

**II International Scientific Conference GCPMED 2019  
"Global Challenges and Prospects of the Modern Economic Development"****CURRENT ISSUES OF LEGAL RESPONSIBILITY IN THE FIELD  
OF TELEMEDICINE**

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

\*Corresponding author

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

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

(c) Private institution of the educational organization of higher education «Medical University «Reaviz», 100, Chkalov Street, Samara, E-mail: sekretar@dkb63.ru

***Abstract***

The market of telemedicine services in Russia is at the formation stage, but the results of the introduction of telemedicine in the world prove that it contributes to the solution of the most important problems in the area. There are attempts to introduce telemedicine into modern healthcare systems, but, unfortunately, this process is often perceived as technocratic one and involves the acquisition and installation of very expensive telemedicine systems in large public health institutions. At the same time, today it is much easier to use Skype or any other free mobile applications available in any gadget, especially since they provide the same level of security as specialized programs. Today, the problems of telemedicine in the Russian Federation can be divided into two groups: problems of implementation and problems of development. Telemedicine provides every citizen with the opportunity to receive qualified medical care at any time, regardless of the territorial location, development of health care and infrastructure of medical support, but at the same time it exacerbates some responsibility issues in the medicine sphere. These problems have a national scale and character. All responsibility questions are regulated nowadays by the domestic legislation. Since legal relations in the telemedicine field may arise between medical organizations, the medical organization and the patient or his legal representative, the procedure for disputes consideration will vary depending on subjects. Disputes between medical organizations fall under the Russian arbitration legislation, while disputes involving patients are considered in the manner prescribed by the civil procedural legislation.

2357-1330 © 2020 Published by European Publisher.

**Keywords:** Telemedicine, responsibility, legislation, consultation, contract, information systems.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 Unported License, permitting all non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

## **1. Introduction**

The World Health Organization has pointed out that responsibility risks of medical professionals providing telemedicine services and the lack of an international legal framework allowing the provision of such services by specialists from different countries are the main obstacles to the global implementation of telemedicine. It makes it the international cooperation in the sphere of dissemination of telemedicine technologies and services impossible and limits the access of patients to the possibility of obtaining highly qualified medical care from the medical personnel of foreign clinics and the possibility of obtaining medical advice from foreign colleagues.

## **2. Problem Statement**

The development of innovative medical technologies allows providing highly qualified medical care not only in a medical institution, but also to patients living far from it. The development of such technologies allows constant monitoring the patient's condition, continuing treatment at home. Among other things, the spread of telemedicine makes it possible to save financial resources of medical institutions and direct them to the purchase of new equipment, personnel training etc. All this becomes possible only in conditions of the well-regulated national legislation, taking into account the international experience in this branch.

## **3. Research Questions**

The study of the peculiarities of the responsibility in the field of telemedicine is aimed at the attraction of the theoretical scientists' and legal practitioners' attention to this problem. The authors set themselves the following tasks: to analyze the national legislation in the considered sphere; to identify the specific characteristics of the responsibility in the field of telemedicine. Another specific question of this research is: what is considered as 'improper provision of medical care' with the use of telemedicine?

## **4. Purpose of the Study**

The research goal is to study the Russian legislation regulating the telemedicine in the country, identify topical issues in terms of the medical responsibility. It was also important for authors to make some recommendations for reforming the Russian legislation in this area.

## **5. Research Methods**

The authors used the following methods in the implementation of this study: comparative legal, logical, method of analysis and synthesis, system method, modeling. And since each individual research method does not allow to create the "full" picture of the actual situation in the research area, the above methods were applied comprehensively.

## 6. Findings

According to the general rule, article 35 of the Arbitration Procedure Code (APC) of the Russian Federation, the claim is presented to the arbitration court of the Russian Federation at the location or place of residence of a defendant. Articles 36-38 of the APC of the Russian Federation define other cases of cases jurisdiction where the greatest interest in relation to the telemedicine is the contractual jurisdiction (Arbitration Procedural Code of the Russian Federation, 2002). For example, the contract for the consultation with the use of telemedicine technology (where the contractor is the Federal State Budgetary Scientific Institution "Scientific Center of Neurology") states that "disputes under this contract shall be settled by the arbitration court of Moscow with observance of the claim settlement procedure". The legal relations connected with the provision of telemedicine services to the patient are regulated by the legislation on protection of the consumers' rights that provides to the patient (customer) the right of a choice of jurisdiction at his own discretion. According to part 7 of Art. 29 of the Civil Procedure Code (CPC) of the Russian Federation, claims about the protection of the consumers' rights can be brought also to the court at the place of residence or a place of stay of the claimant or in a place of the conclusion or execution of the contract that does not exclude filing the claim according to the general rule (Art. 38 of CPC of the Russian Federation): at the location of a medical organization (Civil Procedure Code of the Russian Federation, 2002). In the case when requirements are addressed to the operator (provider) of telemedicine services, the patient may also exercise the right to file a claim at the place of his residence according to part 6.2. of Art. 29 of the CPC of the Russian Federation (Civil Procedure Code of the Russian Federation, 2002). This provides for jurisdiction at the choice of the plaintiff in the case of the rights protection of a personal data subject, including claims for damages and (or) compensation for moral damage.

Nowadays, there are several information systems in the Russian Federation that provide telemedicine services and unite various medical organizations. "Mobile Medical Technologies" LLC is considered to be the leading Russian developer of online projects in the field of healthcare and telemedicine. The company owns two major projects "Online Doctor" and "Pediatrician 24/7". Both services work with licensed clinics around the clock. For providing its services, "Online Doctor", according to the documentation presented on the official website, uses the information system of the service administrator relating to type of 'other information systems' established by the Law. It is created on the basis of the "Mobile Medical Technologies" LLC software (the certificate on the state registration of the computer program No. 2016661187 of October 03, 2016) and used by medical organizations for rendering medical care with the application of telemedicine technologies (Mobile Medical Technologies" LLC. Official website, 2013).

Identification and authentication of a customer is carried out by means of authorization via the strengthened qualified electronic signature or the simple electronic signature in ESIA (the portal of Russian Public Services). By registering in the service "Online Doctor" and choosing a medical professional to receive telemedicine services, the customer concludes a contract for the provision of medical services directly with the medical organization where the chosen doctor works and there is a license for the appropriate type of the medical care. The service "Online Doctor" itself acts as an intermediary and administrator of the service, that is, allows the contract parties to use a special information system to provide telemedicine services. In addition to the acceptance of the contract for the

provision of medical services, the patient must sign (give) the informed voluntary consent for different types of medical interventions and the consent to the processing of personal data and transfer of information constituting the medical secrecy, as well as accept the offer of regular payments and terms of the online cards usage.

Thus, the activity of the service "Online Doctor" corresponds to the current legislation of the Russian Federation. The situation with the service "Yandex.Health" has developed differently. Despite the work principle similar to "Online Doctor", at the beginning of 2019 the situation was so: to sign an electronic document with an electronic signature within the Service, the customer can use various types of authorization on the service platform depending on the own choice: alphabetic, numeric, symbolic or combined codes generated by Yandex and received by the user in the form of a message to the phone number; logins and passwords of social accounts or accounts on the services of "YANDEX" LLC, which are a key of the electronic signature. The service involves assumes signing of the informed voluntary consent for different types of medical interventions, but with a conventional electronic signature as indicated above, not with a strengthened qualified electronic signature or a simple electronic signature in the ESIA. An indication of the signing the consent with a conventional electronic signature is also contained in the contract-offer for the provision of medical services.

Thus, we can conclude that the activity of the service "Yandex.Health" does not comply with the current legislation of the Russian Federation at least in the order of signing the informed voluntary consent by the patient. It should be noted that the leading domestic telemedicine services have found options for anonymous provision of services. As it was mentioned earlier, telemedicine services ("Yandex.Health", "Online Doctor", etc.) are operators of information networks, but they do not participate directly in the provision of medical services. By registering in the service, the patient confirms his consent to the processing of personal data and medical intervention, indicating the minimum data about himself. When a patient wants to receive a telemedicine service anonymously, his personal data remain only with the operator of the information network and is not transferred to the medical organization. This approach very conditionally meets the requirements of the current legislation, as the basis for the provision of telemedicine services is still a contract for the provision of paid medical services, which does not imply any anonymity. We believe that the above method used by telemedicine services should be reflected in the by-law normative legal act on the procedure for obtaining telemedicine services. We can agree with the point of view of those authors who think that "the protection of declared personal data looks more like a myth in the era of globalization, computer and transnational crime". Because every year there are new devices and new technologies, scientific and technological progress is continuing bringing with itself new opportunities including for criminals. A new challenge is posed by computer and transnational crime (Samoilova, 2017).

Currently, communication network operators and operators of information systems are responsible for the information security. There are three main types of threats to the information security: violation of integrity; violation of availability; violation of confidentiality. In addition to medical organizations and patients, at least two types of persons are involved in the provision of telemedicine services too: a communication operator, and, in some cases, an operator of the information system. End-users (patients, medical workers – employees of a medical institutions, regional employees, etc.) get access to application

services via the Internet. In accordance with the Decree of the Government of the Russian Federation from 10.09.2007 № 575 "On approval of rules of rendering telematic communication services" (2007), access to information systems of information-telecommunication networks, including the Internet, is carried out on the basis of contracts with the communication network operator rendering telematic communication services. End users of information systems used for providing telemedicine services get access to these services via the Internet, so the connection of the system to the Internet is mandatory (Decree of the Government of the Russian Federation from 10.09.2007 № 575, 2007).

For non-performance or improper performance of obligations under the contract, the operator shall be liable to the customer – the medical organisation or the patient in the following cases: violation of terms of providing access to the data communication network using the communication line; violation of the terms of provision of telematic communication services stipulated in the contract; non-provision of telematics services stipulated in the contract; poor provision of telematic communication services; violation of the established restrictions on the dissemination of information about the customer, which became known to the operator in the process of the contract execution. The customer and (or) the user has the right to demand full compensation for losses caused by the violation of specified terms of the telematic communication services provision. This means that if it is impossible to provide a consultation by a doctor (doctors' council) in the period established by the legislation or the contract because of the lack of access to the Internet, the medical organization can claim damages by the operator. The operator of the information system participates in the provision of telemedicine services when a medical organization does not operate its own medical information system.

An example when the organization providing telemedicine services and the operator of the medical information system are the same structure is the telemedicine service DOC+ ("New Medicine" LLC). According to the Federal law from 27.07.2006 No. 149-FZ "About information, information technologies and information protection", the information system is a set of information contained in databases and providing its processing with the use of information technologies and other technical means (2006). The operator of the information system is understood as a citizen or a legal entity engaged in operating the information system, including the processing of information contained in its databases. The operator of the telemedicine system "Yandex.Health" is "Clinic Yandex.Health" LLC. However, the access to some databases of this system is carried out by the operator of "YANDEX" LLC. The sphere of the activity of information systems operators in the telemedicine can be divided into two blocks: ensuring the smooth functioning of the system (technical part) and ensuring the safety of information and personal data with the limited access. In the scientific literature, it is noted that the system operator is responsible for the proper organization of users' training in the field, including training in remote monitoring of the patient's health.

Having access to a large amount of personal information by its processing, including information of a special nature about the health of a citizen and information constituting a medical secret, telecommunication operators and their employees bear several types of responsibility. According to the general rules of the Federal law from 27.07.2006 N 149-FZ "About information, information technologies and information protection" (Art. 17) (2006) and the Federal law from 27.07.2006 No. 152-FZ "About personal data" (Art. 24) (2006), persons whose rights and legitimate interests have been violated in connection with the disclosure of limited access information or other unlawful use of such information,

have the right to apply in accordance with the established procedure for the judicial protection of their rights. This includes claims for damages, compensation for the moral damage, protection of honor, dignity and business reputation, that means in civil law. Disclosure of information and personal data may be punished by the norms of the Code of the Russian Federation on Administrative Offences from 30.12.2001 No. 195-FZ (article 13.11, 13.12, 13.13, 13.14) (2001) and the Criminal Code of the Russian Federation from 13.06.1996 No. 63-FZ (Art. 137, 272) (1996). The legal literature there is a question about the responsibility of the system operator in different cases of providing telemedicine services. For example, in the opinion of some authors, one question "remains behind the scenes": "who is responsible for the detection of a critical deviation of indicators? It this a doctor, another health worker involved in the provision of medical services, or the operator of the information system (in the latter case it is an automated analysis) (Morozov, Vladzimirsky, Varyushin, & Aronov, 2018).

In our opinion, according to the paragraph 56 of the order of organization of medical aid with the use of telemedicine technology (Order of the Ministry of Health of the Russian Federation from 30.11.2017 No. 965n "On approval of the procedure of organizing and providing medical care with the use of telemedicine technologies", 2017), the treating doctor is responsible for investigating critical deviations of indicators in the health status of the patient from limit indicators, the doctor who ordered remote monitoring of health status of the patient. However, the operator of the information system is responsible for the technological support of data transmission on health indicators. For example, if the information system unit in which remote surveillance operations are carried out does not respond in the manner described in the system (for example, by giving an audible signal), then the operator as the service provider is responsible for the damage it caused. Telecommunication operators and operators of information systems in the telemedicine should be considered from the point of view of service providers and be guided by the provisions of the civil legislation in case of occurrence of bases for attraction of the operator to responsibility for the harm caused to life and health of the patient. We can divide the responsibility of the communication operator and the information system operator by the place of occurrence of threats to the information security in the operation of information systems. There are at least two options: within the boundaries of information systems – that is, in the responsibility area of the operator of the information system; outside the information systems – that is, in the responsibility area of the communication operator.

Indeed, in some cases, it is not easy to prove the operator's guilt in the process of providing a telemedicine service. For example, the doctor may not advise the patient properly because he was unable to see any significant details in a demonstrated picture of the patient's body (part of the body). In such a situation, the question of the responsibility of the information system operator or the communication operator for the quality of the broadcast video signal, the responsibility of the doctor for "inattention" and the responsibility of the patient for poor-quality video remains open.

## **7. Conclusion**

The Russian legislation regulating the sphere of telemedicine is still young and indisputable. It is necessary to formulate a definition of the concept of "improper provision of medical care", fixing it in the legislation. The authors believe that the most correct way to understand the improper provision of medical care as its provision with the violation of established professional medical norms and rules, which include

medical care standards and procedures approved at the federal level, as well as clinical recommendations. It is necessary to adopt a legal act regulating the anonymous provision of domestic telemedicine services (when information of a confidential nature remains by the communication operator or the information system operator). The issues of the responsibility differentiation for improperly rendered service with the application of telemedicine technologies between the doctor and the information system operator or the communication operator are not fully regulated. The question of a higher protection degree for specific data remains open: personal data of clients, information constituting a medical (medical) secret. Hence, there are issues on their guilt evidence, its degree and severity in the provision of such services.

## References

- Arbitration Procedure Code of the Russian Federation from 24.07.2002 N 95-FZ (amended 26.07.2019) (2002). Retrieved from: <http://base.garant.ru/12127526/> Accessed: 23.10.2019. [in Rus.].
- Civil Procedure Code of the Russian Federation from 14.11.2002 № 138-FZ (amended 26.07.2019). (2002). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_39570/](http://www.consultant.ru/document/cons_doc_LAW_39570/) Accessed: 23.10.2019. [in Rus.].
- Code of the Russian Federation on Administrative Offences from 30.12.2001 No. 195-FZ (amended 02.08.2019) (2001). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_34661/](http://www.consultant.ru/document/cons_doc_LAW_34661/) Accessed: 23.10.2019. [in Rus.].
- Criminal Code of the Russian Federation from 13.06.1996 No. 63-FZ (amended 02.08.2019) (1996). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_10699/](http://www.consultant.ru/document/cons_doc_LAW_10699/) Accessed: 23.10.2019. [in Rus.].
- Decree of the Government of the Russian Federation from 10.09.2007 № 575 (amended 25.10.2017) «On approval of rules of rendering telematic communication services» (2007). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_71035/](http://www.consultant.ru/document/cons_doc_LAW_71035/) Accessed: 23.10.2019. [in Rus.].
- Federal law from 27.07.2006 No. 149-FZ "About information, information technologies and information protection", from 27.07.2006 № 149-FZ (amended 18.03.2019) (2006). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_61798/](http://www.consultant.ru/document/cons_doc_LAW_61798/) Accessed: 23.10.2019. [in Rus.].
- Federal law from 27.07.2006 No. 152-FZ (amended 31.12.2017) "On personal data" (2006). Retrieved from: [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_61801/](http://www.consultant.ru/document/cons_doc_LAW_61801/) Accessed: 23.10.2019. [in Rus.].
- Mobile Medical Technologies LLC. Official website. (2013). Retrieved from: <https://mmtpro.ru/about> Accessed: 10.09.19.
- Morozov, S., Vladzimirsky, A., Varyushin, M., & Aronov, A. (2018). Distribution of responsibility for poor quality medical care when using telemedicine technologies. *Journal of Telemedicine and eHealth*, 1-2, 10. [in Rus.].
- Order of the Ministry of Health of the Russian Federation from 30.11.2017 No. 965n "On approval of the procedure of organizing and providing medical care with the use of telemedicine technologies (2017). Retrieved from: <https://www.garant.ru/products/ipo/prime/doc/71751294/> Accessed: 23.10.2019. [in Rus.].
- Samoilova, D. (2017). *Protection of private life of a citizen as a myth in the era of scientific and technological progress*. Penza: Publishing house «Science and Education». [in Rus.].