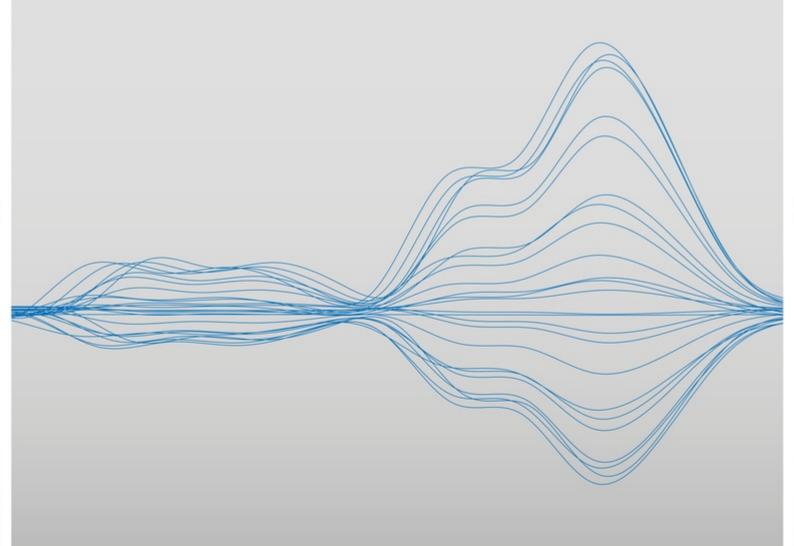
RUSSIA

Telehealth around the world: a global guide





Introduction

The COVID-19 pandemic has caused healthcare systems around the globe to rapidly, and in some cases, radically rethink the delivery of medical care. The global expansion of telehealth services is one way we have seen this transformation occur. This has resulted in significant opportunities in the field, as well as unprecedented regulatory change.

As a quickly evolving area, 'telehealth' can have different meanings in different contexts. In this Global Guide, telehealth refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries. We have adapted this definition from the World Health Organisation's definition of telehealth.

Telehealth is not a new concept – healthcare providers, academics and technology developers have been advocating for its use for decades. There are many benefits to the widespread adoption of telehealth, including improved access to healthcare services, risk mitigation, convenience and flexibility, and in many cases, a reduction in overhead costs. However, the use of telehealth is not without its challenges. For example, it is not suited to all forms of healthcare, its implementation and adoption can be time consuming and costly, and additional care must be taken in relation to the transfer of patient health information.

The restrictions of movement in many parts of the world due to COVID-19 has caused governments to recognise the potential of telehealth, and amend laws and regulations seemingly overnight to enable healthcare providers to deploy telehealth solutions. Many governments have adopted telehealth reforms in a matter of weeks, which may otherwise have taken years to be considered and introduced.

Although many of these reforms presently have an expiration date (dependent on the duration of the COVID-19 pandemic), there is likely to be continued growth in telehealth due to the advantages of such a service – even after the pandemic. There are enormous opportunities in the telehealth space for businesses already operating in this field, businesses considering expanding into telehealth, and start-ups.

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis. As the field of telehealth, and the regulations underpinning it, remain highly dynamic and subject to change, this document is intended as a general guide and does not constitute legal advice. Should you wish to discuss any aspects of telehealth with a specialist lawyer, please contact us below.

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Russia

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Is the use of telehealth permitted?

Yes. In Russia, rules on telehealth were adopted in 2017. On 29 July 2017, Article 36.2., governing telemedicine, was added to the Federal Law "On Basics of Health Protection of Citizens in Russia" No. 323-FZ dated 21 November 2011 (the "Health Protection Law"). On 30 November 2017, the Russian Health Authority also adopted Order No. 965n "On Endorsement of the Order of Providing Medical Assistance with the Aid of Telemedicine Technologies" (the "Order") which sets out the requirements relating to the provision of medical services through telehealth technologies.

How is telehealth regulated?

Telehealth is regulated mainly as a medical service under Russian law.

Russian law refers to telehealth as involving "telemedicine technologies". "Telemedicine technologies" are defined under the Health Protection Law as information technologies enabling the remote interaction between healthcare professionals and patients (or the legal representatives of minor patients) relating to the conduct of consultations and medical observations of the patient. Accordingly, telehealth is understood as providing medical services on a remote basis.

A state medical licence is required to perform telehealth. However, initial consultations cannot be made through remote technologies and must be performed on an in-person basis.

Beyond licensing requirements, the structure of Russia's telehealth rules is that these rules will apply only to "medical assistance" (which is defined by the Health Protection Law to mean a complex of actions aimed at maintenance or restoration of health, including the provision of medical services) provided on a remote basis. Therefore, if a service is provided not specifically for medical assistance, the rules for telehealth will not be applied. Nevertheless given the breadth of the definition of "medical assistance", most consultations, observations or follow ups could be expected to fall within the regulatory framework.

Are there specific fields of healthcare in relation to which telehealth services are currently available, and do they involve the use of proprietary technology or platforms?

Telehealth services are only available if they can be provided on a remote basis. By way of example, primary medical consultations, which include physical checkups of patients, establishing diagnoses, and prescribing medicines, can only be performed through an inperson appointment with a licensed clinic or healthcare professional. Although statutory amendments to extend the breadth of telehealth services (e.g., to include diagnosing medicial conditions and prescribing medicines) were considered, they were ultimately rejected.

Telehealth services are not limited to the same doctor or clinic which performed the initial consultation or examination. Neither the Health Protection Law or the Order provides explicit requirements for the patient to stay with the same doctor or clinic after the initial inperson consultation or examination. Therefore, a patient can start with one doctor or clinic and continue through telehealth services after that.

There are also some technical requirements for telehealth services in Russia. Telehealth services can only be performed with the use of state-approved IT systems which allow for precise identification and verification of both healthcare providers (clinics or healthcare professionals) and patients. Specifically, the unified system of identification and authentication ("ESIA") must be used.

ESIA is regulated by the Resolution of Russian Government No. 977 dated 28 November 2011. In brief, this is a state-run system that is used for official interaction between state officials, and / or between state officials and citizens, and ensures all users identification and authentication based on enhanced e-signature. Some industry participants have indicated that this system is somewhat bulky and inconvenient to use, especially by patients, which may impact the uptake of the use of telehealth services. In light of the abovementioned licensing requirements, the limitations on the scope of services which can be provided, and the cumbersome technical requirements, telehealth services are performed in limited scope in Russia.

Does the public health system include telehealth services, and if so, are such services free of charge, subsidised or reimbursed? Where the public health system does not include telehealth services, are such services covered by private health insurance?

As discussed in Fields of healthcare, because of its limitations, telehealth services are not yet widely used in Russia. As of today, there is no established mechanism on providing subsidised or reimbursed telehealth services as distinct from other medical services. However, we are aware that some private health insurance companies consider coverage of telehealth services in scope of their insurance, but this is at early stage of development.

Do specific privacy and/or data protection laws apply to the provision of telehealth services?

There are no specific privacy and / or data protection laws that apply to the provision of telehealth services in Russia, but general data protection rules would apply to require any telehealth provider to ensure that any personal data of a patient is processed properly, with the patient's consent and / or based on an agreement with the patient, and that a copy of such data is stored in Russia (data localisation rules).

How should the cross-border transfer of personal information collected and processed in the course of telehealth services be carried out to ensure compliance with applicable privacy laws?

There are no specific rules on cross-border transfer of telehealth data in Russia. However, general data protection rules governing cross-border transfer of data would apply. Such rules would primarily require that any cross-border transfer of personal data is made with the patient's consent and / or based on an agreement with the patient, and that a copy of such data is stored in Russia (data localization rules).

Are there any currently applicable codes of conduct on the use of telehealth systems and/or security of telehealth data in your jurisdiction?

As discussed in Availability of Telehealth, on 30 November 2017, the Russian Health Authority adopted the Order No. 965n "On Endorsement of the Order of Providing Medical Assistance with the Aid of Telemedicine Technologies" which sets out the requirements for providing medical services with the aid of telemedicine technologies.

Are any specific laws, regulations, or self-regulatory instruments expected to be adopted in the near future?

Presently, no.

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