

ROMANIA

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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Romania

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Is the use of telehealth permitted?

Yes, telehealth is permitted in Romania.

How is telehealth regulated?

Government Emergency Ordinance no. 196/2020, which entered into force on 19 November 2020 ("GEO no. 196/2020"), represents the general legal framework regulating telehealth.

GEO no. 196/2020 is implemented through Government Decision no. 1133/2022 regarding the approval of the Methodological Norms for the implementation of the provisions of the Government Emergency Ordinance no. 196/2020 for the amendment and completion of Law no. 95/2006 on healthcare ("GD no. 1133/2022"). GD no. 1133/2022 regulates the medical specialties and the list of services that are the object of telehealth services, the conditions for the organization and operation of telemedicine.

Before GEO no. 196/2020 was adopted, there was limited legislation regarding specific types of telehealth, such as telehealth targeted at rural areas.

In addition, specific legislation relating to temporary general telehealth rules was applicable in the context of the COVID-19 pandemic.

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?

GEO no. 196/2020 covers prophylactic and curative telehealth services and regulates the following services: (i) remote consults, (ii) tele-expertise, (iii) teleassistance, (iv) teleradiology, (v) telepathology and (vi) remote monitoring of the patient.

The services can be performed by any means of telecommunication, irrespective of the audio or video platform, the electronic equipment, cable networks, optic fibre, radio, satellite or other such means that are used. The communication platforms that are used must ensure the security of the data.

The medical specialties and the list of services that can be performed through telehealth are regulated through GD no. 1133/2022..

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?

GEO no. 196/2020 and its methodological norms apply to both public and private healthcare providers.

GEO no. 196/2020 provides that the telehealth services may be reimbursed from public funds in accordance with the general rules for reimbursement of medical services. This means that some telehealth services can be free of charge for patients, similar to face-to-face medical services.

Private health insurance, which can be taken up with private healthcare providers, may cover other telehealth services, depending on the package or offer of each private healthcare provider.

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

There are no telehealth-specific data protection laws in Romania, however more general privacy legislation may be relevant.

The main piece of legislation on the protection of personal data is Regulation (EU) 2016/679 (GDPR). The GDPR provides specific rules for the processing of data concerning health, which is classified as belonging to a special category of personal data.

Additionally, two national pieces of data protection legislation could also potentially impact the provision of telehealth services: (i) Law no. 190/2018 on implementing measures to Regulation (EU) 2016/679 ("**Law 190/2018**"), and (ii) Decision no. 174/2018 for establishing the list of the processing operations for which it is mandatory to perform a data protection impact assessment ("**Decision 174/2018**").

According to Law 190/2018, *"the processing of genetic data, of biometric data or of health data for the purpose of automated decision-making or profiling is permitted with the explicit consent of the data subject or if the processing is carried out under explicit legal provisions, with appropriate measures protecting the rights, freedoms and legitimate interests of the data subject"*. Furthermore, *"the processing of health data for the purpose of ensuring public health cannot be subsequently performed for other purposes by third entities"*.

Pursuant to Decision 174/2018, a data protection impact assessment is required inter alia in the following cases:

- the processing of personal data in order to perform a systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person;
- processing on a large scale of genetic data, biometric data, data concerning health or data concerning a natural person's sex life or sexual orientation;
- processing on a large scale of personal data of vulnerable persons, through automatic means of systematic monitoring and/or recording of behaviour;
- processing on a large scale of personal data through the innovative use or the implementation of new technologies; and
- processing on a large scale of data generated by devices with sensors that transmit data over the Internet or other means

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?

Cross-border transfers of telehealth data must be carried out in accordance with Chapter V (*Transfers of personal data to third countries or international organisations*) of the GDPR.

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

We are not aware of the existence of such public codes of conduct.

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

We are not aware.

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