

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 Lithuania. Telemedicine is defined as the provision of healthcare services remotely using information and communication technologies. Legal acts also provide definitions of specific telemedicine services, as indicated under item 4.
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>There is no one general legal act that would provide a legal framework regarding telemedicine in Lithuania. Telemedicine is regulated by the specific Orders of the Minister of Health of the Republic of Lithuania (the 'MoH'), including:</p> <ul style="list-style-type: none">• the Description of the procedure for the provision of telemedicine services, approved by MoH Order No V-116, dated 27 January 2014;• the Description of the procedure for the provision of emergency telemedicine services, approved by MoH Order No V-1825, dated 11 August 2022;• the Description of the procedure for providing remote consultations by a doctor and a member of the family physician's team to a patient and of a doctor's consultations to a doctor, and paying for their costs from the budget of the Compulsory Health Insurance Fund, approved by MoH Order No V-2569, dated 10 November 2020; and• the Description of the procedure for providing primary outpatient mental healthcare services, approved by MoH Order No V-861, dated 17 September 2012.
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>There are no specific licensing requirements for telemedicine in Lithuania. All healthcare specialists and institutional healthcare providers must obtain and maintain a licence granted by the State Health Care Accreditation Agency under the MoH.</p> <p>Telemedicine services may be provided only by duly licenced healthcare specialists and institutional healthcare providers, with an exception for social workers, who belong to the family physician's team.</p>
4. Was telemedicine authorised during the Covid-19 pandemic?
<p>Telemedicine in terms of doctor-to-doctor consultations was authorised in Lithuania in 2014, while remote doctor-to-patient healthcare services were implemented in 2018, with a very limited scope (ie, only for continuation of treatment).</p> <p>Before the Covid-19 pandemic, 57 per cent of all outpatient consultations were with family physicians and 98 per cent through direct consultations; thus, remote consultations played a small role.¹</p> <p>With the Covid-19 pandemic, Lithuania introduced strict public health measures, including</p>

¹ See [www.who.int/europe/publications/m/item/lithuania-multi-disciplinary-primary-health-care-during-the-covid-19-pandemic-improving-access-through-remote-consultations-\(2021\)](https://www.who.int/europe/publications/m/item/lithuania-multi-disciplinary-primary-health-care-during-the-covid-19-pandemic-improving-access-through-remote-consultations-(2021)) accessed 16 May 2023.

lockdown, physical distancing and limits to movement, making primary healthcare services less accessible through direct consultations. The MoH introduced specific measures for a transformation of the service delivery model from direct to remote consultations, generally allowing all consultations by family physicians and their team to be provided remotely.

In addition, primary healthcare services were also expanded on a doctor-to-doctor level, allowing family physicians to remotely consult with narrow specialists on complicated cases. It was a crucial component aiming to deliver a safe decision support system for family physicians delivering a wider range of services remotely.

Overall, the pandemic challenges have served as a good opportunity to scale up the remote delivery of primary healthcare services provided by multi-profile primary healthcare teams.

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?

During the pandemic, remote healthcare services were extended based on the temporary orders of the MoH, the State-Level Emergency Manager, which expired after the quarantine was over. In the post-pandemic scenario, remote consultations were developed and telemedicine became regulated on a more specific and definitive basis by the Description of the procedure for providing remote consultations of a doctor and a member of the family physician's team to a patient and of a doctor's consultations to a doctor and paying for their costs from the budget of the Compulsory Health Insurance Fund, approved by MoH Order No V-2569, dated 10 November 2020.

One year after the pandemic started, remote consultations in Lithuania became sustainable and a routine practice in primary healthcare. However, there is space for improvement to address current health trends, such as allowing a wider range of remote healthcare services (eg, doctor-to-patient consultations by secondary-level specialists) and regulating emerging healthcare practices, though there are not even draft laws yet.

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

Legislation expressly defines the following teleservices: (1) telemedicine services; (2) emergency telemedicine services; (3) remote consultations provided by a family doctor and members of the family physician's team; (4) remote doctor-to-doctor consultations; and (5) remote primary ambulatory mental healthcare services as follows:

- telemedicine service: digital transfer of test data (by the internet or digital media) from the tests performed in one healthcare institution to another healthcare institution, evaluation and description of the data of such tests, and forwarding of the results (description of the data and conclusions) to the institution that performed these tests;
- emergency telemedicine service: consultation provided by a doctor working or consulting in the emergency department of a healthcare institution providing multi-profile inpatient tertiary personal healthcare services to a doctor and/or patient in the emergency department of another healthcare institution using specialised audio-visual and electronic communication tools;
- remote consultation of a family doctor and a member of the family physician's team: a method of providing ambulatory personal healthcare services when using remote communication tools and when such services are provided to the patient by a family doctor or a member of the family physician's team who are in different locations at the same time;
- remote doctor-to-doctor consultation: a method of providing outpatient personal healthcare services when outpatient personal healthcare services are provided using remote communication tools and when a doctor working in one healthcare institution providing outpatient personal healthcare services consults another healthcare institution providing outpatient personal healthcare services (or a doctor with another professional qualification or from another department of the same institution) for assessing the health

<p>status of patients, prescribing diagnostic and/or therapeutic services, tests and procedures, and prescribing medicinal products and medical devices, regarding the issuance, renewal of electronic certificates of incapacity for work, electronic certificates of pregnancy and maternity leave and/or other healthcare issues, both of them being in different places at the same time or at different times; and</p> <ul style="list-style-type: none"> remote primary ambulatory mental healthcare service: a service provided to a patient by a psychiatrist of a mental health centre, a child or adolescent psychiatrist and/or a medical psychologist using information and electronic communication technologies that allow the identification of a person without going to an institution providing primary outpatient mental healthcare services.
<p>7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.</p>
<p>Both doctor-to-doctor and limited-scope patient-to-doctor telemedicine services are allowed, as described above.</p>
<p>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.</p>
<p>In Lithuania, telemedicine is available within the public health system on the same terms as healthcare services provided directly. It is under mandatory insurance coverage funded by the Compulsory Health Insurance Fund. The main applicable legislation is the Description of the procedure for providing remote consultations of a doctor and a member of the family physician's team to a patient and of a doctor's consultations to a doctor and paying for their costs from the budget of the Compulsory Health Insurance Fund, approved by MoH Order No V-2569, dated 10 November 2020.</p> <p>There are also private clinics outside compulsory health insurance coverage that provide telemedicine services to patients for additional fees.</p>
<p>9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.</p>
<p>There are no specific insurance requirements applicable to telemedicine service providers; however, they should comply with all general requirements applicable to healthcare service providers.</p>
<p>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</p>
<p>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).</p>
<p>All duly licenced primary healthcare team members (family physicians and team members (nurses, social workers, physical therapists, advanced nurse practitioners and lifestyle specialists)), as well as psychologists and psychiatrists may provide remote consultations to patients. Doctor-to-doctor consultations may also be provided by other healthcare specialists that provide secondary and/or tertiary outpatient personal healthcare services.</p>
<p>11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?</p>
<p>No, general education requirements applicable to healthcare professionals apply.</p>
<p>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</p>
<p>No, general licensing requirements applicable to physicians and other healthcare specialists</p>

apply.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
Institutional healthcare providers providing remote consultations must meet all general requirements for the provision of healthcare services and 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 tested, or the institution provides and receives consultations.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
There is a state-run e-health platform – the Information system for electronic health services and collaboration infrastructure (IS EHSCI) – developed in Lithuania, which covers both healthcare services provided physically and telemedicine services. The MoH is responsible for running the system. The system is intended to combine various data registers, store electronic health records and utilise the functions of e-prescriptions and e-references, as well as establishing a database of medical images. Until 2019, e-prescribing was the most advanced section of e-health, but the system was substantially developed in 2020 and later, adding records for outpatient and inpatient care, vaccinations, health certificates and Covid-19 test results, as well as allowing a greater degree of information exchange. Currently all patient personal data and medical documents related to the provision of remote personal healthcare services must be stored and managed in this e-health platform.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There is a requirement to have remote communication tools and equipment (means of visual and/or audio communication (including software and communication platforms) and/or other electronic communication technologies that enable the identification of a person and can be used for the provision of primary personal healthcare services for the provision of remote consultations. The healthcare institution has the right to choose the means of remote communication for the remote provision of primary healthcare services. Professionals are forbidden from using their personal mobile devices (phones, computers and tablets) to connect to software, tools or communication platforms, as well as their personal accounts created on these platforms.
16. Does legislation provide for specific rules concerning patients' medical records?
Yes, all patients' personal data and medical records related to the provision of remote personal healthcare services must be stored and managed in the IS EHSCI platform.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
No, there are no explicit geographic location requirements applicable to the provision of telemedicine services. In the context of European Union cross-border health service regulation, in the case of telemedicine, it shall be deemed that health services are provided in the Member State in which the healthcare provider was established.
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
Yes, prior to a remote consultation, the healthcare professional must obtain the patient's consent for a remote consultation.

19. Is there any other important requirement that should be highlighted?
It is not possible to provide only telemedicine services. It is mandatory that both healthcare specialists and institutions meet all the general licensing requirements for the provision of healthcare services.
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>Yes. During remote consultations, patient's personal data (including health data) are processed according to the requirements of legal acts of the EU and the Republic of Lithuania governing the processing of patients' personal data.</p> <p>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, institutions must:</p> <ul style="list-style-type: none"> • assess the scope of data processed, including additional data processed in a 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 (healthcare professionals, 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 healthcare 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 healthcare institution and the institution receiving the consultations. 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 healthcare 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>Legislation establishes that the healthcare institution has the right to choose the means of remote communication for the remote provision of healthcare services and must use secure means in terms of data transmission (security used to provide remote consultations is not evaluated). In addition, testing data must be transmitted through secure computer communication channels and means. However, the specific criteria and requirements for security systems are not regulated by national legislation.</p> <p>The State Data Protection Inspectorate has adopted a recommendation on safety measures to be evaluated by the healthcare facility if messaging, video transmission tools or other software</p>

are used in the provision of telemedicine services, including:

- the terms and conditions of the tools or software, privacy policy and other documents in order to evaluate their reliability, security and other significant circumstances;
- whether the selected means of providing remote healthcare services ensure the possibility of implementing the rights of data subjects established by the GDPR;
- whether other data processors will be used and, if so, whether they will ensure adequate organisational and technical measures that meet GDPR requirements;
- whether the tool used to provide remote healthcare services collects cookies and, if so, how and under what conditions (when applicable);
- what personal data will be processed when connecting to and/or using the remote healthcare service provision tool;
- whether there are conditions for sharing documents with health data available when using the means of providing remote healthcare services (ie, share, attach, send and show), are such practices allowed in the internal healthcare documents and, if so, under what conditions (eg, sending data is possible only by protecting data or their sets with passwords and archiving tools (ZIP, RAR etc)); and
- whether the owner of the telehealth delivery tool has access to the shared document.

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

General data legal requirements for the transfer of personal data under the GDPR apply for the 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 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 to (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 healthcare institution takes the necessary measures to provide appropriate safeguards, such as including specific clauses in the agreed contract with the non-European importer of the 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?

Yes, all patients' personal data and medical records related to the provision of remote personal healthcare services must be stored and managed in the IS EHSCI platform. Hence, companies providing remote healthcare services must register and receive access to the national e-health platform.

Regarding the requirements for the recording of data in the patient's medical records, there are specific requirements for what kind of data must be recorded in the medical records. Video

and/or audio recording is prohibited during remote consultations.

LIABILITIES

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

The patient is entitled to compensation for damages caused in violation of his/her rights during the provision of healthcare services. The terms for the compensation for the damages are set out primarily in the Law on the Rights of Patients and Compensation for the Damages to Their Health of the Republic of Lithuania.

Lithuania has recently adopted a model where the damage to patients arising out of treatment is compensated in a centralised manner, despite the fault of the healthcare institution or doctor. Hence, all healthcare institutions are obliged to pay contributions to the account of the Lithuanian State Health Fund, the amount of which is calculated from the annual income (turnover) of the personal healthcare institution for the provision of personal healthcare services for the previous calendar year. The collected funds are directly used for compensating patients for their claims. After patients are compensated for damage from this account, the right of recourse against the person who caused the damage and/or the personal healthcare institution where the person who caused the damage works is not acquired, except if the damage was caused intentionally, as well as if the person who caused the damage was drunk or under the influence of medicine, drugs or other intoxicating substances. In the latter cases, healthcare professionals would be subject to administrative or even criminal liability.

TELEMEDICINE NUMBERS AND TRENDS

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

According to data from the World Health Organization, the number of remote consultations in Lithuania increased as the number of Covid-19 cases increased. At the start of the pandemic, the Lithuanian e-health system was in the process of redevelopment. An important shift towards the digitalisation of services, as well as the need for rapid, accurate and wide-ranging data collection prompted a much wider use of e-health by residents, providers and public administrations. Remote consultations became more acceptable for a specific group of the population, especially the younger generation, who prefer to solve their health problems remotely.

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 most important trends expected for the market are the following:

1. The scope and number of various telemedicine solutions are growing. Parts of these solutions are currently not regulated or fall into the grey zone. Therefore, the regulatory environment should be developed to cover or regulate today's unregulated areas, for example, a wider scope of telemedicine services in general, shifting towards the digitalisation of healthcare services and a wider scope of digital (remote) solutions.
2. The development of the Lithuanian digital health system (development of the e-health infrastructure, solutions and integration into the EU e-health space) needs to achieve high-quality and effective healthcare focused on population needs.
3. The data maturity and interoperability of the e-health system needs to increase, with a view to contributing to the creation of the European Health Data Space (European Commission, 2021b) and cross-border services.