

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Nicole U N Kien and Claudia de Geus, LS&H Lawyers & Mediators

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LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine as an information and telecommunication service falls within the scope of Directive 2000/31/EC on Electronic Commerce in the sense that it defines an information society service as a 'service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service' and therefore is allowed in the Netherlands.

Furthermore, the Dutch Government has included telehealth (also known as e-health in the Netherlands) as part of a stimulus package (Stimuleringsregeling E-Health Thuis) to encourage innovations in healthcare, particularly given that it is thought that e-health can make healthcare more effective and affordable.

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

There are several rules that the healthcare industry should follow, but there are no specific regulations that apply to telemedicine. In general, telemedicine is regulated by the Medical Device Act (Wet op de medische hulpmiddelen) and the Medical Device Regulation (EU) 2017/745. The Medical Treatment Contracts Act (the 'WGBO') forms the basis of all healthcare in the Netherlands. The WGBO sets out the rights and obligations that play a role in the treatment agreement between healthcare providers and patients. The treatment agreement is an agreement that (automatically) arises when a healthcare provider offers help to a patient. This is also the case when the treatment contact is wholly or partly via e-health. The Medicines Act (Geneesmiddelenwet) is also applicable to telemedicine.

However, there are several restrictions regarding telemedicine. For example, under Article 67 of the Dutch Medicines Act, it is prohibited for anyone to prescribe medicines via the internet to persons whom the prescriber has never met in person, or who do not know the prescriber or whose medication history is not available. One important legal framework is the Healthcare Quality, Complaints and Disputes Act (Wet kwaliteit, klachten en geschillen gezondheidszorg or 'Wkkgz'). The Wkkgz defines standards for the provision of good-quality care. The healthcare provider must meet these standards per care request and situation.

In the case of telemedicine, Regulation (EU) 2016/679 (the General Data Protection Regulation (GDPR)) applies, as well as the Processing Personal Data in Healthcare Act (Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg). The Processing Personal Data in Healthcare Act includes safeguards for clients/patients in electronic data exchange. New legislation is being drafted to make digital data exchange the standard in healthcare, for example, the Electronic Data Exchange in Healthcare Act (Wet elektronische gegevensuitwisseling in de zorg).

E-consultations are included in regular health services and can be claimed by physicians, following from the Performance and Tariff Decision General Practice and Multidisciplinary Health Care 2020 by the Dutch Healthcare Authority (Nederlandse Zorgautoriteit). For healthcare providers who offer their services online, the electronic commerce regime applies. Article 3:15d of the Dutch Civil Code is particularly relevant, in which the general information obligation for providers of information society services (ie, online services involving an economic activity, such as e-health) is embedded.

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

The key licensing bodies for telemedicine are the same bodies responsible for the general licensing of healthcare providers. New and existing health and youth care providers must report to the administering body of the Ministry Health, Welfare and Sports (Centraal Informatiepunt Beroepen Gezondheidszorg or CIBG). This applies if one provides care that falls under the Wkkgz:

- care under the Healthcare Insurance Act (Zorgverzekeringswet or 'Zvw'), also if it is paid via a personal care budget (persoonsgebonden budget or 'pgb');
- long-term Care Act (Wet langdurige zorg or Wlz), also if it is paid via pgb;
- other forms of care, such as alternative medicine, and care not aimed at health, such as cosmetic care; and
- private care.

Care providers that fall under the Healthcare Insurance Act or Care Act must satisfy the requirements in it. One of these requirements is that care providers must have a complaints procedure in place. The Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd or IGJ) checks that new care providers comply with all the legal requirements. Healthcare providers must provide good and safe healthcare, even if they use e-health. The IGJ supervises this. In its supervision, the IGJ pays attention to, among other things, the organisation and implementation of e-health, patient involvement, exchange of information and information security.

The points that the IGJ pays attention to are described in the assessment framework 'Use of e-health by healthcare providers'. The Wkkgz is the legal framework for this supervision, together with other laws and regulations

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

The only recent change was to include e-health as part of a stimulus package (Stimuleringsregeling E-Health Thuis) to encourage innovation in healthcare. However, during the coronavirus crisis, the government has released extra funding to improve access to e-health through some schemes.

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?

Please see the answer above.

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

According to 2021 research,¹ Dutch general practice includes: (1) teleconsultations; (2) telemonitoring; (3) e-consultations; (4) online ordering of repeat prescriptions; and (5) others. As it was mentioned above, it is prohibited for anyone to prescribe medicines via the internet to persons whom the prescriber has never met in person, or who do not know the prescriber or whose medication history is not available.

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

Anyone who has consented to telemedicine services is able to use them if the responsible

¹ Jelle Keuper, Ronald Batenburg, Robert Verheij and Lilian van Tuyl, Use of E-Health in Dutch General Practice during the COVID-19 Pandemic, 2021 <https://doi.org/10.3390/ijerph182312479> accessed 16 May 2023.

healthcare provider does not refuse telemedicine, and meets all the qualification criteria and law requirements.
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.
A telemedicine service is reimbursed under the same terms as if 'normal' or in-person service was provided. ² The main applicable legislation is the Health Insurance Act (Zorgverzekeringswet). The Health Insurance Act describes which medical devices (eg, e-health technology) are eligible for reimbursement from the basic health insurance package.
9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.
There are no special requirements applicable to the telemedicine services provided.
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).
As mentioned, in the Netherlands, telemedicine comes as a part of regular health assistance. Thus, only licensed health providers can practise distance health with consumers.
11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?
There are no special education requirements applicable to telemedicine service providers.
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
The registration requirements for telemedicine providers are the same as those for regular healthcare providers.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
There are no special licenses or authorisations mandatory for telemedicine providers.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
Legal entities offering telecommunication platform and data filing services must meet all the Dutch and European legislation requirements regarding the establishment of the e-platform. The company needs to be registered with the Business Register at the Netherlands Chamber of Commerce (Kamer van Koophandel or KVK), and income tax and VAT (belasting op de toegevoegde waarde or 'BTW') must be paid. Moreover, it is important that the telemedicine platform satisfies the standard framework. A

² Government encouraging the use of eHealth (telehealth)www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth accessed 16 May 2023.

standard framework is necessary to assess the architecture for healthcare information flows and to test whether a building block fits within the desired information system.

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

No legal requirements are established regarding electronic equipment or internet speed/stability.

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

Healthcare providers, such as hospitals and general practitioners (GPs) must keep medical records for each patient. A patient has the right to view his/her medical records. This is possible for free and via the internet. The GDPR underlines this right.

The WGBO, the Processing Personal Data in Healthcare Act and forthcoming legislation, that is, the Electronic Data Exchange in Healthcare Act, may be also applicable to patients' medical records.

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

Telemedicine as a healthcare service also falls within the scope of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. Thus, it can be provided across the European Union by the relevant specialist.

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

Physicians in the Netherlands are not required by law to provide any warnings about telemedicine specifically, although they do have a general information obligation. When telemedicine is not the best way to deliver high-quality care, the healthcare provider must notify the patient of the services' limits and recommend that they have an in-person session.

Informed consent is an important concept in the WGBO. For example, healthcare providers may only act if they have permission from the patient. When using e-health, it is recommended to pay extra attention to describing the way in which the treatment will take place. The patient must clearly understand what he/she is giving permission for.

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

The Royal Dutch Medical Association (Koninklijke Nederlandse Maatschappij tot bevordering der Geneeskunst or 'KNMP') invented a guideline for telemedicine providers. According to it, telemedicine is possible only if:

- the patient has been adequately informed by the doctor about the telemedicine service;
- the patient has provided the doctor with accurate and pertinent medical information;
- the relevant professional standard is considered;
- the doctor must introduce himself/herself to the patient because the patient's identification has been properly verified; and
- the doctor makes it abundantly apparent that online guidance is founded on the information provided by the patient and the accessible medical file.

If the healthcare provider is not the patient's usual doctor, he/she must inform the patient's doctor (a GP) about the treatment recommendations made.

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.
The general privacy regulations are in effect.
21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?
The GDPR prohibits the processing of certain special categories of personal data, including genetic data, data concerning health and other types of sensitive personal data.
22. Does the applicable regulation provide for requirements for the transfer of information abroad?
General GDPR rules apply. A transfer of personal data to a third country or an international organisation may take place where the European Commission has decided that the third country, a territory or one or more specified sectors within that third country, or the international organisation in question ensures an adequate level of protection. Such a transfer shall not require any specific authorisation.
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?
General GDPR rules apply, as well as the WGBO, the Processing Personal Data in Healthcare Act and, possibly, forthcoming legislation, that is, the Electronic Data Exchange in Healthcare Act.
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>Liability is the same as in traditional doctor-patient care relationships.</p> <p>However, if medical equipment proves to be ineffective for its intended purpose, the practitioner is responsible for it. The Dutch Civil Code's Article 6:77 codifies this regulation.</p> <p>There are different types of liability, which can relate to both individuals and organisations. A distinction can be made between disciplinary, criminal, administrative and civil liability. This could include claims for damages from patients or clients, but regulators can also impose fines.</p> <p>For example, if a doctor or mental health psychologist does not meet the requirements of an e-consultation, he/she can have a complaint submitted to the Regional Disciplinary Court for Health Care. While disciplinary law is not directly about damage but more about the error, in the case of a claim or civil action, the point is that a mistake was made and damage resulted from it. For instance, a healthcare provider is liable for the proper implementation of the treatment agreement, which may be at his/her expense if faulty resources are used during the implementation.</p> <p>It follows from case law that there is no liability if the aid is considered suitable at the time of use according to prevailing medical insight, and is therefore 'state of the art'. Whether a doctor is liable also depends on whether he/she has acted in accordance with professional standards. If this could not be acted upon because an e-health solution was used, the healthcare provider should have chosen not to use it.</p> <p>On the top of that, there is a treatment agreement between the patient and doctor (Article 7:446, paragraphs 1 and 2 of the Dutch Civil Code). This agreement entails an obligation to perform</p>

acts in the field of medicine, and the nursing and care of the patient (Article 7:446, paragraph 3 of the Dutch Civil Code). A doctor may be expected to behave with the due care of a reasonably competent and reasonably acting colleague. If the doctor does not do this, there is a shortcoming in the fulfilment of the treatment agreement. The basis of the liability is then a breach of contract pursuant to Article 6:74 of the Dutch Civil Code.

TELEMEDICINE NUMBERS AND TRENDS

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

The Dutch Government publishes information and updates on telehealth on its website. The National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu or RIVM) also provides information on telemedicine. Moreover, the availability and use of e-health is monitored annually through the Dutch e-health monitor.

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 recent pandemic has hastened e-health's development, which has significantly increased the use of telemedicine. The most important trends seem to be market growth and telemedicine's technological improvement. The Electronic Data Exchange in Healthcare Act is also expected to come into force.