

## 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?

Telemedicine is allowed in Denmark. As a rule, telemedicine is subject to the same regulation as other healthcare services. However, no clear definition of telemedicine has been laid down in Danish legislative acts. See question 2.

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

Telemedicine is subject to compliance with the general regulatory framework governing provision of health services, for example:

- Danish Act No 210/2022 on health (the 'Health Act');
- Danish Act No 995/2018 on complaints and damages claims in the healthcare sector (the 'Healthcare Compensation Act');
- Danish Act No 731/2019 on authorisation of healthcare professionals (the 'Authorisation Act');
- Danish Executive Order No 3/2013 on authorised healthcare professionals' patient records (record keeping, storage, dissemination and transfer etc) (the 'Health Records Order'); and
- Regulation (EU) 2016/679 on data protection (GDPR) and the supplementing Danish Act No 502/2018 on data protection (DPA);

The Danish Patient Safety Agency (DPSA) has published Guidance No 9796/2021 on liability on the use of telemedicine between healthcare professionals to assist in situations where an authorised healthcare professional uses, for example, video, images, audio or measurement results to involve another authorised healthcare professional, who is not physically present where the patient is, in the treatment of the patient. The guidance addresses, in addition to questions on liability, questions on information and consent, confidentiality and disclosure of health information and record keeping in relation to the use of certain telemedicine services. See in more detail below.

In Denmark, treatment of patients is not restricted only to healthcare professionals (HCPs) authorised by the DPSA. Treatment can be performed by anyone, provided it does not expose the patient to an apparent risk.

Meanwhile, the use of certain professional titles, including that of 'læge' (in English: doctor), and certain activities are reserved for HCPs. Individuals who are not authorised by the DPSA cannot use reserved titles and or perform reserved activities.

According to the Authorisation Act, HCPs are obliged to exercise the profession with due care and attention. Further to the requirement on due care, the Health Act lays down an obligation for general practitioners to exercise their profession in accordance with national treatment guidelines..

Thus, as a rule, telemedicine (in itself) is not considered an activity or service that is reserved for HCPs. The performance of telemedicine must comply with the general requirements and if performed by an HCP it may not, in all cases, be in line with the applicable treatment guideline or general professional standards.

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

The DPSA authorises HCPs pursuant to the Authorisation Act and is tasked with the supervision of health services provided in Denmark. The DPSA is an authority under the Ministry of Health.

As described above, telemedicine is subject to the general framework governing provision of health services in Denmark and no specific licence is required to offer services by way of telemedicine.

The Danish Patient Complaints Agency handles complaints from patients related to treatments.

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

Telemedicine was not specifically authorised during the Covid-19 pandemic as telemedicine was never prohibited or specifically regulated in Denmark. However, the Covid-19 pandemic saw an increase in the use of telemedicine in Denmark and video consultations were among other measures implemented across the healthcare sector.

Fear of hospital bed shortage during Covid-19 may also have played a part in advancing Region Zealand's planned set up involving an eHospital, offering decentralised telemedicine services in several areas to limit the strain on patients physically present at the regional hospitals.

In regard to clinical trials, the Danish Medicines Agency (DKMA) published a guidance on exceptional measures in clinical trials under Covid-19, which, inter alia, extended access to exemptions and the use of telemedicine. The extended access was not renewed with the latest update of the guidance, and the guidance and authorised exemptions expired on 31 December 2021.

To reduce risk of Covid-19 spreading, the Ministry of Health also published guidelines encouraging consultations by phone and video whenever possible. General practitioners and medical specialists in private practice were referred to use the app *MinLæge* (in English: MyDoctor) for easy and secure telemedicine services.

**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 present legislation already accommodates telemedicine tacitly. It is not expected that there will be an express authorisation of telemedicine. However patient safety and other valid considerations may justify the introduction of specific requirements for the solutions used.

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

As a rule, any type of teleservice is allowed and is subject to the applicable legislation on healthcare and patient safety, including the general obligation to exercise due care and attention and to follow applicable treatment guidelines. See the answer to question 2 and 10.

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

Anyone can use telemedicine services. HCPs may provide telemedicine services subject to compliance with the general requirements for authorised HCPs, including the general obligation to exercise due care and attention and to follow applicable treatment guidelines. See question 2.

The HCP assumes independent responsibility for the professional conduct of the work and for compliance with the legal provisions and treatment guidelines applicable to a given specialist area. Provision of both doctor-doctor and patient-doctor telemedicine services are allowed.

**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.**

The majority of healthcare services in Denmark are financed by general taxes and mainly provided free of charge. When telemedicine is used as a service in the Danish public health sector, treatment is generally provided free of charge for citizens in the same way as other treatments.

The Health Act lays out which groups of individuals are entitled to which health services.

In the primary sector, it is ensured by collective agreement that general practitioners must offer e-consultations for a certain charge compensated by the regions. The charge for e-consultations is lower compared to in-person consultations. However, in relation to the collective agreement, e-consultations should be understood as simple, concrete requests of a non-urgent nature, which do not require answers to additional questions from the doctor. In other words, it is a simple form of contact, typically via a mail-like function.

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

Providers of health service through telemedicine are subject to the same rules as any other provider of health service. See question 2.

Patients in Denmark can seek compensation through the Danish Patient Compensation scheme if they suffer a treatment injury in Denmark.

The scheme covers treatment in hospitals, at general practitioners, nursing homes and residential institutions where the treatment took place. The Patient Compensation scheme applies regardless of whether the treatment took place in a public or private institution.

The Danish Patient Compensation awards compensation to the claimant. However, compensation is financed and paid from the place where the injury occurred. Compensation for injuries that occur in regional health care (eg, public hospitals or at the general practitioner's) is paid by the region concerned. Compensation for injuries sustained in municipal health care is financed by the municipality concerned. Compensation for injuries in private hospitals, private clinics or private practitioners is financed by the region of establishment with the possibility of recourse against the private provider.

**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**

<b>applicable rules (eg, nurses, psychologists, nutritionists, alternative health therapies providers, etc).</b>
<p>Anyone can use telemedicine services. HCPs may provide telemedicine services subject to compliance with the general requirements for authorised HCPs, including the general obligation to exercise due care and attention and to follow applicable treatment guidelines. See also question 2.</p> <p>HCPs may delegate the performance of most tasks to assistants (see Executive Order no 1219/2009 on the use of assistance – delegation of reserved healthcare activities). The order sets out the conditions under which an HCP authorised under the Authorisation Act may delegate reserved healthcare activities, subject to requirement to ensure that the assistant is qualified and to supervise as necessary.</p> <p>Guidance No 9796/2021 on liability, involving telemedicine between healthcare professionals, provides that each HCP has an independent responsibility to ensure that the assessments and treatments they carry out are sound and are supported by the necessary examinations and information.</p> <p>The guidance further states that it is the responsibility of the management to ensure that the necessary framework is in place for the individual health professional to exercise and use telemedicine services with due care and diligence. Management shall, as appropriate, develop instructions and procedures to ensure that patients are properly examined and treated when using telemedicine.</p> <p>See question 16 on patient records.</p>
<b>11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?</b>
No.
<b>12. Is there any registration requirement applicable to physicians that provide telemedicine services?</b>
No. There is a general requirement for all private, municipal, regional and state healthcare facilities to be registered in the Healthcare Facility Register through the DPSA.
<b>13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</b>
No special licences or authorisations are mandatory 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>Executive Order No 160/2013 on standards for IT application in the health sector and the related guidance No 9331/2013 lay down requirements applicable to all IT-solutions and platforms used in the Danish healthcare sector, which also cover telemedicine.</p> <p>The order stipulates that the government, regions, municipalities, private hospitals and clinics, including practicing healthcare professionals, are obliged to ensure that their IT systems use the standards for IT application in the health sector approved by the Danish Health Data Agency (DHDA). The executive order mandates the DHDA to approve standards, including data</p>

standards, classifications and interface standards, for IT applications in the health sector upon consultation with the national board of health IT. The DHDA lays down the requirements, including requirements to documentation, that standards must satisfy to be approved.  The standards are available at <a href="http://www.medcom.dk/standarder">www.medcom.dk/standarder</a> .  In addition, see below under 'Data Privacy Aspects'.
<b>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</b>
See the answer to question 14.
<b>16. Does the legislation provide for specific rules concerning patients' medical records?</b>
<p>Yes. Chapter 6 of the Authorisation Act lays down the general requirement to keep patient records and provisions regarding the content of such records. The Patient Records Order supplements the Danish Health Act and lays down requirements for patient records for all authorised HCPs and persons acting under their responsibility when providing patient treatment.</p> <p>Guidance No 9796/2021, on liability in the use of telemedicine between HCPs, addresses questions on record keeping in relation to the use of certain telemedicine services., See also question 1.</p> <p>The general principle is that the obligation to keep a patient record is imposed on any HCP who carries out examination or treatment of patients (irrespective of the medium).</p> <p>It follows from the guidance document that an HCP who, by telemedicine, obtains advice from another HCP in relation to the treatment of a patient, is responsible for ensuring that the advice and dialogue is recorded. The medical record shall contain, as appropriate, information on the referral and the advice given, the name or other unique identifier of the HCP providing the advice, the title and, if necessary, the place of work. The person giving advice in the context of the treatment of a patient is not obliged to keep a medical record.</p>
<b>17. Are there geographic location requirements applicable to the provision of telemedicine services?</b>
<p>No, there are no geographic location requirements applicable to the provision of telemedicine services. The Authorisation Act and the requirement to obtain an authorisation is only applicable to HCPs located in Denmark. There is no requirement that a telemedicine service provider must be established in Denmark.</p> <p>In regard to provision of telemedicine services to patients located in Denmark by an HCP established in another EU member state, reference is made to noted Directive 2011/24/EU, preamble 19 and article 3(1)d). It provides that in such cases of telemedicine the applicable rules are those of the Member State where the HCP is established.</p>
<b>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</b>
The general rules under the Health Act apply to consent of treatment and sharing of health data and no explicit consent to telehealth is required. Please see below under 'Data Privacy Aspects'.
<b>19. Is there any other important requirement that should be highlighted?</b>
No.

## 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.

There are no specific data privacy rules regarding telemedicine. However, personal data must always be processed in accordance with the GDPR and the DPA.

This means that the processing must comply with the general data protection principles stipulated in GDPR Article 5 (a)-(f), eg, legitimate purpose, data minimisation, retention of personal data and the principle of proportionality.

The principles themselves are as follows:

- Personal data should be processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency').
- Personal data should be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes ('purpose limitation').
- Personal data should be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation').
- Personal data should be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy').
- Personal data should be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed ('storage limitation').
- Personal data should be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage using appropriate technical or organisational measures ('integrity and confidentiality').
- Responsibility: the data controller is responsible for compliance with the above principles. Several of these principles apply to the data processor, as well.
- Consequently, the processing of personal data must be carried out in accordance with these principles.

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

According to the GDPR a data controller is required to implement appropriate technical and organisational security measures to protect personal data against risk, in particular from accidental or unlawful destruction or loss, alteration, unauthorised disclosure or access in accordance with the GDPR Article 32. This also applies for systems containing patient information.

The following are examples of the security measures which may be appropriate:

- pseudonymisation and encryption of personal data,

- ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services; and
- a process for regularly testing, assessing, and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

On a more practical level, it is important to ensure that staff training on data security is in place, that there are staff protocols and policies for dealing with data security incidents and that there is a log to record security breaches and how they have been managed.

Specifically for Denmark, it is a requirement from the Danish Data Protection Agency that sensitive and confidential information is sent encrypted when transmitted over an open net such as the world wide web.

Consequently, companies must either use Transport Layer Security (TLS) encryption or end-to-end encryption in order to fulfil the requirements from the DPA.

Confidential information could for example be personal identification numbers (CPR number) where sensitive personal data could be information relating to health.

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

The GDPR restricts transfers of personal data to countries outside the EU/EEA or international organisations unless the rights of the data subject are otherwise protected, or an exception applies.

The personal data may, however, be transferred to a third country or international organisation provided that at least one of the following is satisfied:

- the Commission has decided that the third country, a territory or one or more specified sectors within that third country or the international organisation ensures an adequate level of protection (GDPR Article 45);
- the data controller or data processor has provided appropriate safeguards and enforceable data subject rights and effective legal remedies for data subjects are available (GDPR Article 46) (examples of safeguards may be those provided for by binding corporate rules or standard data protection clauses); or
- exceptions for specific situations exist (GDPR Article 49).

However, even if there is a legal basis to transfer data to a third country, it is still a requirement to implement technical and organisational security measures to minimise the risk of the personal data being transferred. See above in section 22.

Consequently, it would be a requirement to rely on the EU Commission's Standard Contractual Clauses when transferring personal data outside EU/EEA to either a data processor or a data controller.

## **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?**

There are no specific rules regarding telemedicine and registration of databases.

However, personal data must always be processed in accordance with the general data protection principles stipulated in GDPR Article 5 (a)-(f), eg, legitimate purpose, data minimisation, retention of personal data and the principle of proportionality. See the principles themselves above in section 20

## LIABILITIES

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

The general legal framework for liability for provision of patient treatment applies (see above). HCPs are obliged to exercise due care and attention and must follow national guidelines. Operators must organise treatment facilities for which they are responsible in a way that ensures HCPs are able to carry out their duties in a professionally responsible manner and comply with the obligations arising from the legislation, including with respect to patient records and delegation to assistants. See the answer to question 2.

With respect specifically to liability, it follows that the HCP and/or the employer (operator) may be liable for damages. Such a claim may be based on contract or tort. See question 9 on insurance requirements and patient compensation. Usually, claims covered through the Patient Compensation Claims scheme cannot be directed against the HCP, except for recourse claims in the event of gross negligence or intentional misconduct.

## TELEMEDICINE NUMBERS AND TRENDS

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

Telemedicine is widely accepted in Denmark and public information concerning the use of telemedicine is available through the relevant authorities and agencies, for example, but not limited to, the DHDA, the DPA, the Danish Patient Complaints Agency, and the relevant guides on the Danish Health Authority's website. For instance, an overview of national clinical guidelines and recommendations prepared by the Health Authority may be accessed by this [link](#).

### 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 is commonly accepted and widely relied on in Danish healthcare. There is definitely a trend towards more telemedicine. Some mentionable projects and other trends are:

- The Framework Agreement on Telemedicine ([link](#))
- Telemedicine for citizens with COPD ([link](#))
- Telemedicine for citizens with heart failure ([link](#))
- Telemedical Wound Assessment ([link](#))
- Common support for telemedicine (*Fælles Understøttelse af Telemedicin* (FUT)) ([link](#))

A relevant and perhaps yet unresolved issue is to what extent telemedicine can be applied without breaching the HCP's obligation to exercise the profession with due care and conscience. Experts do not necessarily agree to what extent physical examinations may be replaced by video calls and surveys.

In collaboration with the Centre for Innovative Medical Technology (CIMT) and with support from HelseFonden (the Health Foundation), the Danish Society for Patient Safety carried out a major analysis of international and Danish experiences with telemedicine and its effects on patient safety. A systematic literature review, in which data from 59 publications has been analysed, shows that telemedicine can have both positive and negative effects on patient safety. Interviews with HCPs have indicated that, in some cases, telemedicine can support care which



is timelier, patient-centred, safe, and more in line with a patient's needs and wishes. In other cases, telemedicine can jeopardise patient safety according to the study.

Another topic is the vast national differences between EU Member States on telemedicine-related laws. The proposed Regulation on the European Health Data Space is a ground-breaking but debated initiative that may have a major impact on the development of telemedicine across the EU, including in particular Denmark. Many organisations and the authorities in Denmark are currently scrutinising the initiative and the possible effects.