

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?
Yes, telemedicine is allowed in Latvia. According to Article 1(29) of the Medical Treatment Law, telemedicine is the provision of remote healthcare service using information and communication technologies. It includes the safe resending of medical data and information necessary for medical treatment in the form of text, sound, pictures or other.
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The term 'telemedicine' was introduced in Latvian legislation to ensure the application of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient's rights in cross-border healthcare. The definition of 'telemedicine' included in Article 1(29) of the Medical Treatment Law derives from the 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. In this document, the European Commission explains what services should be considered as telemedicine, for example, teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology; call centres/online information centres for patients; and remote consultation/e-visits or videoconferences between health professionals. In its document, the European Commission also states that, for the purposes of the document, the maintenance of health information portals, electronic health record systems and the electronic transmission of prescriptions or referrals (e-prescription and e-referrals) are not regarded as telemedicine services. The understanding included in the document indicated above, applies to the definition included in Article 1(29) of the Medical Treatment Law: any electronic services for the management of health records are not considered telemedicine services. However, please note that in the case in which a healthcare professional (HCP) issues an e-prescription or e-referral during the provision of telemedicine services, such an issuance would be included in the provision of telemedicine services (eg, a general practitioner issues an e-prescription during a teleconsultation via phone).</p> <p>Before the Covid-19 pandemic, telemedicine was not a highly popular or generally used medical practice in Latvia. Usually, it was limited to receiving distance consultations from general practitioners on various issues that did not require immediate medical help or immediate face-to-face consultation. However, due to the Covid-19 pandemic, the need for non-contact healthcare provision arose. Therefore, Cabinet Order No 103 'On declaring a state of emergency' dated 12 March 2020 (and subsequent Cabinet Orders No 655 and No 720, as well as other related regulatory enactments) established that outpatient healthcare shall be primarily provided remotely (ie, telemedicine), and in cases in which it was not possible to provide healthcare remotely, medical intuitions could arrange face-to-face consultations, ensuring that each patient had a specific appointment time (including setting an exact time of arrival), with a sufficient period of time between patients' appointments to ensure that they do not meet and other precautions.</p> <p>As of now, although Covid-19 cases have significantly decreased and most of the restrictions have been lifted in Latvia, section 237 of Cabinet Regulation No 662, 'Epidemiological Safety Measures for the Containment of the Spread of Covid-19 Infection' still establishes that outpatient healthcare shall be primarily provided remotely. Nonetheless, any significant increase in telemedicine as it was seen during the peak of the Covid-19 pandemic has not been indicated</p>

because not only medical institutions but also individual HCPs struggle to determine when it is appropriate to provide telemedicine services, the indicators that determine when it would be crucial to have a face-to-face consultation and the most favourable solutions for each individual patient.
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
According to Article 7 of the Medical Treatment Law, the supervision of medical treatment (including telemedicine) is carried out by the Ministry of Health and other institutions specified in related regulatory acts. According to section 3.1 of the Cabinet Regulation No 309 'Regulations of the Health Inspection', the Health Inspection monitors the implementation of regulatory acts binding on medical institutions in the field of healthcare and work capacity expertise, as well as the professional quality of healthcare services and work capacity expertise. The Health Inspectorate also registers and maintains a register of medical institutions, medical personnel and medical support persons.
4. Was telemedicine authorised during the Covid-19 pandemic?
Yes, please refer to item 2.
5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?
As already indicated under item 2, despite the introduction of the principle that outpatient healthcare shall be primarily provided remotely during the Covid-19 pandemic, any significant increase in telemedicine services as was seen during the peak of the Covid-19 pandemic has not been indicated. Considering that section 237 of Cabinet Regulation No 662, 'Epidemiological Safety Measures for the Containment of the Spread of Covid-19 Infection', established the aforementioned principle, it is most likely to cease to exist in the post-pandemic era. As of now, it is hard to predict whether the principle will be included in another regulatory act permanently because issues related to the provision of telemedicine services remain, and the practice is rather new and not widely used.
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?
As provided under item 2, telemedicine services indicated in the 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 are acceptable. However, in Latvia, services such as teleconsultation, call centres/online information centres for patients and remote consultation/e-visits are the most commonly used telemedicine services.
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
According to Article 3 of the Medical Treatment Law, healthcare is defined as the complex measures implemented by healthcare service providers, including telemedicine and activities with medicinal products and medical devices for ensuring, maintaining and renewing a patient's health. Therefore, in Latvia, telemedicine services are usually understood as patient-doctor services.
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
In general, telemedicine services in Latvia are not funded by the state budget (the National Health Service administers the state budget funds for healthcare); however, during the Covid-19 pandemic, certain exceptions were introduced, for example, according to section 265 of the

Cabinet Regulation No 555, 'Procedures for the Organisation of and Payment for Healthcare Services', consultations provided remotely by general practitioners in accordance with the list of manipulations were funded by the National Health Service until 31 December 2022.

No other exceptions are applicable as of now. There are no guidelines issued by state authorities, despite the fact that most of the authorities involved in the healthcare sector have indicated that telemedicine services shall be developed and further regulated.

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

N/A

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 and alternative health therapy providers).

For medical institutions (including individual doctor's practices) to be able to provide telemedicine services, a medical institution shall fulfil the following conditions:

- The medical institution shall be registered in the Register of Medical Institutions in accordance with the procedure set out in Cabinet Regulation No 170 'On the Register of Medical Institutions'.
- HCPs and medical support staff employed in the medical institution shall be registered in the Register of Medical Practitioners and Medical Support Staff in accordance with the procedure set out in Cabinet Regulation No 317 'Procedure on the Establishment, Update, and Maintenance of the Register of Medical Practitioners and Medical Support Staff'.
- The medical institution shall be able to ensure secure processing of medical data and information necessary for the provision of telemedicine services.
- According to section 17(1) of Cabinet Regulation No 60 'Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units', the medical institution shall ensure quality management of medical services (ie, telemedicine services) by ensuring that quality control is done regularly, patients' claims and recommendations are considered, treatment results are analysed and the quality of services is improved.
- According to sections 18 and 19 of Cabinet Regulation No 60 'Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units', the medical institution shall provide 'information technologies connected to the internet and software that provides patient data storage and processing, observing the limitations of availability of information' and develop 'information protection provisions and provisions regarding procedures for medical information processing'.
- The medical institution should ensure that patients' rights under the Law on the Rights of Patients are complied with.

According to Articles 1(2) and 26 of the Medical Treatment Law, HCPs (or medical practitioners) provide healthcare services; therefore, they are authorised to provide remote health services (telemedicine). Medical support practitioners (non-HCPs), according to Articles 1(25) and 12.1 of the Medical Treatment Law, do not have the right to engage in medical treatment, but are directly involved in the healthcare process, which means that they could be involved in the telemedicine service, but are not authorised to provide such a service independently.

According to Cabinet Regulation No 317, 'Procedure on the Establishment, Update, and Maintenance of the Register of Medical Practitioners and Medical Support Staff', nurses and nutritionists are considered HCPs; therefore, they would be able to provide a limited scope of telemedicine services (eg, nurses would be able to provide certain, specific recommendations

related only to patient care).
Medical support practitioners and other non-HCPs are not authorised to provide telemedicine services.
11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?
No, general requirements apply.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
No, general requirements apply.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
No, general requirements apply.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
No, applicable regulatory enactments do not provide for any specific requirements related specifically to telemedicine. In addition, there are no official guidelines or recommendations issued by the regulatory authorities regarding telemedicine services.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
According to section 18 of Cabinet Regulation No 60 'Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units', the medical institution shall provide information technology with an appropriate internet connection and software, which ensures the storage and processing of patient data, observing the limitations of information availability. There are no other statutory requirements or guidelines indicating specific parameters.
16. Does legislation provide for specific rules concerning patients' medical records?
No, applicable regulatory enactments do not provide for any specific requirements related specifically to telemedicine.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
No, applicable regulatory enactments do not provide for such restrictions and/or limitations.
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
According to Article 6 of the Law on the Rights of the Patients, medical treatment shall be permitted if a patient has given informed consent. The patient has the right to ask questions and receive answers prior to giving informed consent. The patient also has the right to refuse any method used in medical treatment without refusing medical treatment at large. This means that, under Latvian law, a patient's consent would be necessary, unless certain other legal norms prevail (eg, a state of emergency is announced that establishes other prevailing rules, such as during the Covid-19 pandemic).

19. Is there any other important requirement that should be highlighted?
N/A
DATA PRIVACY ASPECTS
20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.
<p>Considering that a unified platform meant for the provision of telemedicine services has not yet been established, as well as corresponding regulation, data privacy issues and risks are rather high because telemedicine services are sometimes carried out through tools that do not ensure proper data protection.</p> <p>However, generally, the legal requirements for remote services are the same as those for services provided physically. The institution must process personal data on the same legal basis (one or more) as usual according to the General Data Protection Regulation (GDPR). Additionally, the institutions must:</p> <ul style="list-style-type: none"> • assess the scope of data processed, including additional data processed in remote consultation, for example, unique codes assigned to the patient or doctor, login names and video data; • assess appropriate technical and organisational measures to correctly identify the person requesting the remote consultation and secure personal data; and • ensure that the data subjects (HCPs, patients and their representatives) are properly informed about data processing. <p>In the case of telemedicine services, the data and results (description) of the sent tests are transferred to the archive of the medical institution receiving the telemedicine service, which must ensure data storage. If the forms are filled in electronically, the institution must ensure compliance with the requirements for the processing of accounting documents and personal data, including special categories of personal data, set by legal acts.</p> <p>In the case of emergency telemedicine services, an agreement must be concluded between the consulting medical institution and the institution receiving the consultation. The agreement must specify the terms for the consultation, including rules for the proper processing of the personal data of doctors and patients (including special categories of personal data).</p> <p>Additionally, the healthcare institution must assess whether the remote provision of healthcare services 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.</p> <p>The medical institution should also document the procedure for the provision of remote healthcare services.</p>
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
<p>According to section 18 of Cabinet Regulation No 60 'Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units', the medical institution shall provide information technology with an appropriate internet connection and software, which ensures the storage and processing of patient data, observing the limitations of information availability. There are no other statutory requirements or guidelines indicating specific criteria and requirements for security systems.</p>
22. Does the applicable regulation provide for requirements for the transfer of information abroad?

According to Article 10 of the Law on the Rights of Patients, information that relates to an identified or identifiable patient shall be protected in accordance with the laws and regulations governing the protection of the data of natural persons, that is, the GDPR.

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 medical 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. Regarding the transfer of imported data established outside the EEA, such a transfer may only take place if there is an adequate level of protection of individuals' (data subjects) fundamental rights to data protection in the non-EEA country to which data is transferred (an adequacy decision granted by the European Commission).

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

- the medical institution takes the necessary measures to provide appropriate safeguards, such as including specific clauses in the agreed contract with the non-European importer of personal data (ie, by concluding Standard Contractual Clauses approved by the European Commission); and
- when the healthcare institution relies on specific grounds for the transfer (derogations), such as the consent of the individual (patient or other data subject).

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?

According to Article 78 of the Medical Treatment Law, in order to ensure the organisation of healthcare and to facilitate the provision of healthcare services, health sector data shall be accumulated in the health information system (state-operated e-health system). Data shall also be provided by medical institutions. Both generally available data and restricted-access data shall be included in the health information system. Restricted-access data on a patient shall be divided into master data (eg, personal information; disease history; disabilities; allergies; and a patient's expressed will regarding the use of the body, and tissues and organs after death) and supplementary data (overviews of outpatient examination/medical treatment of a patient, referrals for the receipt of an outpatient/inpatient service, sick leave certificates and e-prescriptions).

LIABILITIES

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

The applicable regulatory enactments do not provide for specific liability for HCPs or medical institutions involved in telemedicine practices; therefore, general rules apply.

HCPs

Disciplinary liability

If the HCP is an employee and works in accordance with the employment agreement, disciplinary liability according to Article 90 of the Labour law could apply. This means that the employer may give a written reproof or issue a reprimand in writing to an employee for the violation of specified working procedures or an employment contract, referring to the circumstances that indicate the violation committed. Prior to expressing a reproof or a reprimand, the employer shall familiarise the employee (the HCP) in writing with the essence of the violation he/she has committed and then request from him/her an explanation in writing

regarding the violation committed. A reproof or reprimand may be issued not later than one month from the day of detecting the violation, excluding the period of temporary incapacity of the employee, as well as the period when the employee is on leave or does not perform work due to other justifiable reasons, but not later than 12 months from the day the violation was committed. Only one reproof or reprimand may be issued for each violation. Within one month from the day of the issue of the reproof or reprimand, the employee has the right to request that such a reproof or reprimand be revoked. If, upon examining a complaint regarding the revocation of a reproof or reprimand, the employer makes the decision not to revoke the reproof or reprimand, the employee has the right to bring an action in court within one month from the day when the relevant decision of the employer was received. If the employer does not examine the complaint within the specified time period and has not provided the employee with an answer regarding the decision made, it shall be deemed that the employer has revoked the reproof or reprimand.

Administrative liability

According to Article 84 of the Medical Treatment Law, for violations of procedures for providing medical opinions or healthcare services, a natural person (either an HCP or non-HCP) can be deprived of the right to practise medicine for a period of six months to two years, subject to a warning or a fine of up to €750. According to very limited case law (eg, Judgments of the Administrative Court of Appeal in the Cases No A42356005, A42511807), the provision of medical opinions shall be very diligent throughout, without any errors and activities that were not carried out. For example, in the case of telemedicine services, the opinion cannot indicate that the patient was inspected or a medical opinion was given for issues that cannot be assessed during the provision of telemedicine services. Violations of procedures for providing healthcare services are understood as any actions or inactions if the case in question required a different approach (violation of a statutory rule, violation of principles etc).

Practising medicine without medical education

According to Article 82 of the Medical Treatment Law, a fine from €50 to €350 is imposed for practising medicine without medical education. Practising medicine or providing healthcare services without medical education could be understood in the following manner: (1) an HCP who is a specialist in a certain field advises a patient in a field in which he/she has not received training (eg, a pulmonologist provides medical assistance related to patient's heart problems when such treatment should be carried out by a cardiologist); (2) a nurse or doctor's assistant carries out functions (outside his/her qualifications) that are within the competence of a doctor; (3) a non-HCP provides healthcare services.

Criminal liability

According to Article 138 of the Criminal Law, for a person who, being a medical practitioner (HCP), fails to fulfil professional duties or fulfils them negligently, if such an offence has, due to the negligence of the offender, caused serious or moderate bodily injury to the victim, the applicable punishment is the deprivation of liberty for a period of up to one year or temporary deprivation of liberty, probationary supervision, community service or a fine. It is unlikely that criminal liability could arise from the provision of telemedicine services because there has to be very serious negligence that has caused serious or moderate bodily injury.

Medical institutions

Administrative liability

According to Article 78 of the Medical Treatment law, in the case in which the medical institution violates any applicable regulatory enactments in the field of healthcare, the Health Inspectorate

can make a decision to suspend the service or operation of the medical institution.

TELEMEDICINE NUMBERS AND TRENDS

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

No, there is no publicly disclosed information concerning the use and acceptance of telemedicine in Latvia. Currently telemedicine in Latvia is a rather new practice that has not been used widely.

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.

As already indicated under item 8, despite the fact that various state authorities have indicated that telemedicine services have to be further developed in Latvia, there are several issues that need to be addressed first in order for telemedicine services to be more widely used:

- legislative changes need to be initiated in order to regulate telemedicine services more thoroughly, setting certain requirements and applicable procedures, as currently, telemedicine services are not specifically regulated;
- technological issues need to be considered in order to provide secure telemedicine services; and
- the involvement of state institutions needs to be revised in order to ensure that telemedicine services are properly supervised; and
- whether certain telemedicine services under certain conditions could be funded by the state needs to be determined.

These issues are mainly indicated by non-governmental organisations (NGOs) and HCPs, while the state authorities are rather reluctant to propose more specific solutions, choosing to remain very general in their proposals regarding telemedicine.

Considering the healthcare sector in Latvia and its financing, it can be assumed that the legal framework of telemedicine will not significantly change in the next few years. For there to be a significant change in the legal framework of telemedicine that would promote a more frequent use of telemedicine services in Latvia, more public discussions and requests need to occur to make this issue more urgent and more important. However, considering the proposed plans indicated by Latvian authorities, the most important trends expected for the market for the next few years are:

- the development of a new platform for the provision of telemedicine services or the improvement of the state-operated e-health system (development of the e-health infrastructure, solutions and integration into the EU e-health space) to achieve high-quality and effective healthcare; and
- increasing data maturity and interoperability of the e-health system with a view to contribute to the creation of the European Health Data Space (European Commission, 2021b) and cross-border services.