

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

In general, telemedicine-related activities are permitted in the Czech Republic – albeit to a limited extent, whereby this field is still in its infancy.

A definition of the term ‘telemedicine’ is presently not incorporated into Czech law. However, Act No 325/2021 Coll, on electronic healthcare (the ‘E-health Act’) defines a broader term, namely ‘electronic healthcare’, encompassing the provision and use of services and information systems linked to a so-called Data Integration Interface, the management, storage and transmission of medical documentation in an electronic form, as well as systems enabling remote access for patients.

The Ministry of Health is presently working on an amendment to the E-health Act that should introduce a new definition of telemedicine. The amendment is currently expected to enter into force in 2024.

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

The legal regulation of telemedicine in the Czech Republic is still not fully implemented – despite the Covid-19 pandemic underscoring the need for both on- and off-site healthcare services. Nonetheless, the Czech government is seeking to improve the legal framework for the fast-growing area of telemedicine and to introduce mechanisms aiding the implementation of digital technologies into the Czech healthcare system. Some aspects of telemedicine have already been incorporated into the legal acts listed below:

1. Act No 372/2011 Coll, on healthcare services (the ‘Healthcare Services Act’) allows for the remote provision of consultation services outside of a healthcare institution.
2. The E-health Act sets uniform standards for the provision of electronic healthcare across the Czech Republic. It mainly governs the use of information technologies and telecommunications systems in the healthcare system, as well as stipulating the rights and obligations of the different parties engaged in electronic healthcare, as well as those of patients.
3. The E-health Act introduces a Data Integration Interface, which serves as a central register of information concerning healthcare institutions, healthcare professionals and patients. The Data Integration Interface is scheduled to become operational on 1 January 2023.

4. The E-health Act came into effect on 1 January 2022; however, some of its provisions become effective over the ensuing years, particularly between February 2022 and January 2024.
5. In addition, Act No 378/2007 Coll, on medicinal products introduced a so-called 'eRecept' ('eRecipe'), namely an electronic system comprising data concerning medical prescriptions and vaccination certificates in an electronic form. The main feature of this system is that medicinal products are prescribed in an electronic form and such prescriptions are saved in a centralised electronic interface. Physicians, health insurance companies, pharmacists and other engaged entities may remotely access prescribed medicinal product records along with specific patient vaccination records.
6. Another telemedicine-related system used in the Czech Republic is a so-called 'eNeschopenka' (ie, an 'E-sick-leave note'), enabling doctors to issue sick-leave notes in electronic form.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

As outlined above, telemedicine is not yet formally recognised under Czech law. Accordingly, no official licensing bodies are presently in existence that are dedicated to the field of telemedicine.

In general, all healthcare service providers must be licenced by regional authorities. If the respective medical-related software fulfils the definition of a medical device, it must be approved by the competent authority (in the Czech Republic, the State Institute for Drug Control).

4. Was Telemedicine authorised during the Covid-19 pandemic?

During the Covid-19 pandemic, numerous physicians performed on-line consultations with those patients requiring ongoing treatment. From March 2020, Czech health insurance companies began to reimburse certain remote healthcare services provided during the period when social distancing measures were in force. Physicians were obliged to offer standard services during regular office hours. Reimbursable procedures primarily included those performed by general practitioners and certain specialists (eg, clinical psychologists and psychiatrists). However, these extraordinary measures are no longer in force.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?

As noted above, the E-health Act created a general framework for healthcare services rendered by electronic means. Some of its provisions will come into force in the upcoming years. Additionally, more detailed telemedicine-related rules will likely be adopted within the next two years.

Furthermore, changes at the European Union level have also been proposed. In particular the European Commission has introduced the European Health Data Space, which aims to

contribute to the creation of a single market for digital health services and products. Discussions in this respect will likely continue in the ensuing months.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis, telesurgery, among others)?

Telemedicine services currently utilised in the Czech Republic primarily include remote consultations, the remote monitoring of patients, and the assessment of certain health-related parameters that can be self-measured and reported by patients and then remotely assessed by doctors.

No explicit list of teleservices is enshrined under Czech law. The Healthcare Services Act only stipulates that consultation services outside of medical facilities can be performed remotely.

In addition, a non-governmental body, the Society of General Practice (*Společnost všeobecného lékařství*) has published a document, titled 'Recommended Diagnostic and Therapeutic Procedures for General Practitioners in the Field of Telemedicine'. This recommendation recognises three types of telemedicine services:

1. telemedicine consultations between physicians and patients;
2. telemonitoring, whereby a doctor (or other healthcare professional) communicates via a device; and
3. tele-consilium on a physician-to-physician basis.

This document, however, was only adopted to help physicians to better adapt to new telemedicine trends, offering interim guidance on telemedicine practices.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Both channels are currently used in the Czech Republic.

8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.

The Czech Republic has a universal healthcare system, based on compulsory individual health insurance coverage, with fee-for-service care.

During the Covid-19 pandemic, health insurance companies adopted special measures and reimbursed remote consultations under existing health insurance policies. However, this was a temporary solution reflecting introduced social distancing and self-isolation measures in response to the outbreak of the Covid-19 pandemic. Remote consultations were thus predominantly used to substitute on-site patient visits, which were prohibited or not recommended during this time. Currently, on-site visits are unrestricted; thus, remote consultations no longer serve as a substitute for any healthcare services typically reimbursed via health insurance policies. Despite the fact that remote consultations are no longer deemed necessary, some health insurance companies continue to reimburse remote consultations under specific conditions, namely when an on-site visit is impossible, for example because of patients

being under dispensary care. Nevertheless, the given healthcare professional is obliged to inform the respective patient of any services that are not fully or partially reimbursed through their health insurance policy prior to its provision.

In this sense insurance company approaches are inconsistent, with debates continuing over the creation of a common standard. Standard reimbursements for telemedicine procedures could, according to some media reports, appear in a government reimbursement decree for 2023.

9. Please indicate whether there are any insurance requirements applicable to telemedicine services providers.

Currently Czech law does not impose any specific insurance requirements applicable to telemedicine services providers.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists, alternative health therapies providers, etc).

Authorised telemedicine services in the Czech Republic are deemed to be healthcare services. Therefore, their provision is limited to healthcare providers and qualified staff. Whether such services can be performed by physicians and/or nurses depends on the nature of the respective telemedicine services.

The provision of specialised healthcare services, such as clinical psychology or nutrition therapy by way of telemedicine tools, is currently not reimbursed and therefore not commonly provided remotely. On the other hand, many of these services may also be performed outside of the scope of Healthcare Services Act and it is common that in such cases individual consultants provide services remotely.

11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

No specific education or training requirements in connection with telemedicine are presently in effect in the Czech Republic.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

No registration requirement is presently in effect in connection with telemedicine services.

13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

No special licences or authorisations are currently required to perform telemedicine services.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
Czech law does not currently stipulate any specific requirements for telemedicine platforms. However, the Society for General Practice does not recommend using publicly available platforms such as Skype or Google, due to the potential security/privacy risks.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
No such requirements are currently imposed in the Czech Republic.
16. Does the legislation provide for specific rules concerning patients' medical records?
Yes. Managing and storing patient medical records must follow those requirements stipulated under the Healthcare Services Act and the Decree on Medical Documentation. The obligations stipulated thereunder include access permits and restrictions, confidentiality obligations and prescribed storage periods.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
No geographic location requirements are presently in effect in connection with telemedicine services.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
<p>In general – unless specific conditions apply – healthcare services can only be performed if a patient provides their free and informed consent.</p> <p>Czech law does not explicitly require the provision and usage of telemedicine services. According to the Explanatory Note to the E-health Act, the use of electronic healthcare services should, to the maximum extent, be voluntary. Therefore, a healthcare professional must obtain patient consent prior to the use of telemedicine for the provision of healthcare services.</p>
19. Is there any other important requirement that should be highlighted?
<p>The cybersecurity aspects of the provision of telemedicine services should be considered.</p> <p>Healthcare providers are already included in the scope of application of the NIS Directive, being categorised as Operators of Essential Services (OESs). As such, they are subject to the</p>

Directive's requirements mandating the adoption of risk management and incident notification processes to ensure network and information system security.

Under the new rules set forth by the NIS 2.0 Directive ('NIS 2.0'), which are likely to be adopted by the end of 2023 and subsequently transposed into the national laws of EU Member States, healthcare providers continue to fall under the scope of EU cybersecurity legislation. They will now be considered 'essential entities' and will, as at present, be subject to cybersecurity and risk management reporting obligations. Under NIS 2.0, healthcare providers will have to take appropriate and proportionate technical and organisational measures to manage potential risks to the security of network and information systems; they will also be obliged to report significant security breaches to the competent authorities and, where appropriate, also to service recipients.

Finally, it cannot be excluded that software solutions based on AI that are utilised for the provision of telemedicine services could also soon be classified as high-risk AI systems, and thus subject to an additional set of compliance rules stemming from the AI Act proposal currently being drafted at the EU level.

DATA PRIVACY ASPECTS

20. Are there data privacy issues that should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

Yes. Data protection is a critical factor in the provision of telemedicine services. Under Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) – which is directly applicable across all EU Member States – health data are deemed to be special categories of data and their processing is permitted only under those specific conditions laid down by the GDPR.

Since Czech law does not mandate the provision and use of telemedicine services – meaning such services are of a voluntary nature – it can be assumed that patient consent would be required to process patient data for the purposes of rendering such services. Patients are also entitled to withdraw their consent to the use of such services at any time.

Generally, the GDPR creates a somewhat strict regulatory framework concerning the protection of personal data, imposing numerous obligations on data controllers and processors. Data subjects (in this case patients) are granted a list of rights they may exercise with a view to protecting their personal data. This includes patient rights to access personal data concerning their health – for example, information contained in their respective medical records, such as diagnoses, examination results, assessments by physicians, or on specific medical procedures. Access rights potentially also apply to records of remote consultations, provided that these are maintained by the respective healthcare professionals.

In addition, the Healthcare Services Act governs the management and maintenance of medical records. Accordingly, medical records may only be kept in an electronic form under special conditions where data security is ensured.

21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

The GDPR essentially provides criteria for security measures that need to be implemented by data controllers in order to enhance the protection of personal data processed for any reason. Such systems may involve pseudonymisation, encryption, access controls and the amount of personal data being limited to what is strictly necessary for a given purpose. No specific safeguards are listed in connection with patient information.

The Healthcare Services Act stipulates requirements for medical records kept in electronic form, such as record identifiers, regular backup copying of data records and record modification safeguards. Access to medical records is obtained based on patient consent – or where a patient is incapable of expressing such consent the access is limited to the patient's closest relatives. Medical record retention periods are governed by the Decree on Medical Documentation.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes. The GDPR authorises transfers of personal data to non-EU countries only under certain conditions, where the purpose of ensuring adequate data protection standards is not compromised.

Transfers of personal data to third countries in relation to telemedicine services may be relevant for using third-party remote consultation platforms, such as Skype or other videoconferencing programmes.

23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?

In general, no registration requirement applies for maintaining databases. However, collecting personal data in a database is deemed to represent the processing of personal data, which is subject to the GDPR.

The GDPR also applies to registers under the E-health Act that become operational from the start of 2023.

Requirements for recording patient medical record data are listed in the Healthcare Services Act and in the Decree on Medical Documentation.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Czech law does not presently offer any specific provisions on the liability of healthcare professionals and healthcare institutions when performing telemedicine services. Rather, in this regard, the liability of healthcare providers is governed via the general rules set forth under the Civil Code and the Criminal Code. In addition, other special legal acts set sanctions for administrative offences committed by healthcare professionals and institutions while performing healthcare services.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

A recent survey carried out by the Faculty of Medicine at Charles University suggested that the majority of patient respondents are open to the use of information and communication technologies in the healthcare sector and would welcome having remote access to medical records both for themselves and for their doctors. However, a fifth of respondents expressed concerns over a lack of the necessary technical skills and a reluctance to the future use of information and communication technologies in the healthcare sector. The survey also suggested that doctors tend not to dedicate specific work times to remote consultations – something perceived negatively by most patient respondents.

According to Eurostat data, around 60 per cent of Czechs would welcome online access to their medical records.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

The E-health Act will gradually come into effect over the ensuing years. This will lead to a gradual transition to e-healthcare services. Upcoming steps include an obligation for healthcare providers to submit information into electronic registers created by the Ministry of Health and to make their own information systems compatible with these registers. Subsequently, a consent administration system, ensuring that a patient can decide to whom to grant access to their data in patient electronic registers will become operational. When fully implemented, the E-health Act seeks to transform the current healthcare system into a fully digital/electronic-friendly form.

Future regulation will likely also address the provision of telemedicine services and set uniform standards. These changes will likely enter into force in 2024.

On an EU level, the European Commission is presently working on creating a so-called European Health Data Space. This will lead to pan-EU healthcare integration, fostering a single market for digital health services and products. It is also expected to offer patients the possibility of easily sharing their health data with healthcare professionals across the EU, and thus simplifying the provision of healthcare services across EU Member States. The European Health Data Space should further establish a legal framework for the use of health data for research, innovation, public health, policy-making and for regulatory purposes, subject to the fulfilment of certain conditions. All this will be carried out in accordance with applicable EU data protection standards.