

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Leena Lindberg and Jonni Tiainen, Krogerus

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 Finland.

Telemedicine has not been defined in Finnish legislation. However, according to the National Supervisory Authority for Welfare and Health's ('Valvira') guidance, telemedicine refers to clinical consultations, diagnostics, observations, monitoring, treatment and clinical decisions and recommendations that are provided based on information and documentation accessed by medical practitioners electronically, for example via video link or smartphone. A similar definition was provided for in policy STM/3756/2015 of the Finnish Ministry of Social Affairs and Health in 2015.

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

There is no special regulation on telemedicine yet. In 2015, the Finnish Ministry of Social Affairs and Health adopted the viewpoint that, in principle, telemedicine services are treated the same way as all other healthcare services. This means that the legal framework, which is applicable to public or private social and healthcare services, applies also to telemedicine services provided in Finland. Public healthcare is governed by the Health Care Act (1326/2010), whereas private healthcare must be organised in accordance with the Act on Private Health Care (152/1190).

According to section 15 of the Act on Health Care Professionals (559/1994), in their professional activities, healthcare professionals must employ generally accepted, empirically justified methods, in accordance with their training, which should be continually supplemented. Each healthcare professional must weigh the benefits of their professional activity to the patient and its possible harms. Healthcare professionals must take account of the provisions concerning patients' rights.

According to Valvira's guidance, telemedicine providers must have access to suitable premises and equipment (including telecommunications), as well as appropriately qualified staff. The services must be clinically appropriate and take account of patient safety. Systems used to transmit and store patient information must meet the relevant legal requirements for confidentiality, as well as data protection and security. Service providers are responsible for ensuring that the appropriate data protection and security arrangements are in place for the purpose of transferring data and processing of personal information.

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

The key licensing bodies for private healthcare, including telemedicine, are Valvira and the Regional State Administrative Agencies (AVIs).

Valvira instructs and monitors private and public healthcare providers. The competent AVI enforces the implementation of the statutory duties of local authorities in the promotion of

welfare and public health. AVIs also monitor public and private social care service providers in their operating areas. Valvira and AVIs issue private healthcare licences which also cover telemedicine. AVIs are also responsible for the registration of self-employed professionals seeking to provide healthcare services, including telemedicine.

Within public healthcare, the licence requirements are not applicable, as the provision of primary healthcare services is a responsibility of the public authorities.

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

Telemedicine was already authorised prior to the Covid-19 pandemic. No special authorisation was granted due to the pandemic. During the pandemic, the Ministry of Social Affairs and Health suggested guiding patients to different telemedicine services, if possible.

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?

There are no concrete legislative proposals related to telemedicine. However, the Ministry of Social Affairs and Health has acknowledged the growing interest for telemedicine services.

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

Valvira's guidance provides a non-exhaustive list of possible telemedicine service types: diagnostics, observations, monitoring, treatment, clinical decisions and recommendations.

Limitations for permissibility follow from rules applicable to healthcare services in general. For example, as per section 15 of the Act on Health Care Professionals (559/1994), healthcare professionals must only use generally accepted and evidence-based procedures and methods in accordance with their training, observe patient rights and consider the benefits and possible harms caused to each individual patient in a balanced manner. Therefore, healthcare professionals must assess whether the services are suitable for delivery by telemedicine and whether telemedicine is appropriate for the patient as an individual, as highlighted in Valvira's guidance.

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

Telemedicine services can be used in both doctor–doctor and patient–doctor dimensions. As regards both dimensions, the use of telemedicine shall depend on whether the provision of a certain service as telemedicine is considered appropriate (see question 6).

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.

Telemedicine is available within public healthcare in Finland. The Social Insurance Institution of Finland ('Kela') also covers a part of the cost of healthcare services, including telemedicine, provided by private operators. The funding model of healthcare services differs in the public and

private healthcare sectors. Public healthcare is funded by tax revenue and, therefore, it is not subject to any mandatory insurance coverage.

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

All healthcare service providers must have an insurance against patient damage as specified in the Patient Insurance Act (948/2019). There are no additional insurance requirements applicable specifically to telemedicine 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).

Healthcare professionals and service providers eligible to practise traditional healthcare may also practise telemedicine when it is considered medically and otherwise appropriate.

All physicians, dentists, pharmacists, psychologists, speech therapists, dieticians, nurses, midwives, public health nurses, physiotherapists, dental hygienists, occupational therapists and opticians are required to be licenced by Valvira before starting to practise their occupation (whether traditionally or by means of telemedicine and regardless of employee status) under the Act on Health Care Professionals (559/1994).

Additionally, the Act on Private Healthcare (152/1990) sets a requirement for service providers to acquire a private healthcare licence, undergo an inspection before starting and notify before substantially changing their operations (sections 4, 7 and 9). In the case of self-employed providers (sole traders,) it is sufficient to notify the competent Regional State Administrative Agency before beginning to provide services.

For rules concerning service providers established outside of Finland, see question 17.

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

There are no specific education requirements for practising telemedicine. The general education requirements for obtaining Valvira's licensing for practising a particular healthcare occupation are laid down in the Act on Health Care Professionals (559/1994) (see question 10).

Additionally, healthcare professionals must maintain and develop the knowledge and skills *needed in their professional activity*. Similarly, employers are required to monitor and create conditions for the learning and development of the healthcare professional (eg, by enabling participation in complementary education and trainings). Sufficient language skills (considering the nature of the activities) are also specifically required. The mentioned requirements are set forth in sections 18 and 18(a) of the Act on Health Care Professionals (1994/559).

In practice, telemedicine providers may set conditions on education and experience in recruitment and provide trainings for their staff. The Finnish Medical Association and the Finnish Society of Telemedicine and eHealth also offer a two-year specialisation programme in health information technology for physicians.

For rules concerning service providers established outside of Finland, see question 17.

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

Self-employed healthcare professionals located in Finland, including physicians, must notify the competent Regional State Administrative Agency for registration purposes before commencing the provision of healthcare services, including telemedicine. See question 10 for more information.

For rules concerning service providers established outside of Finland, see question 17.

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

Private sector service providers other than sole traders must obtain a licence and undergo an inspection prior to offering their services, as well as notify any substantial changes (including ending the provision of healthcare services) in their services. As per policy STM/3756/2015 of the Ministry of Social Issues and Health and Valvira's guidance, this licence also covers the provision of telemedicine services.

The application for the private healthcare licence must be submitted to (i) the competent Regional State Administrative Agency or, (ii) if the applicant's operations cover an area of at least two Regional State Administrative Agencies, to Valvira.

Conditions to obtain the licence include:

- (i) the number and qualifications of personnel required for the proposed activities;
- (ii) inspected and approved premises and equipment consistent with the proposed activities;
- (iii) a director responsible for healthcare services who has the appropriate training, the right to practise a relevant profession and work experience; and
- (iv) activities that are medically appropriate and conducive to patient safety. A Finnish Business ID is also required to obtain the licence.

For rules concerning service providers established outside of Finland, see question 17.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

Any *information system intended for the storage or other processing of patient data* (as defined in the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021), section 3) must comply with the so-called *essential requirements* relating to functionality, interoperability, data protection and information security, and accessibility both when using the system independently and together with other information systems intended to be connected to it. The Finnish Institute for Health and Welfare (THL) maintains lists of essential requirements based on the purpose of the system/application.

These systems must also be *classified* according to their risk level into one of the categories B/A1/A2/A3, *registered* with Valvira, and their *compliance must be demonstrated* with a certificate (categories A1–A3) or a written account (category B). THL maintains a list of the criteria and procedures to be followed in demonstrating compliance (see question 21).

General purpose information systems, software packages or applications (office software, CMS, general messaging platforms, etc) are neither registered nor subject to similar requirements lists. If they are used to process client data, the service provider must ensure full compliance with all data protection and security requirements and other legislation concerning the creating, processing and storage of client/patient data, and be able to demonstrate compliance. The Finnish Data Protection Ombudsman has deemed the use of general (non-encrypted) email for conveying health-related or otherwise sensitive information non-compliant regardless of patient consent.

Software falling under the definition of a medical device/in vitro medical device as per the regulations (EU) 2017/745 ('MD regulation') or (EU) 2017/746 (IVD regulation) must also fulfil the *requirements* specified in said regulations and national legislation concerning medical devices. The competent supervisory authority registering and overseeing such software is the Finnish Medicines Agency (Fimea).

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

The equipment, including internet connections, must be appropriate.

The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) sets a requirement that the patient, the service provider, other parties processing customer data and their representatives *as well as IT equipment* must be *reliably identified or authenticated* (section 17).

Requirements laid out in the Act on the Provision of Digital Services (306/2019) implementing the accessibility directive (EU) 2016/2102 concerning, for example, ease of use, compatibility with commonly used software and data transmission services and the obligation to maintain an accessibility statement may be applicable if the telemedicine service is produced or funded publicly.

16. Does the legislation provide for specific rules concerning patients' medical records?

The Act on the Status and Rights of Patients (785/1992) imposes an obligation on healthcare professionals and units to prepare and maintain patient records (section 12) and stipulates that their contents may only be disclosed to those personally participating in treatment within or on behalf of the operating healthcare unit unless consent is obtained from the patient (see question 18).

Decree 94/2022 of the Ministry of Social Affairs and Health lays out detailed rules on patient records, including requirements on integrity, useability, access and use rights, time limits, detailed contents, corrections and logging.

An entry must be written after each *patient service event*, which contains all information about the event necessary to ensure the good quality of the planning, implementation and monitoring of the patient's care (section 11 of Decree 94/2022). With regards to *consultations between two professionals*, the healthcare professional in charge of the patient's treatment must write a patient record entry about consultations significant for the patient's diagnosis or treatment. If the identity of the patient could be revealed based on the consultation, the person being consulted must also make a patient record entry or retain the information concerning consultation in some other way (section 15 of Decree 94/2022).

For information on the security, form and transfer of patients' medical records, see questions 21–23.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

No explicit requirements on geographic location are laid down in law.

Free movement of services is a fundamental principle of the European Union. As per the Act on Cross-Border Health Care (1201/2013) and Directive 2011/24/EU ('the Patient Directive'), service providers based within the European Economic Area (EEA) may freely offer their services (including telemedicine) from another EEA country to patients in Finland in accordance with the licensing and other requirements of the EEA country they are established in. In such cases, the patients must, inter alia, be informed about applicable legislation, insurances and competent supervisory authorities.

For (i) EEA-based service providers offering their services to Finnish service providers (sub-contracting) and (ii) service providers established in third (non-EEA) countries, the requirements under Finnish law apply similarly as with regard to service providers offering services in Finland. Therefore, limitations on location follow indirectly from the requirements described under other questions in this questionnaire concerning, for example, information systems, equipment, occupational practice rights/licensing, the private healthcare licence (including the requirement of a Finnish Business ID) or registration and inspections by authorities.

It should also be noted that the patient must, if necessary, be either given the opportunity for a physical consultation or be referred to another service provider, as highlighted in Valvira's guidance.

18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

For all intents and purposes, yes. The nature of the consent(s) required depends on the specific situation.

Making and implementing treatment decisions

Treatment must be given in mutual understanding with the patient as per section 6 of the Act on the Status and Rights of Patients (785/1992). This applies also to minors, in so far as possible considering their age and level of development.

Certain qualitative requirements apply to the consent under section 5 of the Act on the Status and Rights of Patients (785/1992). The patient must be given information in an understandable form about factors relevant to the decision-making, such as their health, different treatment options and their relevance and effects. Interpreter services should be used if possible and necessary.

If a patient is unable to decide on their treatment, their legal representative or next of kin should be consulted and treatment be given in accordance with the patient's express will and personal interests.

Consultations between professionals

Patient document information is confidential and may only be disclosed to those participating in the patient's treatment. If informed consent is obtained from the patient (or legal representative), *information necessary for the examination and treatment of the patient* may also be disclosed to another healthcare unit or healthcare professional.

Exemptions to the obligations to obtain consent apply to situations where the patient's life or health is in danger and consent cannot be obtained, and to situations covered by legislation concerning involuntary treatment of, for example, mental health patients.

Chapter 4 of the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) regulates in detail the conditions and procedures relating to patients' consent for transferring their data.

Consent as a legal basis for the processing of personal data

Even if consent for a particular treatment has been obtained, a separate consent must be obtained with regard to the disclosure, transfer or other processing of the patient's/data subject's personal data if consent is used as a legal basis for the processing of personal data. A patient's consent within healthcare is conceptually different from consent as a legal basis for processing as per Articles 6–7 of the GDPR.

Section 5 of the Data Protection Act (1050/2018) sets the age of consent in relation to the offering of information society services at 13, meaning that for children below 13 years of age, consent must be authorised by the patient's parent/legal representative.

19. Is there any other important requirement that should be highlighted?

Section 4(a) of the Act on the Status and Rights of Patients (785/1992) obliges providers of healthcare services to, in mutual understanding with the patient (or legal representative), *draw up a plan concerning the diagnosis, treatment or rehabilitation of the patient*, including the implementation schedule and organisation of the care. Simpler services where the drawing up of such a plan would be obviously unnecessary, such as temporary advice services, are exempted from this obligation.

As per section 15 of the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021), access rights must be based on work tasks so that each healthcare worker can only access customer or patient data they need for their work.

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. The GDPR and other EU legislation set the general framework for data privacy.

The general national derogations are laid out in the Data Protection Act (1050/2018), which is applicable if the controller is established in Finland:

1. The age limit for offering information society services to minors, without their parent's or legal representative's consent, is set at 13 (see question 18).
2. The processing of the Finnish personal identity code is generally allowed with the consent of the data subject, if stipulated in law, or if necessary (eg, to implement the rights and obligations of the data subject or the controller).
3. The unlawful exploitation or disclosure of any information concerning, inter alia, another person's characteristics, personal circumstances or financial status is prohibited.
4. Certain limitations are set on the rights of the data subject to be informed about the processing and to gain access to their personal data, due to reasons such as anticipated serious harm caused by the provision of the information to the health or treatment of the data subject.

The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) contains the sector-specific, detail-level legislation on data protection and data security in healthcare, including the division of (joint) controller responsibilities between public authorities

and service providers, as well as rules concerning the security of patient information (see question 21).

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

Chapters 4–8 of the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) lay out the central healthcare-specific national data security rules.

Chapter 4 covers access rights, identification, authentication and logging requirements and conditions for data disclosure or transfer.

Chapter 5 obliges service providers to maintain a self-monitoring plan on data protection, data security and databases.

Chapter 6 contains rules on the purpose, classification, registration, adaptation and monitoring of information systems and applications (see question 14).

Chapter 7 covers essential requirements for information systems and applications (see question 14), including accountability, interoperability testing and data security evaluations.

Chapter 8 concerns guidance and oversight, including the obligation to notify deviations and public authorities' rights to carry out inspections and issue orders to fix defects or prohibit the use of non-compliant systems.

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

Articles 44–46 of the GDPR set out a general framework for transfers of personal data. Within the EEA, the transfer of data is, in principle, allowed if other conditions for the processing of the data are fulfilled. Transfers to third countries require certain safety mechanisms.

Though not technically forbidden, various requirements on functionality, interoperability, data protection and information security, registration and certification can in practice render the transfer of patient data abroad practically difficult.

The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) requires service providers to become users of national information system services (called 'Kanta') maintained by the Finnish Social Insurance Institution, and to use data structures in their information systems and customer documents which enable the use, transfer, storage and protection of the documents with the help of said information system services.

The Act on the Secondary Use of Health and Social Data (552/2019) sets out specific data security requirements for the use environments where data materials could be handled which must be complied with also in transferring health data abroad for secondary uses (including R&D, innovation activities and knowledge management).

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?

The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (784/2021) requires service providers to become users of national information system services (Kanta) maintained by the Finnish Social Insurance Institution, and to use data structures in their information systems and customer documents which enable the use, transfer, storage, and protection of the documents with the help of said information system services (sections 7–9).

See question 16 for the obligation to maintain patient records and question 14 for requirements for information systems.

LIABILITIES

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

The Patient Insurance Act (948/2019) applies to all telemedicine services. An entity engaged in healthcare services and a self-employed person as well as an employer of healthcare professionals must have insurance against liability under the Act (section 6). A contract condition that differs from the provisions of the Act to the detriment of a policyholder, insured person, injured person or other person eligible for compensation shall be void unless otherwise provided in the Act (section 3). Compensation is granted for a personal injury if it is likely that it has been caused by, inter alia, any examination, treatment or other similar healthcare service, provided that an experienced healthcare professional would have acted differently and thus avoided the injury (section 23).

TELEMEDICINE NUMBERS AND TRENDS

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

The Finnish Institute for Health and Welfare has conducted research on telemedicine services. According to research about trends of telemedicine services in 2013–2020, in Finland, telemedicine has become more common in healthcare almost every year since the beginning of monitoring in 2013. In 2020, 10.7 million telemedicine contacts were registered in Finland. The research was conducted on the basis of data from a public service called 'Avohilmo', via which it is possible to follow the development of telemedicine services in Finland. Avohilmo is a database of outpatient care contacts.

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 research indicates, telemedicine services are going to become even more common. The Finnish Ministry of Social Affairs and Health has acknowledged this development in its legislative proposals. However, no clear changes or reforms have been announced.