

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?
<p>There is no specific legislation for telemedicine in Sweden. Healthcare providers offering telemedicine are subject to the same national rules as healthcare providers giving medical care in the traditional sense. The Swedish National Board of Health and Welfare (<i>Socialstyrelsen</i>) (the Board) did however lay down specific guiding principles in 2018 for the provision of telemedicine. The principles provide that: (1) telemedicine may be used only where applicable law or medical experience do not implicate that a physical visit is required; (2) the remote medical service is tailored to the patient's individual needs and ability to use the service; (3) the healthcare provider has sufficient information on the patient's medical condition; and (4) necessary follow-up and coordination with other actors is possible.</p> <p>There is no uniform definition of telemedicine in Sweden and it is not further described in law. The Board uses the term digital healthcare services, which includes healthcare services provided through a digital distance contact, that is, through some form of digital communication where the patient and the healthcare professional are physically separated (eg, providing care via an app, phone call or video link). However, there is also no regulation either allowing or forbidding the use of other forms of telemedicine, such as the use of robotic surgery, as long as it is compliant with applicable national legislation.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>As described in the response to Question 1, there is no specific legal framework governing telemedicine in Sweden. Telemedicine services are subject to compliance with the regulatory framework concerning healthcare and the medical profession in general, such as the Swedish Health and Medical Services Act (<i>Hälso- och sjukvårdslag</i> (2017:30)), the Swedish Patient Act (<i>Patientlagen</i> (2014:821)) the Swedish Patient Safety Act (<i>Patientsäkerhetslagen</i> (2010:659)) and the Swedish Patient Data Act (<i>Patientdatalagen</i> (2008:355)) as well as additional regulations from the Board on inter alia quality management system (Regulation SOSFS 2011:9) and medical records (Regulation HSLF FS 2016:40).</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>The Swedish Health and Social Care Inspectorate (<i>Inspektionen för vård och omsorg</i>) (IVO) carries out the supervision of health and medical care and issues certain permits in the area (eg, permits for blood and tissue establishments). The IVO's supervision covers both healthcare providers (ie, healthcare organisations) and licensed healthcare professionals in their professional activities. With a few exceptions for certain specific specialised areas of care, there are no licence or permit requirements for healthcare providers in Sweden. However, all healthcare providers are required to register their operations with the IVO no later than one month prior to commencing the operations. All registered healthcare providers are listed in the IVO's caregiver registry (<i>Vårdgivarregistret</i>) and are subject to the inspectorate's supervision.</p> <p>Certain healthcare professionals may only render healthcare services if they have a licence (eg, physicians, nurses, psychologists etc). The Board examines and issues licences for Swedish healthcare professionals.</p>
4. Was telemedicine authorized during the Covid-19 pandemic?

Telemedicine has been available on the Swedish market for many years. It has however come into focus even more during and after the Covid-19 pandemic. Swedish Regional Councils, which are responsible for ensuring that appropriate healthcare is available to all Swedish citizens and residents, reported a strong increase in the use of telemedicine services during the pandemic compared to the preceding years, ranging from renewal of prescriptions to medical consultations involving diagnosis, treatment etc. The increase in demand extends to both private and public healthcare providers and is considered to be a consequence of the Covid-19 pandemic.

During 2020–2021, the Swedish Medical Agency (the MPA) performed a pre-study on decentralised clinical trials, with the aim of improving the conditions for performing decentralised clinical trials and trials with decentralised elements. The MPA participated in the work leading up to the EU recommendation paper on decentralised elements in clinical trials, published in December 2022 (see also the response to Question 5, below).

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?

The Covid-19 pandemic required the adoption of temporary measures facilitating telemedicine, to limit the spread of the coronavirus and to handle the pressure placed on the healthcare system. As an example, the Stockholm Regional Council, being responsible for all publicly financed healthcare in the Stockholm region, adopted provisional measures such as allowing publicly financed digital patient visits in a broader range of areas within healthcare and adjusting the compensation to healthcare providers for such remote consultations.

The Swedish Government concluded in its Digi-physical Health Inquiry of 2019 that telemedicine could offer efficiency, accessibility and quality improvements to healthcare. However, the government did not see any need for creating a specific national system for the digital healthcare services. Instead, it was considered of importance of coordinating digital services with the physical healthcare services to a greater extent. The government has proposed a model for a more coordinated primary care system in a legislative bill (proposition 2021/22:72).

Moreover, in the post-pandemic scenario (although not as a direct consequence of the Covid-19 pandemic), a greater focus, both at an EU and national level, has been placed on the use of decentralised clinical trials. For example, the EU Decentralised Clinical Trials Project Group published a recommendation paper on the use of decentralised elements in clinical trials in December 2022.

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

As mentioned in the response to questions 1–3, above, teleservices are not specifically regulated in Swedish law. As long as such services comply with general healthcare regulations, they are considered to be permitted in Sweden. Such services must also comply with general Swedish and EU rules on for example, processing of patient data.

Moreover, as mentioned in the response to Question 1 above, the Swedish National Board of Health and Welfare laid down specific guiding principles in 2018 for the provision of telemedicine. The principles provide that telemedicine may be used only where: (1) applicable law or medical experience do not implicate that a physical visit is required; (2) the remote medical service is tailored to the patient's individual needs and ability to use the service; (3) the healthcare provider has sufficient information on the patient's medical condition; and (4) necessary follow-up and coordination with other actors is possible. Healthcare operations are carried out under the responsibility of each healthcare provider and the healthcare professionals being involved in each patient's care, so it is the responsibility of such healthcare stakeholders to ensure that any telemedicine services provided are adequate for the care of each patient, given the specific circumstances in each case.

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

<p>Anyone can benefit from telemedicine services in Sweden. Both doctor-doctor and patient-doctor remote medical services are allowed and are frequently used.</p>
<p>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.</p>
<p>The healthcare system in Sweden is decentralised. It is therefore the responsibility of the Swedish Regional Councils and, in some cases, municipalities. Swedish healthcare is divided into public and private sectors and telemedicine is available in both sectors. There are two types of private healthcare. The first is healthcare services provided by a private company under contract with a Regional Council or municipality. In the event of such contract, the cost for private and public healthcare is the same and such private operations covered by the contract are financed by the public. The second type is healthcare services provided by a private company without a contract with a Regional Council or municipality. In such cases, the patient is responsible for the cost of treatment and care received.</p> <p>Public healthcare and private healthcare contracted with for example, Regional Council or a municipality is mainly funded by the Swedish Regional Councils and municipalities. Healthcare is also, to a certain extent, funded by patient fees. The reimbursement models and levels for telemedicine may however differ between the Regional Councils.</p> <p>It is common for digital primary healthcare providers to be subcontractors to a physical healthcare centre, which in turn has a contract with a region offering reimbursement for digital healthcare services provided within the public system of choice (<i>valfrihetssystem</i>). In such a situation, the digital healthcare provider is reimbursed via the main provider (the healthcare centre) and does not receive reimbursement directly from the Regional Council.</p> <p>Residents from all over Sweden can seek care from digital healthcare providers. When a patient who is resident in one Swedish region seeks care in another region, reimbursement is regulated between the two Regional Councils involved through a national agreement for out-of-county healthcare. The Swedish Association of Local Authorities and Regions (<i>Sveriges Kommuner och Regioner</i>) has established recommendations to the Regional Council regarding reimbursements for out-of-county healthcare and certain requirements that healthcare providers must meet in order to receive the reimbursement.</p> <p>All Swedish healthcare providers are required by the Swedish Patient Injuries Act (<i>Patientskadelagen</i> (1996:799)) to hold a patient insurance policy. The obligation to have patient insurance covering anyone who provides healthcare, including a healthcare provider which provides telemedicine services.</p>
<p>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</p>
<p>See the response to Question 8, above. The insurance requirements for telemedicine services are the same as for healthcare providers in general.</p>
<p>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</p>
<p>10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)</p>
<p>In Sweden, everyone who can practice health services under the Swedish healthcare legislation can also practice telemedicine, as long as it complies with the healthcare legislation. Alternative health therapies which are not healthcare do not fall within the scope of such and are therefore not under the scope of telemedicine services.</p>
<p>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</p>

No. Not in addition to the requirements applicable to healthcare professionals in general. Healthcare providers are responsible for ensuring that any telemedicine services provided are appropriately performed, so healthcare providers may determine specific education requirements for healthcare professionals within its own operations.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
No. Not in addition to the general licence and permit requirements applicable to physicians, and the notification requirement applicable to healthcare providers.
13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.
There are no such special mandatory licences or authorisations for institutional healthcare providers engaged in telemedicine services.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
No. However, the healthcare provider must ensure that the introduction and use of a telemedicine platform complies with applicable laws and regulations on for example, patient safety, information security and data privacy, including national sector-specific regulations such as those relating to healthcare information technology systems.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There are no legal requirements regarding electronic equipment and internet speed for telemedicine services. However, as stated in Question 14, above, telemedicine services must be provided in a way which ensures for example, patient safety, information security and data privacy.
16. Does the legislation provide for specific rules concerning patients' medical records?
Yes. Rules on medical records are stated in for example, the Swedish Patient Data Act, the Patient Safety Act and The National Board of Health and Welfare's regulation regarding medical records and the processing of personal data within the healthcare (<i>Socialstyrelsens föreskrifter och allmänna råd om journalföring och behandling av personuppgifter i hälso- och sjukvården</i> (HSLF-FS 2016:40)). Telemedicine services must be recorded in medical records in compliance with the rules applicable to medical records in general. When using digital health services, regulation HSLF-FS 2016:40 stipulates that if 'open networks' (eg, the internet) are used in the processing of patients' personal data, each healthcare provider is responsible for ensuring the safety of the personal data contained in the system, including by use of a two-factor authentication method for remote connection to the system. The healthcare provider is also responsible for storing medical records in such way that they are readable during the applicable, regulated retention periods.
17. Are there geographic location requirements applicable to the provision of telemedicine services?
If the telemedicine provider is considered to be a Swedish healthcare provider (if providing eg, a digital platform for telemedicine/online consultation targeting healthcare services to Swedish patients) the operations must adhere to Swedish rules on healthcare. Such rules may lead to obstacles in terms of actively offering medical or healthcare services to Swedish patients by a healthcare provider which is not organised in Sweden. For example, it would most likely not be compliant with Swedish rules for a Swedish healthcare provider to market or offer healthcare services and medical advice provided by a physician or other healthcare professional which is not licensed to practice medicine in Sweden. There is however no ban on consultations between patients and doctors located in different regions in Sweden, although certain restrictions may be stated in agreements between Regional Councils and private digital healthcare providers on the

marketing of digital healthcare services outside of the region where the services are to be provided.
18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?
In accordance with the Swedish Patient Act, healthcare activities may not be conducted without the patient's consent, unless certain regulated exceptions are in hand (such as the emergency care of an unconscious person). It is therefore necessary to obtain patient's consent to engage in telehealth services.
19. Is there any other important requirement that should be highlighted?
We are not aware of any other important requirement to be highlighted in this context.
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.
<p>Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. A healthcare provider must comply with, and take into consideration, applicable laws and regulations regarding data privacy both when offering healthcare services physically and digitally. Aspects regarding information security and data privacy should be part of the healthcare provider's systematic quality work. Fundamental provisions on the processing of personal data within Swedish healthcare and the obligations concerning medical records are stated in the Swedish Patient Data Act and in the Board's regulation HSLF-FS 2016:40. Such Swedish sector-specific legislation also contains provisions supplementary to the EU General Data Protection Regulation (EU) 2016/679 (GDPR). As further described in the response to Question 16, a healthcare provider needs to take certain measures when using open networks (ie, the internet) in the processing of patient data. In general, it is also important that the healthcare provider ensures, for example through processes and routines, that the regulatory framework is complied with, and that patient data is handled correctly in a digital healthcare encounter. This may involve ensuring that during the healthcare encounter, the healthcare professional is positioned in such way and uses equipment that prevents other people from hearing the conversation or seeing the images displayed during the meeting.</p> <p>In this context, it should be noted that healthcare professionals are subject to statutory secrecy rules, which, if breached, can lead to a criminal penalty.</p> <p>Furthermore, issues may arise if a digital healthcare provider uses cloud solutions to store or otherwise process patient health data, especially if a third-party cloud service provider is used. Even if the relevant servers may be located within the EU, the cloud service provider may be organised in a third country (such as the US), which entails risks of the processing being deemed non-compliant with third country transfer provisions of the GDPR. It is also of great importance that the patient data located on servers (especially servers located outside the premises of the healthcare provider) is sufficiently encrypted to protect such data in compliance with Swedish data privacy and statutory secrecy provisions.</p>
21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?
See the response to Question 20, above. When using open networks (ie, the internet) in the processing of patients' personal data, there are certain explicit requirements and official recommendations (constituting good practices), including for example, the use of a two-factor authentication method for remote connection to the system. It is further of great importance that risk assessments have been carefully carried out before processing any health data, including to establish appropriate access limitation measures to ensure, for example, that the data is protected from unauthorised access (unauthorised access by third parties as well as unauthorised access within the healthcare provider's organisation).

22. Does the applicable regulation provide for requirements for the transfer of information abroad?
<p>In addition to rules set out in the GDPR on processing special categories of personal data (including health data) and transfer of such data to third countries, disclosure of patient data is regulated and limited under the Swedish Public Access to Information and Secrecy Act, the Swedish Patient Safety Act, and the Swedish Patient Data Act.</p> <p>When telemedicine is provided by foreign operators based in countries other than Sweden, the handling of personal data abroad is an issue to take into consideration, such as assessing the extent to which it is possible to disclose data in medical records through direct access to a digital provider abroad. In this regard, Swedish legislation is unclear, and the situation must be evaluated on a case-by-case basis. Consequently, an assessment must always be made of the extent to which it is possible to disclose medical records and patient data through direct access to a digital healthcare provider abroad.</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>We are not aware of any specific database requirements applicable to healthcare providers that provide telemedicine services. There are however general requirements regarding the recording of data in the patient's medical record which apply also to telemedicine. Such requirements are set out inter alia in the Swedish Patient Data Act and regulations issued by the Board.</p>
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>Swedish healthcare providers have extensive responsibilities in relation to injuries and events that could have led to injuries within their healthcare. These responsibilities include investigating complaints and incidents, reporting serious injuries and incidents that could have led to serious incidents to IVO, reporting healthcare professionals who pose a risk to patient safety, informing patients who have suffered from an injury within the healthcare, reporting adverse reactions to medicinal products etc. As stated in the response to Question 8 above, all Swedish healthcare providers are required to hold a patient insurance which covers liabilities when a patient is injured within healthcare. A patient may also claim damages by suing a healthcare provider in Swedish courts.</p> <p>Chapter 6 of the Patient Safety Act sets out general obligations of healthcare professionals. In most cases the healthcare provider is responsible, as an employer, for incidents within healthcare caused by a healthcare professional. However, the IVO has a right to take measures (including disciplinary) if a healthcare professional is not fulfilling its obligations under any regulation applicable to healthcare activities. Further, the licence of a healthcare professional (as applicable) may be withdrawn for example, if the healthcare professional in question has been grossly negligent in the exercise of their profession, has been guilty of a serious offence likely to affect their trust as a healthcare professional, or otherwise has proved to be manifestly unfit to pursue the profession. A healthcare professional may also be subject to criminal penalty if they have conducted a criminal offence within the healthcare practice.</p>
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
<p>For example, the Swedish eHealth Authority (<i>E-hälsomyndigheten</i>) together with Statistics Sweden (<i>Statistikmyndigheten</i>) made a statistical study on the user experience of telemedicine in Sweden in 2021. This included a comparison with a corresponding 2019 study. According to the study report, the Covid-19 pandemic has resulted in an increase of the use of digital healthcare in Sweden (ie, digital meetings with healthcare professionals). The report states that</p>

15 per cent of the population had used the internet or a digital service to perform a video meeting with healthcare personnel during 2021, compared to only eight per cent in the 2019 survey.

Furthermore, the Swedish Agency for Health and Care Services Analysis (*Myndigheten för vård och omsorgsanalys*) has produced a report about the use of digital healthcare services and states inter alia that digital healthcare services are mainly used by children and younger adults, urban residents, people who do not have a chronic illness and people with relatively good socio-economic conditions.

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.

According to a study performed by the Swedish Internet Foundation, almost 20 per cent of the Swedish population do not know how to use digital healthcare services. Even though a greater number of people know how to use an application for a digital health meeting in 2022 compared to the previous year, there are challenges in making digital healthcare available (not only in theory but in practice) to a greater number of people.

According to the study report, there is also a worry that the total consumption of healthcare services increases with digital healthcare solutions, and that the Regional Councils will carry unnecessary costs for healthcare that would not otherwise be conducted. The reimbursement for digital healthcare services is to a great extent already subject to discussion, and models for suitable reimbursement will most likely be developed further and adjusted in future.

National strategies and governance are required to create conditions that will allow telemedicine to use its full potential. Structural changes, facilitation of exchange of information and harmonised information systems, investments, and collaborations between different healthcare providers are examples presented in the report of possible measures that could be considered by the legislator to secure quality and improve the provision of telemedicine.