

<b>TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES</b>
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<b>LAWS AND REGULATIONS ON TELEMEDICINE</b>
<b>1. Is telemedicine allowed in your country? If so, how is it defined?</b>
<p>Telemedicine is allowed in Switzerland. There are no legal provisions specifically for telemedicine in Switzerland, and there is no definition of telemedicine in the general laws on medical services. In authorisations for telemedicine centres the authorities distinguish between the provision of medical services with personal consultations between patients and service providers and remote contact, which includes contact by telephone.</p>
<b>2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.</b>
<p>There is no specific legal framework for telemedicine. The general provisions and standards for medical services apply for the authorisations, regulatory issues, the standards of services and liability.</p> <p>Switzerland is a federal state, divided into 26 cantons. Based on the Swiss Federal Constitution any competence which is not expressly allocated to the federation lies with the cantons. This applies not only for the competence to pass laws, but also for the competence to enforce laws. As a consequence, Switzerland is rather pragmatic and flexible when there is a need to implement a new system. The legal regulation normally follows later, often after the EU has passed regulations. The system works considerably well on this basis, as policy makers and stakeholders have a reasonable attitude.</p> <p>There is the 'Swiss Federal Law on the university professions' (<i>Bundesgesetz über die universitären Medizininalberufe, Medizininalberufegesetz</i>, SR 811.11) regulating the education and the right to provide services of medical doctor, dentist, veterinarian and pharmacist. Further there is the 'Swiss Federal Law on Health Professions' (<i>Bundesgesetz über die Gesundheitsberufe, Gesundheitsberufegesetz</i>, SR 811.21) which is applicable to the education and the right to provide services of nurses, physiotherapists, ergo-therapists, midwives, nutritionists, optometrists and osteopaths.</p> <p>The cantonal laws provide the rules for the licences/authorisations to perform medical services and the legal basis for the oversight of the providers, including all aspects of their professional conduct, by the cantonal authorities.</p>
<b>3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.</b>
<p>The key licensing bodies for telemedicine are the same bodies responsible for the general licensing of both institutions and persons providing healthcare services, because Swiss law does not differentiate between telemedicine and medical services provided with direct patient contact. As stated above, the authorities of the 26 cantons undertake such functions.</p>
<b>4. Was telemedicine authorized during the Covid-19 pandemic?</b>
<p>There was no change in the legal provisions during the Covid-19 pandemic. Providers of telemedicine require the same kind of licences as any other medical service provider. No specific authorisation is required to provide telemedicine in Switzerland. However, the pandemic accelerated the development of a variety of different structures for providing telemedicine services.</p>

<b>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?</b>
The pandemic will not prove to be a driver for regulatory change. Cost and efficiency in combination with a shortage of qualified personnel and an aging society are the main drivers.
<b>6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)</b>
As there is no regulation, any services which can be provided remotely are legal, for example, second opinions, teleconsultation, telediagnosis, telesurgery, tele-screening etc.
<b>7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.</b>
Patients must expressly agree to telemedicine services. A medical service provider is free to decide whether they wish to offer telemedicine services.
<b>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.</b>
As a consequence of the lack of specific regulations for telemedicine there are also no specific rules on the funding. There are very few telemedicine services which can be charged. If there is no tariff for a specific service, it cannot be charged. The fact that many telemedicine services cannot be charged delays potential development in telemedicine.
<b>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</b>
Telemedicine service providers need the same kind of insurance as their competitors who offer personal consultations.
<b>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</b>
<b>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.)</b>
Any person or entity which can provide medical services in Switzerland (and holds the necessary licences) can perform telemedicine services.
The question is only whether a specific service can be performed as telemedicine service or has to be performed in a personal consultation.
<b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b>
No, none.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
No. All physicians must hold a cantonal licence to exercise their profession, unless they are employed in a hospital. There is federal register of all physicians, regardless of whether they perform telemedicine.
<b>13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
Entities that provide telemedicine services must have their headquarters in Switzerland and must hold a licence from the canton where the entity's business is based.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>

<p>The providers of telemedicine services require the same licences as the competitors who offer personal consultations. The only difference is that a provider who offers personal consultations requires a licence in each canton where the services are offered, whereas telemedicine providers are normally based in one canton and provide their services across Switzerland based on the licence issued by the home canton.</p>
<p><b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b></p>
<p>There are no legal requirements regarding electronic equipment and internet speed for telemedicine services, not even with respect to robotic surgery. The responsibility lies completely with the healthcare provider.</p>
<p><b>16. Does the legislation provide for specific rules concerning patients' medical records?</b></p>
<p>Cantonal laws state the requirements for medical records. The rules are very similar in all the cantons. Medical records may be kept on paper or electronically, and they must be complete, genuine, correct and stored safely for at least ten years. There are a number of programs available for storing medical records safely and confidentially over the required period.</p>
<p><b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b></p>
<p>Telemedicine services may only be provided by Swiss organised legal entities or persons with a licence from one of the cantonal authorities. Inter-cantonal consultations between patients and doctors located in different cantons of the federation are not prohibited.</p>
<p><b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b></p>
<p>Telemedicine services require the patient's or the patient's legal representative free informed consent with respect to telemedicine consultation and the transmission of their images and data.</p>
<p><b>19. Is there any other important requirement that should be highlighted?</b></p>
<p>The remote issuance of medical reports, sickness certificates or medical prescriptions require, in addition to other usually mandatory information, that the professional's electronic signature follows specific requirements concerning electronic signatures based on the 'Swiss Federal Law on Electronic Signatures' (<i>Bundesgesetz über die elektronische Signatur</i>, SR 943.03).</p>
<p><b>DATA PRIVACY ASPECTS</b></p>
<p><b>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.</b></p>
<p>The general rules on data privacy apply. Medical data is highly sensitive data, requiring the utmost diligence with regard to protection. There is the Federal Act on Data Protection (FADP, SR 235.1) law on data protection applicable to the federal administration and private entities/persons who store data, and the cantonal data protection laws applicable to cantonal administrations. The legal framework is widely based on the EU General Data Protection Regulation (EU) 2016/679.</p>
<p><b>21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?</b></p>
<p>No, it is the responsibility of the service provider to ensure data protection. Any failure to protect data may result in sanctions by the authorities and potential liability.</p> <p>The pragmatic approach in Switzerland considers the data protection aspects of medical services (including telemedicine) to be no different to others such as in banking or the insurance business.</p>
<p><b>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</b></p>

The Swiss Federal Act on Data Protection allows cross-border disclosure, unless the privacy of the data subjects would be seriously endangered, in particular due to the absence of legislation which guarantees adequate protection.

In the absence of legislation that guarantees adequate protection, personal data may only be disclosed abroad if:

1. sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection abroad;
2. the data subject has consented in the specific case;
3. the processing is directly connected with the conclusion or the performance of a contract and the personal data is that of a contractual party;
4. disclosure is essential in the specific case in order either to safeguard an overriding public interest or for the establishment, exercise or enforcement of legal claims before the courts;
5. disclosure is required in the specific case in order to protect the life or the physical integrity of the data subject;
6. the data subject has made the data generally accessible and has not expressly prohibited its processing;
7. disclosure is made within the same legal person or company or between legal persons or companies that are under the same management, provided those involved are subject to data protection rules that ensure an adequate level of protection.

The Federal Data Protection and Information Commissioner (the Commissioner, Art 26) must be informed of the safeguards under paragraph 2(a) and the data protection rules under paragraph 2(g). The Federal Council regulates the details of this duty to provide information.

**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?**

Medical service providers are required by law to keep medical records, they can also outsource the storage of data. It is mainly the healthcare regulations which regulate the medical records. Data protection plays a secondary role as the healthcare regulations are more specific (see response to Question 16, above).

**LIABILITIES**

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

There is no specific liability rule regarding telemedicine. Swiss law provides a liability based on fault which also applies to telemedicine. This liability starts with the question whether telemedicine was the suitable form for the service and then all the other questions on care in performance of the service follow.

**TELEMEDICINE NUMBERS AND TRENDS**

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

No, not in Switzerland.

**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 stated above in the response to Question 5, cost and efficiency in combination with a shortage of qualified personnel and an aging population are the main drivers for the developments. The market will grow, also with the new technologies, which are the same in all developed countries.

There is a further legal aspect. Telemedicine also allows joint treatments by different persons and entities. Therefore, the set-up of treatments becomes more complex. In such a system not only data protection but also patient safety will become an increasing challenge for the service providers but also for legislators who have to follow the developments with required legal framework.