary functions. These include 2 national telemedicine systems (the National Telehealth Technology Assessment Resource Center and the Center for Connected Health Policy); 12 regional (for example, the Northwest Regional Telehealth Resource Center. In addition, there are several other systems that perform support functions (for example, the Leading Telehealth Association – a non-profit organization engaged in the development of innovative solutions for telemedicine systems).

7. Conclusion

In Russia telemedicine technology is regulated by the federal legislation, but it is far from the perfect one. This legislation contains vague expressions and rules in conflict with provisions of other legal acts. Many key points of services were not included in the scope of the legal regulation. In the U.S.A., the telemedicine sphere is regulated by laws of individual states. Currently, the legal regulation of telemedicine differs in all 50 U.S. states, despite some similarities in the terms used. For example, in some states, telemedicine services are included in the state law on general medicine, while in others, telemedicine is

addressed through the Federal Medicaid program, a joint federal-state program. Despite the different understanding of telemedicine in both the U.S.A. and Russia, telemedicine technology is not considered as a separate service. The questions that have accumulated in Russian legislation need to be solved in close mutual cooperation of lawyers and medical professionals, taking into account the practice of using telemedicine technologies in our country and abroad.

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