

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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Date of completion: 30 November 2022

LAWS AND REGULATIONS ON TELEMEDICINE

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

Telemedicine is allowed in Estonia. There is no general legal definition of telemedicine in national legal acts. However, in the context of emergency medical care, the 18 December 2018 Regulation No 65 of the Minister of Health and Labour, 'The requirements for the staff and equipment of ambulance crews and the work instructions of ambulance crews', defines telemedicine as provision of emergency medical care by means of information and communication technology (ICT) in a situation, where a physician is located at the ambulance base or other permanent establishment and the patient on the site of the incident.

The European Commission defines the telemedicine as provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.

As per 'Communication from the Commission to the European Parliament, the Council, the European Economic, and Social Committee, and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems, and society', certain telemedicine services shall be acceptable.

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

Telemedicine is not specifically/universally regulated in Estonia and is subject to compliance with the broader regulatory framework concerning provision of healthcare services in general, such as Health Services Organisation Act and regulations thereof, Health Insurance Act and regulations thereof, the General Data Protection Regulation (GDPR) and Personal Data Protection Act, among others. Only certain aspects are specifically regulated, for example, reimbursement of telemedicine services and documentation of telemedicine services.

Telemedicine services may only be provided by a service provider that holds an activity licence for provision of medical care (there are different types of licences) and complies to all requirements for personnel, premises and equipment applicable to the specific type of the licence. It is not possible to provide only telemedicine services, or to acquire a licence for provision of telemedicine services only.

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

The key licensing bodies for telemedicine are the same bodies responsible for the general licensing of health services providers as detailed below.

In Estonia, all health service providers must obtain and maintain a licence granted by the Health Board. Only domestic companies (ie, companies established and organised in accordance with Estonian laws) may hold activity licences for the provision of health-related services.

Estonian Health Insurance Fund (EHIF) is the supervisory authority for reimbursement of telemedicine services and other healthcare services from the public insurance fund.

Generally, physicians and other health care professionals (dentists, nurses, midwives, etc) may only render health services in Estonia if they are duly registered with the Health Board.

At the national level, the Estonian Ministry of Social Affairs is the highest authority in all matters related to public health and provision of health services.

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

No major regulatory changes concerning telemedicine were adopted during the Covid-19 pandemic. The regulation was the same as it was before and is now.

Reimbursement by EHIF for remote visits started in spring 2020 (during the pandemic). Remote therapies (physiotherapy, psychotherapy, speech therapy and occupational therapy) were included into the EHIF's list of health services in the beginning of 2021.

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?

No major changes have been made to the telemedicine regulation in the post-pandemic scenario.

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

There is no explicit list of telemedicine services allowed or prohibited. Telemedicine solutions may be used as a part of healthcare service in so far as the quality of the service is ensured and the method used is evidence-based.

EHIF reimburses the following telemedicine services (EHIF's health care services list): remote occupational therapy, remote visit (video visit), remote physiotherapy, teleconsultation, remote psychotherapy, remote speech therapy, e-consultation (electronic consultation between family physician and a specialised physician).

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

Doctor-doctor and patient-doctor remote medical services are allowed, provided that the personal data protection and health care quality requirements are met.

If offered by the healthcare provider, anyone who has expressly consented to telemedicine consultation can enjoy telemedicine services, as long as the responsible physician does not refuse to use telemedicine and indicates the need of in person medical consultation.

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.

In Estonia, telemedicine is available within the public and private health system. Regulation No 64 of the Government of the Republic, dated 30 June 2022, 'The list of health services of the health insurance fund', and Regulation No 9 of the Minister of Social Affairs, dated 19 January 2007, 'The procedure for the assumption of a payment obligation of an insured person by the health insurance fund and the methods for calculation of the payments to be made to health care providers', mainly state the reimbursable services, preconditions and reimbursement limits of telemedicine services.

The telemedicine service is reimbursed if the applicable requirements are met: telemedicine service is suitable for handling the specific situation (the healthcare provider and healthcare professional are responsible and liable for evaluating the suitability of a telemedicine service), consent of the patient for use of telemedicine services is obtained and documented, information and communication solutions and systems used for provision of telemedicine service comply with applicable law (including personal data protections laws), identification of the patient complies with applicable requirements.

Telemedicine services included into the EHIF's healthcare services list are under mandatory insurance coverage because these are considered as valid methods for consultation and therapy. For telemedicine services not included into the EHIF's list, the patient must pay in full.

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

There are currently no specific insurance requirements applicable to telemedicine services providers. Starting from 1 July 2024, all healthcare service providers must insure their liability (general compulsory liability insurance).

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).

In principle, all HCPs registered with the Health Board may provide remote services within their competence. However, the healthcare provider and the healthcare professional are liable for suitability and quality of remote services. All solutions used must comply to all applicable requirements: data protection, medical devices, health care quality and other requirements.

In addition, not all telemedicine services are reimbursed by the EHIF. EHIF reimburses the following telemedicine services (EHIF's health care services list): remote occupational therapy, remote visit (video visit), remote speech therapy, remote physiotherapy, teleconsultation, remote psychotherapy, e-consultation (electronic consultation between family physician and a specialised physician).

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

No, there are no specific education or training requirements for physicians to provide telemedicine services. The healthcare provider and healthcare professional must ensure the quality and suitability of the telemedicine service to the patients' needs and health condition.

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

No, there are no specific registration requirements applicable to physicians that provide telemedicine services. All physicians must be registered with the Health Board to be allowed to provide health care services in Estonia.

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

Institutional healthcare providers providing remote consultations must have a licence granting the right to provide the appropriate outpatient personal healthcare service at the operating address(es), with regards to which the patient is consulted or the institution provides and receives consultations. In the context of the European Union (EU) cross-border medical care regulation, in the case of telemedicine, it shall be deemed that health services are provided in the Member State in which the healthcare provider has been established.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

No, there are no specific requirements applicable to the telemedicine platforms. All general requirements for health information systems, health services and personal data protection apply. Depending on the circumstances, the telemedicine platform or solution may qualify as a medical device, in which case the respective set of regulatory requirements applies in addition.

All patient personal data and medical documents related to the provision of remote healthcare services must be forwarded to the state-run e-health platform, Health Information System. The system is intended to combine various data registers, store electronic health records, utilise functions of e-prescriptions and e-references, as well as establishing a database of medical images.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There are no specific legal requirements regarding electronic equipment and internet speed for telemedicine services. However, the solution used must ensure the quality of the healthcare service, comply to data processing requirements and enable identification of a patient.
16. Does the legislation provide for specific rules concerning patients' medical records?
Telemedicine services must be documented and recorded in the patient's medical records and forwarded to the Health Information System in compliance with rules applicable to medical records in general. Consent for use of telemedicine service must be documented and recorded (mainly for reimbursement purposes).
17. Are there geographic location requirements applicable to the provision of telemedicine services?
There are no geographic location requirements applicable to the provision of telemedicine services. In the context of EU cross-border health services regulation, in the case of telemedicine it shall be deemed that health services are provided in the Member State in which the healthcare provider has been established.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
Telemedicine services require the patient's or the patient's legal representative free informed consent with respect to telemedicine service and must be documented in the patient's medical records.
19. Is there any other important requirement that should be highlighted?
N/A
DATA PRIVACY ASPECTS
20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.
Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. Processing of personal data (including health data) in the EU is mainly regulated by European Law (including GDPR). There are also national laws, such as Personal Data Protection Act, Health Services Organisation Act, and regulations thereof, that regulate specific aspects of processing of patients' data (eg., storage terms, who and on which grounds can access and process data, logging requirements, etc).

Generally, the legal requirements for remote services are the same as for services provided physically. The institution must process the personal data on the same legal basis (one or more) as usual according to the GDPR. Additionally, the institutions must:

1. assess the scope of data processed, including additional data processed in remote consultation (eg, unique codes assigned to the patient or doctor; login names; video data);
2. assess appropriate technical and organisational measures to correctly identify the person requesting the remote consultation and secure personal data; and
3. ensure that the data subjects (healthcare professionals, patients, their representatives) are properly informed about data processing.

Additionally, the healthcare institution must assess whether the provision of healthcare services remotely requires carrying out a data protection impact assessment and, if so, a detailed and comprehensive assessment of potential risks and measures to reduce (control) such risk must be carried out.

The healthcare institution should also document the procedure for the provision of remote health care services.

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

The legislation establishes that the healthcare institution has the right to choose the means of remote communication for provision of healthcare services remotely and must use secure means in terms of data transmission. However, the specific criteria and requirements for the security systems are not regulated by the national legislation.

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

General legal requirements for transfer of personal data under the GDPR apply for transfer of information abroad.

Any such transfer must take place only if the level of protection of natural persons under the GDPR is not undermined. When the transfer takes place within the European Economic Area (EEA), the healthcare institution (as a data controller) must ensure that the transferred data is processed under the appropriate legal basis under the GDPR, the rights of patients and other data subjects are ensured, and that the technical and organisational measures implemented by the data receiver are no less strict than the measures applied by the healthcare institution itself.

When the transfer is taking place to an importer established outside the EEA, such transfer may only take place if there is an adequate level of protection of individuals' (data subjects) fundamental right to data protection in the non-EEA country to which data is transferred to (an adequacy decision granted by the EU Commission).

In the absence of an adequacy decision, personal data may still be transferred under specific conditions:

1. the health care institution takes the necessary measures to provide appropriate safeguards, such as including specific clauses in the agreed contract with the non-

<p>European importer of the personal data (ie, by concluding Standard Contractual Clauses approved by the EU Commission); and</p> <p>2. when the healthcare institution relies on specific grounds for the transfer (derogations) such as the consent of the individual (patient or other data subject).</p> <p>To specific services or aspects of data transfers, specific EU or national regulations apply. For example, in case of cross-border health services within EU, state-operated cross-border health record exchange platform is used.</p>
<p>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?</p>
<p>Yes, all patients' personal data and medical records related to the provision of remote personal healthcare services must be forwarded to the Health Information System. Hence, the companies providing remote healthcare services must register and receive an access to the national e-health platform.</p> <p>Regarding the requirements for recording of data in the patient's medical records, there are specific requirements as which data must be recorded in the medical records.</p>
<p>LIABILITIES</p>
<p>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</p>
<p>Providers of healthcare services and, some healthcare professionals personally (qualified physicians, dentists, independent nurses and midwives), are liable for the wrongful violation of their own obligations, particularly for errors in diagnosis and treatment, and for violation of the obligation to inform patients and obtain their consent.</p> <p>Providers of healthcare services are also liable for the activities of persons assisting them and for any defects in the equipment used upon provision of health care services.</p> <p>Healthcare services shall at the very least conform to the general level of medical science at the time the services are provided, and the services shall be provided with the care which can normally be expected of providers of healthcare services. Generally, only evidence-based treatment methods, duly registered medicinal products and equipment may be used. Use of generally unrecognised methods on provision of healthcare services is allowed under specific circumstances.</p> <p>Therefore, healthcare service providers and healthcare professionals must ensure the quality of healthcare provided in person or remotely and are liable for violation of their obligations. Depending on the circumstances, civil and/or criminal procedures may be initiated upon violation of obligations and/or applicable requirements.</p>
<p>TELEMEDICINE NUMBERS AND TRENDS</p>
<p>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</p>

There are some surveys and statistics available on the website of the EHIF. Between 16 March 2020 and 17 July 2020, there were 279,991 remote visits in the specialised medical care field. In psychiatry, for example, 60 per cent of visits were conducted remotely. In other specialty fields the rates of remote visits were lower (between 10 to 50 per cent), the lowest rate of remote services was in general surgery.

According to local surveys, mostly the patient benefits from the telemedicine solutions (time saved in comparison to in-person visit). The amount of work required by the physician remains the same – or in some cases even increased in case of telemedicine services (due to lack of technology knowledge and skills, poor quality of data, documentation cannot be performed simultaneously, etc).

An important shift towards digitalisation of services, as well as the need for rapid, accurate and wide-ranging data collection, prompted much wider use of e-health by residents, providers and public administrations. Remote consultations became more acceptable.

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.

It is considered important to actively develop telemedicine and remote services and to shift towards digitalisation of healthcare services. The most important trends expected for the market for the next few years are:

1. development of Estonian Health Information System and other platforms (development of the e-health infrastructure, solutions and integration into EU e-health space) to achieve high quality and effective health care; and
2. increasing data maturity and interoperability of the e-health system and cross-border services.

The biggest challenge is the development of operational models, funding and reimbursement models for the telemedicine services.