

## 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?

There are no specific laws or regulations that address telemedicine specifically, and telemedicine is allowed to the extent that it is in line with applicable law and regulations.

Telemedicine is not defined explicitly in Norwegian law, but the Social and Health Ministry of 2001 applied the following definition in the circular I-12/2001, 'Telemedicine and responsibility': Telemedicine is defined as 'examination, surveillance and administration of patients and education of patients and personnel with assistance from systems giving access to expertise and patient information, independent of where the patient and the competence is geographically located'. The term 'administration' in this definition is meant to include systems for electronic journaling, epicrisis and physician referral. It is likely that Norwegian authorities will define 'telemedicine' in the same manner as in the European Union, and the definition of telemedicine adopted by the European Commission in its Communication on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689, is also likely to be applied in practice. This definition is: 'the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients'.

In Regulation 25 June 2021 No 2226 on the coverage of expenses for examination and treatment by a doctor, e-consultation is defined as 'electronic or telephone communication between the patient and the medical specialist or his deputy, including a LIS1 doctor where the e-consultation must be worthy of a medical record, cf. ordinary consultation/patient visit'.

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

In the absence of a specific national regulation on telemedicine, the general legal framework for health services will apply. Norwegian acts and regulations are generally technology-neutral and can thus facilitate health services that are cost-effective and user-friendly, such as telemedicine.

Healthcare services are regulated in the Health Personnel Act (Act of 2 July 1999 No 64). This act applies to health personnel and business organisations who provide healthcare (cf Health Personnel Act section 1 (1)). Healthcare is defined as any treatment that has a preventive,

diagnostic, therapeutic, health-preserving, rehabilitating or nursing or care purpose, and that is being executed by health personnel (cf Health Personnel Act section 3 (3)).

In addition, the Health Personnel Act sets out the general principle that healthcare services must be operated with the professional responsibility and diligent care that can be expected based on the qualifications of the health personnel, the nature of the work and the situation in general (cf Health Personnel Act section 4). In practice, some healthcare services currently demand physical presentation, such as doctor-certified sick leave.

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

The key licensing bodies for telemedicine are the same as those for healthcare personnel in general.

All healthcare personnel in Norway must obtain and maintain a licence from the Health Directorate (Helsedirektoratet) according to the terms in the Health Personnel Act section 48 et seq. The Health Directorate is an executive agency and professional authority under the Ministry of Health and Care Services. The authorisation granted is consequently given on the state level.

The Norwegian Board of Health performs the supervision of healthcare personnel. The board has national jurisdiction. The board can issue, for example, warnings and withdraw authorisations, licenses and approvals for a speciality.

Anyone who has authorisation or a license as a healthcare personnel is registered in the national healthcare personnel register (*Helsepersonellregisteret* or 'HPR'). The register contains information about the current authorisation, license and right to prescribe medicine, and any restrictions on the aforementioned, as well as categories of specialisation for physicians, dentists and opticians.

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

There was no specific authorisation for telemedicine during the Covid-19 pandemic in general, but a temporary right to doctor-certified sick leave based on teleservice consultations was granted during the pandemic. In addition, the authorities generally encouraged the usage of digital services, such as consultations by video, to prevent the danger of infection, protect patients and healthcare personnel, and maintain a safe and effective national health service. For example, the authorities gave specific advice on the usage of video consultation. The Directorate for e-health has stated that the use of digital health services increased considerably during the pandemic.<sup>1</sup>

<sup>1</sup> See [www.ehelse.no/aktuelt/korona-okt-bruk-av-digitale-helsetjenester-i-befolkningen](https://www.ehelse.no/aktuelt/korona-okt-bruk-av-digitale-helsetjenester-i-befolkningen) accessed 16 May 2023.

**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?**

So far, there has been no change in the regulatory landscape in the post-pandemic scenario by way of specific regulations or guidelines on how to use telemedicine. That being said, the pandemic forced speedy digitalisation, as well as impacting, presumably, how telemedicine is perceived, not only by health personnel but also the general public and regulators. In 2021, more than one million e-consultations were held by primary care doctors (the population in Norway is 5.4 million).

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

As of today, doctor-certified sick leave cannot be granted in practice based on teleservice consultations as the authorities require physical consultation, but a draft proposal has been issued facilitating the use of e-consultation if physical consultation is not possible (but physical consultation must take place as soon as possible after the e-consultation). Otherwise, the legality of using a teleservice depends on whether the teleservice is performed with professional responsibility and diligent care (cf Health Personnel Act section 4). For instance, health personnel must assess whether the information received during the teleservice is sufficient or whether additional information or physical presence is required. Of relevance are the conditions of the patient, which treatment options are available and whether the healthcare professional will be able to perform a proper consultation and/or treatment. So far, there is little guidance on how the Norwegian authorities apply these general principles when monitoring healthcare personnel that are using teleservices or other digital health services. However, there have been some articles in the media in which the Norwegian Health Authority has expressed its concern related to such services in general, and especially related to the prescription of antibiotics based on consultation via teleservices only.

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

Anyone can make use of telemedicine services, provided the requirements of professional responsibility and diligent care are fulfilled. These requirements are personal responsibilities for healthcare personnel. If the individual healthcare provider considers that in-person medical consultation is necessary for these requirements to be met, telemedicine services cannot be used. Both doctor-doctor and patient-doctor telemedicine services are allowed.

**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.**

In Norway, the healthcare system is founded on the principles of universal access, decentralisation and free choice of provider.

The system is financed by taxation, together with income-related employee and employer contributions, and out-of-pocket payments (co-payments). All residents are covered by the National Insurance Scheme (NIS or Folketrygden), managed by the Norwegian Health Economics Administration (Helseøkonomiforvaltningen or 'HELFO'). The National Insurance Scheme is regulated by the National Insurance Act. Private medical insurance is limited.

Telemedicine is an accepted working method nowadays, and NIS has its own rates (distributed on out-of-pocket payments and refunds) for the various forms of this type of patient contact.

**9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.**

There are no insurance requirements applicable to telemedicine service providers specifically.

**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).**

The regulation regarding authorising healthcare professionals in Norway is detailed and encompasses 33 groups of healthcare personnel, including nurses, psychologists, nutritionists and paramedics (cf Health Personnel Act section 48). The applicant must comply with the educational requirements for the respective profession in order to obtain authorisation (cf Health Personnel Act section 48a).

In addition to the groups of healthcare personnel who can obtain authorisation, the legal definition of healthcare personnel also includes personnel in the health and care service, personnel working in pharmacies executing healthcare and students executing healthcare, (cf Health Personnel Act section 3 (1) paragraphs 2 and 3).

In principle, all these groups of healthcare personnel can practise telemedicine in Norway. As already mentioned, the legality of telemedicine depends on whether it can be performed with professional responsibility and diligent care (cf Health Personnel Act section 4). This means that the healthcare professional must always evaluate whether telemedicine in each consultation meets these criteria every time. If not met, then telemedicine – if practised – is illegal.

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

According to the Health Personnel Act section 4, health personnel shall perform healthcare according to their professional qualifications, and shall, if necessary and possible, request assistance or refer the patient to another health professional. There are no specific education requirements or training that healthcare professionals need to meet or attend to provide

telemedicine services.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
There is no registration requirement applicable to physicians that provide telemedicine services other than the general requirement regarding registration in the national health personnel register (HPR).
<b>13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
No special license or authorisation is required for institutional healthcare providers engaged in telemedicine services.
<b>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</b>
<b>14. Are there specific requirements applicable to the telemedicine platform?</b>
<p>When using digital medical records, the Patient Medical Records Act (Act 20 June 2014 No 42) section 7 requires that the platform is set up and organised in such a way that legal requirements are fulfilled, such as legal requirements regarding secrecy, prohibition against unlawful access to health information, the right to oppose the processing of health information, the right to access information, health personnel's duty to provide documentation and provisions regarding making health information available, including for other health personnel, and information security and internal control.</p> <p>In addition, the regulation concerning standards and national electronic health solutions requires the use of standards, standard systems, approved software, an encoder, classification systems and national electronic health solutions (Health Personnel Act section 1).</p>
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
There are no legal requirements regarding electronic equipment and internet speed specifically for telemedicine services.
<b>16. Does legislation provide for specific rules concerning patients' medical records?</b>
In Norway, the Patient Medical Records Act explicitly provides provisions on patients' medical records. The act contains regulations about, among other things, who has a right to process health information, professional secrecy, right to information, duties for firms who process health information and rules regarding supervision. The purpose of the act is to ensure that the processing of health information takes place in a way that provides patients and users with high-quality healthcare by ensuring that relevant and necessary information is quickly and efficiently

available to healthcare personnel, while at the same time ensuring that information is not shared with unauthorised persons (cf Health Personnel Act section 1 letter a). The act also has the purpose of securing patient and users' data protection, patient safety, and right to information and cooperation (cf Health Personnel Act section 1 letter b). Further and more precise provisions are given in the regulation on patient journals (FOR-2019-03-01-168).

In addition, the Health Personnel Act also provides rules concerning medical records. Anyone providing healthcare has a duty to write down or register, among other things, relevant and necessary information about the patient and the healthcare provided (cf Health Personnel Act sections 39 and 40). The rule is general, which means that it also concerns healthcare provided digitally and with the use of teleservices. This duty concerns the health personnel in charge of every individual case. If healthcare personnel use the telemedicine method only to obtain advice from a specialist, it is not necessary for the specialist to create his/her own medical record for the patient.

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

No.

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

Free informed consent from the patient or the patient's legal representative is the groundwork for all treatment provided to a patient in Norway (cf Patients and User Rights Act (Act 2 July 1997 No 63) section 4-1). Consent can be limited to not include the use of telehealth, but, in general, one assumes that consent includes the use of telehealth.

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

No.

**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.**

Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. The patient's personal data in medical records must be preserved in accordance with requirements related to the privacy and professional secrecy of the information set forth in the applicable legal framework, particularly:

- The General Data Protection Regulation 2016/679 (the 'GDPR') (<https://gdpr-info.eu/>);
- HTL: Helse- og omsorgstjenesteloven (Health and Care Services Act)

(<https://lovdata.no/dokument/NL/lov/2011-06-24-30>);

- PBL: Pasient- og brukerrettighetsloven (Patient Rights Act)  
(<https://lovdata.no/dokument/NL/lov/1999-07-02-63>);
- PJF: Pasientjournalforskriften (Patient Records Regulation)  
(<https://lovdata.no/dokument/SF/forskrift/2019-03-01-168>);
- PjL: Pasientjournalloven (Patient Records Act)  
(<https://lovdata.no/dokument/NL/lov/2014-06-20-42>);
- HPL: Helsepersonelloven (Health Personnel Act)  
(<https://lovdata.no/dokument/NL/lov/1999-07-02-64>);
- ARKL: Arkivlova (Archives Act)  
(<https://lovdata.no/dokument/NL/lov/1992-12-04-126>); and
- FIKT: Forskrift om IKT-standarder i helse- og omsorgstjenesten (Regulation on ICT standards in the healthcare and care services)  
(<https://lovdata.no/dokument/SF/forskrift/2015-07-01-853>).

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

Yes, applicable regulations provide for criteria and requirements for security systems to protect the patient's information. The GDPR applies through the Norwegian implementation, 'The Personal Data Act'. In addition, several sector specific laws are relevant for security systems used to protect patient's information.

Article 32 of the GDPR implies a risk-based approach to the security of the processing of personal data. When processing personal data, one must take appropriate technical and organisational measures to ensure the level of security appropriate to the risk. This may include pseudonymisation, encryption, ensuring the ongoing availability of processing systems and assessing such measures on a regular basis. Similar minimum requirements are stipulated in the sector-specific regulations (eg, the Patient Records Act sections 22 and 23, and the Health Registry Act section 6). In addition, the Regulation on ICT-standards in the healthcare sector includes several minimum requirements (eg, for the use of software) for the electronic processing of personal health data.

The Directorate of eHealth has established the Code of conduct for information security and data protection in the healthcare and care services sector (the 'Code').<sup>2</sup> This is a comprehensive *guideline* for organisations and enterprises in the healthcare and care services sector. Even though it is not mandatory, it reflects both best practice, as well as the level of security and data

<sup>2</sup> The Code is available in English at <https://ehelse.no/normen/documents-in-english> accessed 16 May 2023.

protection needed in order to comply with the requirements in both the GDPR and sector-specific laws and regulations when processing health data. The appendix 'Overall summary of the requirements of the Code' maps all the specific technical and organisational requirements in the Code against the relevant provisions that form the legal basis.<sup>3</sup>

In order to be linked to, and utilise, the national infrastructure for electronic communication in the health sector (the Norwegian Health Network), all providers of health services must enter into an 'affiliation agreement' with the Norsk Helsenett SF. By the force of this agreement, the entity admitted to the infrastructure is obliged to comply with the Code. By this mechanism, health service providers ensure that the receivers of health-related data – that is, collaborating partners of many kinds – within the network all meet the standards of the Code, and thus of the legal provisions. Failing to meet the information security standards of the Code may lead to the exclusion of the contract-breaching entity.

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

Yes, chapter V of the GDPR and the Schrems II judgment set requirements for the transfer of personal data to third countries (ie, countries that are not members of the EU or European Economic Area (EEA)). The protection of personal data in the import country must be 'essentially equivalent' to the protection of personal data in the EU/EEA. The transfer of personal data must be subject to appropriate safeguards in accordance with chapter V of the GDPR.

**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 Health Registry Act regulates the processing of health data in filing systems that is not meant for treatment purposes, but for statistical purposes, health analysis, research, quality improvement, planning and emergency preparedness in the health sector. The Health Registry Act includes specific requirements for the establishment of such filing systems. A prerequisite for establishing such filing systems is to have a legal basis in applicable legislation. Each of these filing systems is subject to its own regulations.

The Patient Records Act regulates the processing of health data for treatment purposes. Filing systems used for treatment purposes must have a legal basis in sector-specific Norwegian law, in addition to the GDPR. Further, the Patient Records Act includes a prohibition on the acquisition of personal health data from such filing systems, unless it is justified for individual healthcare or there is a legal basis in applicable legislation.

<sup>3</sup> The appendix is available in English at <https://ehelse.no/normen/documents-in-english/Appendix%20%E2%80%93%20Overall%20summary%20of%20the%20requirements%20of%20the%20Code.docx> accessed 16 May 2023.



## LIABILITIES

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

In Norway, there is a system of compensation to patients who have suffered an injury related to error or omission in the healthcare treatment (cf Patient Injury Act (Act 15 June 2001 No 53)). The act applies to injuries caused by institutions in the public health service, injuries caused during transport by ambulance and injuries caused by health personnel providing healthcare in accordance with public authorisation or license (cf Patient Injury Act section 1). Claims for compensation according to the Patient Injury Act are handled by the Norwegian System of Patient Injury Compensation ('NPE').

The scheme is mainly funded by the regional healthcare trusts, but contributions are also paid by individual hospitals, counties, municipalities and private health services.

Further, a healthcare professional who is violating his/her legal obligations may be criminally prosecuted, but a range of other measures may be taken by the authorities, such as the withdrawal of a licence and the right to prescribe medicine. Healthcare personnel may, moreover, be personally liable for losses incurred in line with general principles on compensation and liability. Furthermore, the employer of the healthcare professional may also be liable for losses incurred due to the violation of applicable legislation.

## TELEMEDICINE NUMBERS AND TRENDS

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

Yes, for example:

- e-consultation at doctors and emergency rooms:  
[www.helsedirektoratet.no/rapporter/e-konsultasjon-helsedirektoratet-og-direktoratet-for-e-helse/E-konsultasjon-per-cent20hos-per-cent20fastlege-per-cent20og-per-cent20legevakt-per-cent202018.pdf/\\_attachment/inline/8b3f4e77-4511-4500-8194-cb1a634c0c23:84604a3c7260d55cec2336507f3c7a504e5e29a7/E-konsultasjon-per-cent20hos-per-cent20fastlege-per-cent20og-per-cent20legevakt-per-cent202018.pdf](http://www.helsedirektoratet.no/rapporter/e-konsultasjon-helsedirektoratet-og-direktoratet-for-e-helse/E-konsultasjon-per-cent20hos-per-cent20fastlege-per-cent20og-per-cent20legevakt-per-cent202018.pdf/_attachment/inline/8b3f4e77-4511-4500-8194-cb1a634c0c23:84604a3c7260d55cec2336507f3c7a504e5e29a7/E-konsultasjon-per-cent20hos-per-cent20fastlege-per-cent20og-per-cent20legevakt-per-cent202018.pdf);
- use of video during the pandemic: [www.ehelse.no/aktuelt/praktiske-rad-til-helsepersonell-om-god-bruk-av-videokonsultasjon](http://www.ehelse.no/aktuelt/praktiske-rad-til-helsepersonell-om-god-bruk-av-videokonsultasjon);
- expectations of e-consultations:  
<https://sykepleien.no/forskning/2021/06/helsepersonells-forventninger-til-e-konsultasjon-en-kvalitativ-studie>; and
- strategy to increase health competence among the public:  
[www.regjeringen.no/contentassets/97bb7d5c2dbf46be91c9df38a4c94183/strategi-helsekompetanse-uu.pdf](http://www.regjeringen.no/contentassets/97bb7d5c2dbf46be91c9df38a4c94183/strategi-helsekompetanse-uu.pdf).

### 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.

Telemedicine offers a range of possibilities for the Norwegian healthcare system, not only in terms of efficiency and costs but also the possibility that it may alter the current standards of care for specific conditions. Especially due to Norway's geography, the usage of telemedicine may be key to ensure modern and high-quality health services throughout the country.

Telemedicine is already an integrated part of the Norwegian healthcare system and we expect the main challenges in the future will be to decide which health services are fit for telemedicine, and specifically, health services that can use software solutions to prescribe medicine.

Development is, to some extent, expected to be driven by privately owned entities that are challenging the established and traditional way of performing health services.