TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Stephan Rau, Nadine Hartung, Sylvia Petereit-Kemter and Lea Hachmeister, McDermott Will & Emery

Date of completion: 2 December 2022

LAWS AND REGULATIONS ON TELEMEDICINE

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

The provision of telemedicine services is generally allowed in Germany, but the term is not (uniformly) defined under German law.

The Medical Associations of Physicians (*Ärztekammern)* in Germany describe 'telemedicine' as a wide range of medical care concepts that have in common the approach of providing medical services remotely in the areas of diagnostics, therapy and rehabilitation, and using information and communication technologies (ICT) for this purpose. The Medical Professional Regulations (*Musterberufsordnung für Ärzte* (MBO-Ä)) refer to 'telemedicine' as patient's 'consultation or treatment via communication media'.

Section 9 sentence 1 of the Medicines Advertising Act (*Heilmittelwerbegesetz* (HWG)) defines remote treatment as the detection or treatment of disease, illness, bodily injury, or pathological complaint that is not based on one's own perception of the human or animal being treated. Furthermore, according to the framework agreement concerning the scope of the provision of outpatient services through telemedicine ('Framework Agreement Telemedicine') between the National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung*) and the Central Association of Statutory Health Insurance Funds (*Spitzenverband der Gesetzlichen Krankenkasen*), the term telemedicine is understood as the collection, recording and transfer of information or the application of medical procedures with the aid of electronic ICT between physicians, between physicians and patients and, if applicable, with the involvement of non-medical professionals in the event that they are not located in the same locality.

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

There is no particular statute that would explicitly permit or prohibit specific telemedical services. Broadly speaking, telemedical services shall be permissible if they are in accordance with medical guidelines and the state of scientific knowledge. Whether or not this is the case depends on the circumstances of the individual case.

Section 7 paragraph 4 of MBO-Ä specifies the requirements for telemedical treatment and allows telemedicine services generally as supportive treatment, provided that the patient treatment basically takes place in personal contact. An exclusive consultation or treatment via telemedicine (without any personal contact), is only permitted in individual cases if: (i) the exclusive telemedicine treatment is medically justifiable; (ii) the required duty of medical care (*ärztliche Sorgfaltspflicht*) is maintained, in particular by the manner in which diagnosis, consultation, treatment and documentation are carried out; and (iii) the patient is explicitly informed about the specific nature and limits of a treatment exclusively via communication

media. In view of the fact that medical professional law is state law, the implementation of Section 7 paragraph 4 of MBO-Ä in the respective state-law is decisive and cannot deviate.

The Federal Master Treaty for Medical Practitioners (*Bundesmantelvertrag-Ärzte* (BMV-Ä) governs the requirements for the performance of telemedicine services in Annexes 31, 31a and 31b. By way of example, the technical requirements for panel doctors are set out in Annex 31b BMV-Ä. According to this, only technical providers that have been certified beforehand may be used.

Advertising for telemedical treatments is only allowed under strict conditions (section 9 HWG). It is only allowed if the treatment to be performed does not require personal contact with a physician according to generally recognised professional standards (section 9 sentence 2 HWG).

General data protection requirements under the General Data Protection Regulation (GDPR) (EU) 2016/679 apply.

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

In general, physicians do not require a licence to provide telemedicine. However, in order to be able to invoice and claim reimbursement from the statutory health insurance (*Gesetzliche Krankenversicherung* (SHI) funds for the performance of remote treatment, physicians need a special billing permission for certain telemedicine services (eg, telemedical monitoring of active cardiac rhythm implants) and must use a certified service provider (Annex 31b BMV-Ä). The service provider must prove its certification to the regional Association of Statutory Health Insurance Physicians (*Kassenärztliche Vereinigung* (KV)). All certified service providers are published in a list by the National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung* (KBV)).

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

Since 2018, telemedicine has been permitted in Germany (section 7 para. 4 MBO-Ä).

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?

Due to the pandemic, various frameworks of telemedicine and related fields have been simplified or changed. However, parts of the regulations have already been withdrawn.

For example, physicians and psychotherapists had been able to offer unlimited video consultations from the period of April 2020 to April 2022. The number of cases or the volume of services had been unlimited due to the pandemic.

In general, the pandemic has not been the reason for the progress in digitalisation. However, it has accelerated the growth of new technologies and measures.

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

Certain procedures are mentioned in the Fifth Book of the German Social Code (*Fünftes Buch Sozialgesetzbuch* (SGB V)) that apply to any medical treatment within the SHI.

Telemedical consultation and telemedical treatment

The supportive use of telemedicine has been permissible for a few years in Germany, while the exclusive remote treatment was allowed by medical professional regulations in 2018.

Telemonitoring

Technical procedures for the data-based timely management of diseases in order to take care of patients remotely are permitted. In telemonitoring, vital parameters or other patient-related data are transmitted from the patient to the physician and, if necessary, therapy adjustments are made based on the data transmission (eg, pacemaker monitoring).

Teleconsult

The consultative exchange between physicians or with members of other healthcare professions is allowed under German law.

Telesurgery

Telesurgery is neither permitted nor prohibited. Telesurgery is simply not yet practiced in Germany because the technical requirements are not yet sufficiently developed. Therefore, it is also not (yet) mentioned in the SGB V or any other law.

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

Both physicians and patients can use telemedicine services.

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.

In general, telemedical services are covered by private health insurance (PHI) and SHI in Germany. Both, SHI licenced physicians and private physicians can bill for telemedicine services.

The standardised statutory fee scale (einheitlicher Bewertungsmaßstab (EBM) specifies the majority of physician services that are in compliance with the principle of economic efficiency and therefore reimbursable within the SHI system. For telemedicine, corresponding billing positions have been assigned to the EBM billing catalogue. So far, this has only been the case for telemedical services in isolated cases (eg, video consulting hour, teleconsultation in the evaluation of X-rays and CT scans, telemonitoring of patients with a defibrillator or CRT system). However, panel physicians or psychotherapists can only bill for telemedical consultation services if they have previously notified to their KV that they will be using a certified video service provider.

The legal situation differs slightly within the PHI sector. Telemedicine services rendered within the PHI sector, are billed under the physician fee schedule (*Gebührenordnung für Ärzte* (GOÄ)) as conservative billing positions in analogous application for telemedicine services. There are no special rules or rates for telemedical services. Even if the fee schedule does not fit the special features of remote treatment, it is applied accordingly.

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

No specific insurance requirements apply. The physician is legally required to have a professional liability insurance for the practise of their profession anyway.

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, alternative health therapies providers, etc).

Telemedicine is a form of medical practice like any other and teleconsultation is open to all qualified healthcare practitioners in Germany, regardless of the medical field in which they work or the type of patients they treat (private or statutory health insurance). Furthermore, telemedicine can also be performed by psychotherapists and billed to health insurance companies.

Medical treatments that non-medical and adequately qualified personnel are permitted to perform may also be carried out or their performance instructed within the framework of remote treatment in individual cases. For example, in the context of wound care by a wound care manager.

Within this framework, the principles of secure technical design of remote treatment, data protection and explicit consent to remote treatment also apply. No special legal provisions of remote treatment by non-physician personnel are in place. In practice, the legal requirements for remote treatment by physicians are followed.

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

Under German healthcare law physicians/practitioners are not required to undergo specific education or training prior to the provision of telemedicine services.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

The service provider must be certified. The panel physicians must notify the service provider to their respective KV.

13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

Under German healthcare law, there is no specific licence requirement or registration of healthcare facilities or the healthcare providers (physicians, nurse, etc) prior to offering

telehealth services in addition to the usual licence and permission requirements for conservative medical services, which are the following:

1. The provision and reimbursement of inpatient physician services within the SHI system requires the admission of the hospital to the treatment of SHI-patients, either by way of inclusion in the state hospital plan (so called 'plan hospitals') on the basis of a planning decision (*Feststellungsbescheid*). Such planning decision constitutes an administrative order and is issued by the competent planning authority of the federal state (Section 108(2), SGB-V). Alternatively, hospitals may be admitted by way of admission contracts with the state associations of the SHI funds (so called 'contract hospitals'; Section 108(3), SGB V). Such admission contracts require the consent of the competent planning authority.
2. The provision and reimbursement of outpatient physician services within the SHI system requires a respective licence as a physician service provider under Section 95, Panel Doctor Approval (*Vertragsarztzulassung* (SGB-V). The licence is granted by way of an administrative order issued by the competent regional admission board *(Zulassungsausschuss*). The licence as outpatient physician service provider may be granted either to individual panel doctors (*Vertragsärzte*)or to Medical Care Centres (MCC). Any legal entity other than doctors' partnership requires a licence as MCC in order to be entitled to render outpatient physician services.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

Digital health platforms may qualify as medical devices according to EU Regulation 2017/745 on Medical Devices (MDR)). As EU regulation, MDR is applicable in Germany and does not have to be transposed into national law.

The regulations are complemented by the German Act on the Implementation of EU Medical Devices Law (*Medizinprodukte-Durchführungsgesetz* (MPDG)). A software application may qualify as a medical device if it has a medical purpose. The intended purpose of a product is the use for which it is intended according to the information supplied by the manufacturer on the label, in the instructions for use, in the performance evaluation, in promotional or sales materials or other product related statements.

As a result of the decisive factor being the intended purpose specified by the manufacturer, the manufacturer has a significant say in the product qualification. According to a landmark decision of the Court of Justice of the European Union (CJEU), even if a product appears to have a medical function, it is not considered a medical device if the manufacturer clearly communicates that it is not intended for a medical use (CJEU decision of 22 November 2013, C-291/11 – *Brain Products*). However, this subjective component of the determination of the intended purpose by the manufacturer must not be misused to turn a product that is objectively only suitable for a medical purpose into a non-medical device by means of a different declaration (German Federal Court of Justice (BGH), decision of 18 April 2013 – I ZR 53/09). Platforms that only offer video consultations as telemedicine services are not classified as medical devices.

Telemedicine platforms are subject to the technical requirements according to Annex 31b BMV-Ä:

1. The transmission of the video consultation is to take place via a peer-to-peer connection between the physician and the patient, without the use of a central server.
2. In the event of a deviation from a peer-to-peer procedure, the video service provider is obliged to ensure an appropriate level of protection by means of suitable technical and organisational measures.
3. The video service provider must ensure that all content of the video consultation is encrypted end-to-end during the entire transmission process in accordance with the state of the art.
4. All content of the video consultation may neither be viewed nor stored by the video service provider.
5. The metadata/technical connection data must be deleted after three months at the latest and may only be used for the processes necessary for handling the video consultation.
6. Passing on the data is prohibited. The video service must not contain any advertising

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

By way of example, the video service provider must ensure that the video consultation is encrypted during the entire transmission (end-to-end) to be certified in accordance with medical professional regulations on IT security and data protection. (See question 14).

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

According to Section 630e German Civil Code (*Bürgerliches Gesetzbuch* (BGB)), the attending physician must document the treatment of a patient, in writing or digitally (patient file). The same requirements also apply in the context of telemedicine. The retention period is usually ten years after completion of treatment (Section 630e paragraph 3, BGB). Longer retention periods exist, for example, for X-ray images.

The physician may instruct the platform operator to maintain patient documentation with the patient's prior consent.

Since January 2021, the so-called electronic patient record (*elektronische Patientenakte* (ePA)) has been introduced in stages up to 2023. SHI have been required to enable their insured persons to use the ePA since 2021. With the patient's consent, the ePA can be used for documentation.

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

In view of the fact that medical professional law is state law, the implementation of Section 7 paragraph 4, MBO-Ä in the respective state-law is decisive. All state medical associations (*Landesärztekammern*) – with the exception of that of Brandenburg – have adopted the provision relevant for telemedicine (Section 7 paragraph 4 MBO-Ä) in their regional professional codes of conduct in identical wording or at least in a comparable form. With

respect to Brandenburg, telemedicine services are still only permitted in addition to a direct patient treatment in person, that is, an exclusive telemedicine treatment is still prohibited in Brandenburg – as it was the case in all federal states before 2018.

Furthermore, the legal situation as to which professional code for physicians applies when telemedical services are provided to patients abroad has not been finally clarified. Section 7 paragraph 4 MBO-Ä does not contain any provisions in this regard. This legal question has not yet been clarified by the highest court.

Under EU law further provisions exist:

1. The Directive 2011/24/EU provides that the law applicable to telehealth is the place of residence of the provider and, therefore, if a provider is entitled to practice telehealth in their own country, they can extend such service to patients in Germany.
2. In addition, the CJEU has long since considered that neither the specific nature of health services nor their organisational and financing models remove them from the ambit of the fundamental EU principle of freedom of movement. As such, patients are free to consult and receive medical treatment in an EU Member State other than their own, including remotely.

Please note that foreign physicians who wish to practice medicine in Germany must have their medical diploma recognised by the federal authority in whose area of competence they wish to work. As things currently stand, there is no such obligation for those practising abroad and providing telemedical services in favour of patients in Germany (eg, teleconsulting).

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

Under applicable data protection and medical professional laws, the patient's explicit consent (oral or written) is required prior to performing the telemedical service. The patient must be informed about the special characteristics of remote treatment. Moreover, the patient has to consent specifically to processing his health data under the GDPR in accordance with Article 9 GDPR. There are limited exemptions to such GDPR consent requirement, for example, where processing is necessary for the purposes of preventive medicine, medical diagnosis, provision of healthcare or treatment.

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

Please note, in Germany a distinction is made between physicians who are licenced within the SHI system and private physicians.

The strict technical requirements under BMV-Ä apply only to SHI licenced physicians. In practice, however, private physicians voluntarily submit to the same strict technical requirements when providing remote medical care. Therefore, in principle, a uniform standard exists for the performance of remote treatments.

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.

Telemedicine is subject to various data privacy regulations in Germany.

Processing of health data is only permitted in accordance with Article 9 GDPR, that is, on the basis of consent or other legal exemptions set out in the GDPR or in German law. Consent must be voluntarily given, specific, informed and unambiguous. Consent may not be required, inter alia, where processing is necessary for the purposes of preventive medicine, medical diagnosis, provision of healthcare or treatment.

Physicians are subject to strict medical secrecy obligations, inter alia, pursuant to professional laws and the German Federal Criminal Code (S*trafgesetzbuch* (StGB)). In principle, physicians may only share patient data with third parties if the respective patient expressly releases the physician from its confidentiality obligations.

Providers of telemedicine services need to comply with specific data privacy requirements to obtain reimbursement in the SHI regime. By way of example, they must cooperate with a certified video service provider (see Question 14).

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

In Germany, data governance is subject to general data protection and security principles under the GDPR. Article 5 GDPR sets out six data protection principles that persons must follow when collecting, processing and storing individuals' personal data: (1) lawfulness, fairness and transparency; (2) purpose limitation; (3) data minimisation; (4) accuracy; (5) storage limitation; (6) integrity and confidentiality. The data controller is responsible for enforcing these principles and must be able to demonstrate the person's compliance practices.

Article 32 GDPR requires that data controllers implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk, including, inter alia, as appropriate:

(i) the pseudonymisation and encryption of personal data;

(ii) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;

(iii) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; and

(iv) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

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

Under German privacy laws, there is no data localisation requirement.

There is a 'single data market' involving all countries subject to the GDPR (ie, the 27 member states of the EU plus Iceland, Liechtenstein and Norway), as well as Switzerland and the UK. For all data transfers within the borders of this market, there are no particular data protection requirements. They are treated like every other data transfer.

Only where data leave the European single data market (eg, to other European countries that do not form part of the EU or to non-European countries) this would qualify as an 'international'

data transfer. Personal data transfer/access to recipients located in third countries which are not covered by an adequacy decision of the EU Commission shall be subject to appropriate safeguards such as standard contractual clauses (SCCs) adopted by the EU Commission or binding corporate rules (BCR). In accordance with the CJEU's *Schrems II* decision, it is also necessary to conduct a transfer impact assessment on the level of protection of data subjects' rights in the relevant third country, and to implement strong safeguards accordingly to ensure the protection of personal data from access by foreign authorities.

Such requirements also apply to pseudonymised or encrypted personal data transferred to or accessible from a third country which is not covered by an adequacy decision of the EU Commission. How-ever, anonymised data fall outside the scope of these requirements because they are not personal data within the meaning of the GDPR or the German privacy laws. Anonymisation is a technical operation that irreversibly alters data, so an individual is no longer identifiable directly or indirectly.

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?

See Questions 12 and 14.

LIABILITIES

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

Liability of Physician

A physician's liability may arise, among other things, in the context of a medical malpractice. Medical malpractice is understood as a violation of the generally recognised medical professional standard, that is, any medical measure that is improper according to the respective state of medical science. From civil law perspective, physician's liability for medical malpractice is based on the treatment contract (section 630a BGB) and/or tort law (section 823 BGB). From a criminal law perspective, a deviation from the required quality in the treatment of a patient that results in an injury may constitute a criminal offence (sections 223, 224, 226, 229 StGB).

Furthermore, under physicians' professional codes of each German federal state (*Berufsordnungen für Ärzte*), physicians are prohibited from accepting or requesting any economic advantage for:

(i) the referral of patients or patient samples;

(ii) the prescription of pharmaceuticals or medical devices;

(iii) the procurement of pharmaceutical or medical devices if directly applied to a patient by the physician; or

(iv) the recommendation of another physician, hospital, pharmacy or any other provider of health services or products.

The violation of any of the aforesaid prohibitions (i) – (iv) constitutes a criminal offence (Section 299a StGB).

In addition, the disclosure of patient data constitutes a criminal offence under Section 203 paragraph 1 StGB. At the same time, this may constitute a civil claim for damages due to a breach of a contractual duty. The disclosure of patient data without the patient's consent may also constitute a violation of Article 83 GDPR. A fine may be imposed for such a violation.

Liability of video service provider

Video service provider may be subject to civil law liability. Under German law, there is contractual liability and tort liability under the BGB, as well as product liability under the Product Liability Act (*Produkthaftungsgesetz* ('ProdHG')). Such liability cannot be restricted by a contract. Medical device software is subject to liability under the ProdHG, even if not offered in a material object as data carrier. Healthcare services are not subject to the ProdHG, but service providers may be liable under the respective contract or under the BGB provisions on tort.

TELEMEDICINE NUMBERS AND TRENDS

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

For many decades, telemedicine was largely restricted under German physicians' professional law. This had already started to change before the Covid-19 pandemic. In 2019, Germany had set the legal basis for telemedicine, including video consultation by physicians, and their coverage by private and public payers. The practical implementation of these laws has been accelerated significantly due to the pandemic and related restrictions on public life. The number of video consultations, online prescriptions and other types of remote patient treatment have meanwhile reached an all-time high. Physicians are now also allowed to issue a certificate for sick leave in a video consultation. Simultaneously, restrictions on the advertisement of telemedicine have, to some extent, been lifted.

The use of telemedicine has increased significantly. Prior to Covid-19 in 2019, the number of digital consultations was fewer than 3,000. In 2020, however, digital consultation use was nearly 2.7 million.

The use of telemedicine increased by a factor of 900 from 2020 to 2021 (see McKinsey & Company*, eHealth Monitor 2021*).

The population-representative study from 2021 shows that reducing the risk of infection is indeed the main reason for using an online consultation (82.1 per cent). However, more than eight out of ten patients (80.8 per cent) also appreciate the digital physician's visit because it means mobility restrictions are no longer a hurdle. Three-quarters (74.9 per cent) of German patients would consider a video consultation if it meant they could get an appointment more quickly. Almost as many (74.6 per cent) were convinced by the argument that they could avoid long travel times. Seven out of ten (69.4 per cent) would consider a video consultation if the waiting time in the digital waiting room was shorter than at the physician's office.

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.

In addition to the introduction of the video consultation, which directly enables the provision and reimbursement of telemedical services, there are various other projects in the context of the digitisation of the German healthcare system that improve both the physician's information options and the prescribable care offerings from the patient's perspective.

In 2015, the Secure Digital Communications and Applications in Healthcare Act (*Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen* ('E-Health Act') set the initial framework for the development of the secure telematics infrastructure (TI) and the introduction of medical applications. Since then, the digitisation of healthcare has been driven forward by various laws. TI connects practices, hospitals, pharmacies and other healthcare providers so that they can communicate with each other more efficiently and in a secure environment. TI also enables insured persons to provide their physicians with health data promptly and securely. Within the framework of the TI, the electronic prescription (*elektronisches Rezept*) is also transmitted. Since September 2022, pharmacies must have implemented processes to process electronical prescriptions. In January 2023, the use of electronic prescription is mandatory for physicians.

The ePA is a central element of digital and networked healthcare and the TI. SHI companies have been obliged to offer their members the ePA since January 2021. Since July 2021, all physicians and psychotherapists must have the necessary equipment to transfer data to the ePA via TI. Digital patient data is now to be collected centrally in one place. Currently, medical information in particular is stored in the ePA. In 2022, it should also be possible to implement, among other things, vaccination records, and in 2023 even nursing data and certificates of incapacity to work. The type and duration of access to the ePA are currently at the patient's discretion. By 2023, corresponding access should also be possible for insurance agents. Insured patients are also to be given the option of making their data from the ePA available for research purposes.

To strengthen cross-border patient safety, the national e-health contact point is also to be established by mid-2023 at the latest, so that insured patients can also make their health data available to physicians in other EU countries in a secure and translated manner, Section 219(d)(6) SGB V.

Furthermore, an upcoming trend are so-called digital health applications (*Digitale Gesundheitsanwendungen* (DiGA)). With the coming into force of the Digital Health Care Act (*Digitale-Versorgung-Ge-setz* (DVG)) in December 2019, an app for prescription for patients was introduced.