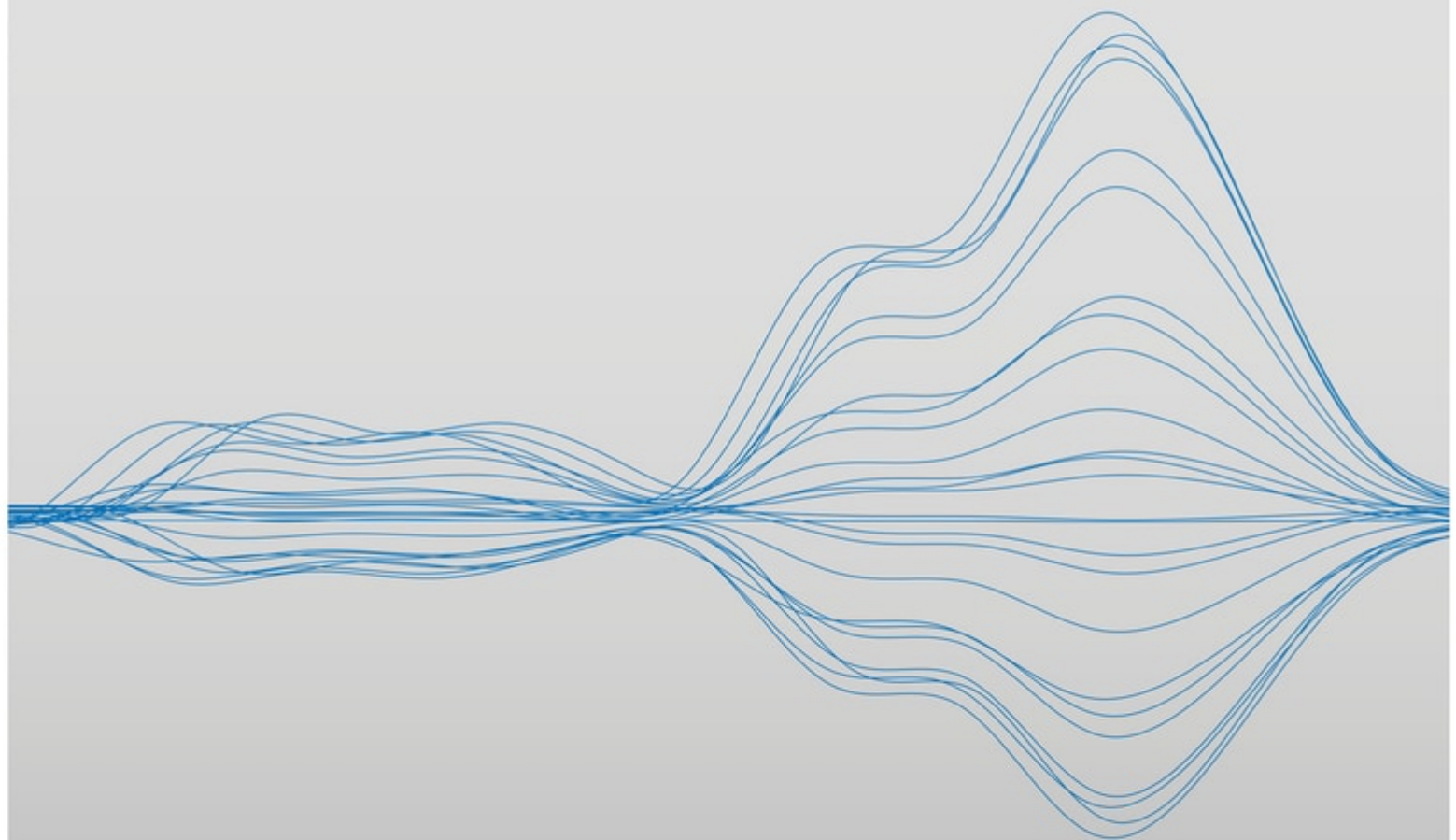


CROATIA

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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Croatia

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Is the use of telehealth permitted?

Yes. Telehealth, in particular telemedicine ("**Telemedicine**"), defined as the provision of healthcare services at a distance (i.e., when a healthcare worker and a patient or two healthcare workers are not in the same location) by using information and communication technologies, pursuant to Article 38 (1) of the Croatian Healthcare Act (*Zakon o zdravstvenoj zaštiti* – "**Healthcare Act**") and Article 2 (1) no 1 of the Croatian Ordinance on conditions, organisation and manner of performing telemedicine (*Pravilnik o uvjetima, organizaciji i načinu obavljanja telemedicine* – "**Telemedicine Ordinance**") in conjunction with Article 257 (1) no 22 of the Healthcare Act, is explicitly recognised and permitted in various aspects throughout the Healthcare Act as well as the Telemedicine Ordinance. Additionally, the Healthcare Act also recognizes Telemedicine as one of the main objectives of the Croatian healthcare realm, according to Article 7 of the Healthcare Act.

How is telehealth regulated?

According to Articles 5 and 35 of the Telemedicine Ordinance, healthcare institutions, healthcare workers, companies performing healthcare activities and private healthcare workers performing telehealth activities in the Republic of Croatia must (i) obtain a four-year Telemedicine Center Approval issued by the Croatian Institute of Emergency Medicine (*Hrvatski zavod za hitnu medicinu* – "**Institute**"); and (ii) be included in the Network of Telemedicine Centres (*Mreža telemedicinskih centara*). This network has been established under the Croatian Decision on the Adoption of the Network of Telemedicine Centers adopted by the Croatian Minister of Health ("**Network Of Telemedicine Centers Decision**"). It is noted that, in relation to the approval from the Institute, the applicant must comply with the various infrastructure, equipment, and software requirements imposed by Articles 28 et seq. of the Telemedicine Ordinance.

Pursuant to Article 3 of the Telemedicine Ordinance, a telemedicine centre can be of two types:

- A telemedicine access centre, being an institution where one can receive telehealth (telemedicine) services; or
- A telemedicine specialist centre, being an institution where one can receive and be provided with telemedicine services according to specialties.

Pursuant to Article 3 (4) of the Telemedicine Ordinance, a telemedicine centre may be stationary and / or mobile, and, moreover, allowed to be performed either with direct interaction of participants (i.e., real-time communication between the service seeker, the service recipient and the teleconsultant), or without direct interaction of participants (see Article 4 (6), (7), and (8) of the Telemedicine Ordinance).

The applicable legislation does not specify the ways telehealth services may be provided. However, the legislation stipulates that telehealth services are provided through a network communication system that forms a common health basis for secure data exchange and interoperability tools (technical standards, classifications and network communication infrastructure). The purpose of such a network is to ensure the connectivity and interoperability of registers and information systems in the public health system of Croatia and to provide common elements for interaction with citizens or other users.

Further, the Healthcare Act provides that the medical and public health data can be collected through the mobile healthcare platform mZdravstvo (in English: *mHealth*) which involves the use of mobile communication devices for the collection of general and clinical health data, the transfer of health information to physicians, researchers and patients, and remote monitoring of medical parameters of the patient.

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?

According to the Network Of Telemedicine Centers Decision, Telemedicine services are available in the context of primary, secondary as well as tertiary care.

Regarding the technology, Article 30 of the Telemedicine Ordinance sets forth mandatory criteria in respect of information, communication, and computer equipment of the telemedicine centre which have to have an European certificate (CE). Those criteria are:

- uninterruptible power supply which must ensure a minimum autonomy of all components of 30 minutes;
- a computer with associated peripheral devices necessary for work; and
- information and communication devices for data transmission and protection.

Moreover, Article 31 of the Telemedicine Ordinance requires the following conditions in relation to information and communication equipment, computer equipment, and infrastructure of the telemedicine centre to be met:

- the computer network used for performing telemedicine activities must be a private computer network, without access to other computer networks and the Internet;
- the possibility of connecting the network information and communication infrastructure with other networks in order to exchange patient data. The connection must be made through a firewall in which traffic is filtered at least by destination IP addresses and ports;
- access to data in the database via any interface may only be granted to an authorised person;
- prevention of access of manufacturers and repairers of computer equipment to patient data. Such data may be accessed only by a person authorised to do so by the data owner (patient);
- the information system must be implemented with backup data storage in at least two spatially distant locations;
- backup of the information system is performed regularly on a daily basis;
- verification of backup copies of the information system is performed once every month in such a way that a fully functional information system is re-established from the backup copy;
- in audio or audio-video conferences, the audio and video delay must not exceed 150 ms; and
- data delay in the network communication infrastructure must not exceed 50 ms.

In addition, pursuant to Article 12 of the Telemedicine Ordinance, the equipment as well as information and communication infrastructure necessary for work in the basic network of telemedicine centres are to be provided by the Croatian Ministry of Health and shall be obtained through public procurement mechanisms. Additionally, such equipment and infrastructure for the operation of telemedicine centres in the expanded network of telemedicine centres are provided by healthcare institutions, companies that perform healthcare activities, and private healthcare workers that perform telemedicine activities.

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?

The public health system includes telehealth services. Pursuant to Article 128 (2) of the Healthcare Act, health institutions that perform professional and scientific activities within the framework of the rights and duties of the Republic of Croatia in the field of public health, occupational medicine, telemedicine, toxicology and anti-doping, transfusion medicine and emergency medicine fall within the scope of "state health institutes".

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

Yes, the following laws apply:

- Croatian Act on Implementation of the General Data Protection Regulation (*Zakon o provedbi Ope uredbe o zaštiti podataka – "Data Protection Act"*);
- Croatian Ordinance on the use and protection of data from medical documentation of patients in the Central Health Information System of the Republic of Croatia (*Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske – "Ordinance on the Use and Protection of Data"*); and
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR").

Rules for protection of personal data implemented in the GDPR apply directly in Croatia. The Data Protection Act and Ordinance on the Use and Protection of Data generally provide for the obligation on users of medical data to keep the data from the patient's medical documentation secret.

Additionally, Article 18 of the Telemedicine Ordinance specifically provides that recording of audio and video recordings during the provision and reception of telemedicine services is allowed only with the written consent of the recipient of the service. For a recipient of a service who is unconscious, has a severe mental disorder, or is a minor, the written consent shall be given by the legal representative or guardian of the recipient of the service. The written consent must contain the reason for the recording, the type of recording and the purpose for which the recording will be used.

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?

The general principles of GDPR apply.

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

According to publicly available information, there are no official guidelines adopted by Croatian authorities exclusively for telehealth – i.e., on how to provide health services. Therefore, general guidelines on privacy and the code of ethics for health workers adopted by Croatian authorities and guidelines of EU authorities are most relevant.

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

According to the relevant authorities, the national strategy on the field of telehealth will be still subject to regulation and developed alongside the digitalisation of health system. Currently, there are no special legal acts in the public discussion or in a legislative procedure.

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