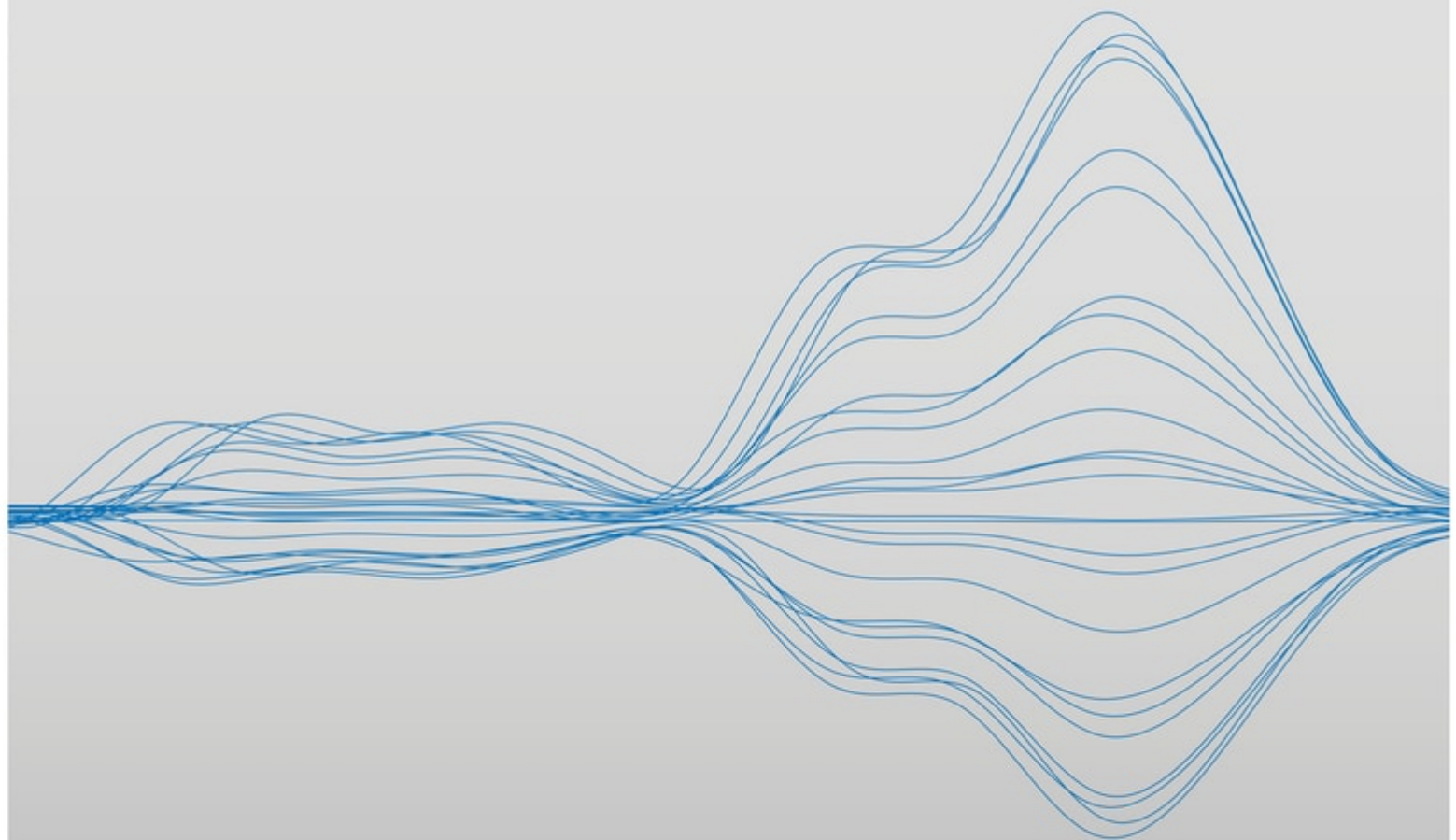


GERMANY

Telehealth around the world: a global guide



Introduction

The COVID-19 pandemic has caused healthcare systems around the globe to rapidly, and in some cases, radically rethink the delivery of medical care. The global expansion of telehealth services is one way we have seen this transformation occur. This has resulted in significant opportunities in the field, as well as unprecedented regulatory change.

As a quickly evolving area, 'telehealth' can have different meanings in different contexts. In this Global Guide, telehealth refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries. We have adapted this definition from the World Health Organisation's definition of telehealth.

Telehealth is not a new concept – healthcare providers, academics and technology developers have been advocating for its use for decades. There are many benefits to the widespread adoption of telehealth, including improved access to healthcare services, risk mitigation, convenience and flexibility, and in many cases, a reduction in overhead costs. However, the use of telehealth is not without its challenges. For example, it is not suited to all forms of healthcare, its implementation and adoption can be time consuming and costly, and additional care must be taken in relation to the transfer of patient health information.

The restrictions of movement in many parts of the world due to COVID-19 has caused governments to recognise the potential of telehealth, and amend laws and regulations seemingly overnight to enable healthcare providers to deploy telehealth solutions. Many governments have adopted telehealth reforms in a matter of weeks, which may otherwise have taken years to be considered and introduced.

Although many of these reforms presently have an expiration date (dependent on the duration of the COVID-19 pandemic), there is likely to be continued growth in telehealth due to the advantages of such a service – even after the pandemic. There are enormous opportunities in the telehealth space for businesses already operating in this field, businesses considering expanding into telehealth, and start-ups.

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis. As the field of telehealth, and the regulations underpinning it, remain highly dynamic and subject to change, this document is intended as a general guide and does not constitute legal advice. Should you wish to discuss any aspects of telehealth with a specialist lawyer, please contact us below.

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Germany

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Is the use of telehealth permitted?

Yes, telehealth is permitted as part of the regular healthcare services in Germany, within certain restrictions.

In Germany, the term 'telehealth' is used, often interchangeably, with the term 'telemedicine'. However, there exists no uniform definition of 'telehealth' or 'telemedicine' under German law. The German Medical Association ("BÄK") describes 'telemedicine' as a collective term for various medical care concepts which have in common that healthcare services for patients including diagnostics, therapy and rehabilitation, as well as medical decision support are provided over spatial distances (or temporal offset) using information and communication technologies ("ICT"). Telemedicine may generally comprise, inter alia, eCare, ePrevention, eAdministration, eResearch, and eLearning.

Telehealth is subject to certain restrictions under German law. As a general rule, physicians, dentists, psychotherapists as well as other healthcare professionals may advise and treat patients in in-person visits exclusively. However, ICT, e.g. authorised e-mail or audio-video chat platforms, may be used to assist in-person treatment of and communication with patients. By contrast, exclusively remote visits, diagnostics and / or treatments, i.e. without any prior real life interaction between healthcare professionals and patients, are only permitted within very strict limitations requiring a case-by-case evaluation of the medical appropriateness. However, based on experiences during the COVID-pandemic, Some German local Medical Associations ("ÄK") seems to interpret and enforce these requirements less strictly than others permitting video-consultation also without prior in-person contact between patient and physician.

How is telehealth regulated?

In Germany, the requirements of telehealth are not regulated in one specific law, but rather in a patchwork of different laws, regulations and directives.

Essential aspects of telehealth, e.g. remote treatment, prescription, reimbursement, documentation and informed consent requirements, are regulated, inter alia, in the new German Patients Data Protection Act ("PDSG"), the German Social Code Book V ("SGB V"), the German Federal Framework Agreement for Physicians ("BMV-Ä"), the German Drug Act ("AMG"), the German Act on Drug Advertising ("HWG"), the Model Professional Code for Physicians in Germany ("MBO-Ä") and the Model Professional Code for Psychological Psychotherapists and Child and Youth Psychotherapists ("MBO-P").

In addition, in December 2019, the German Digital Healthcare Act ("DVG") entered into force, introducing digital health apps as a new category of medical benefits which may be prescribed by doctors and have to be reimbursed by the Statutory Health Insurers ("SHI" – "GKV") subject to further requirements according to Sec. 33a of the SGB V.

Are there specific fields of healthcare in relation to which telehealth services are currently available, and do they involve the use of proprietary technology or platforms?

The scope of permitted applications of telehealth in Germany is very broad and there are no limitations to specific fields of medicine,

dentistry or psychotherapy. Telemedicine can be an integral part of almost every medical specialty. Furthermore, since April 2022, there is now also the possibility of telemonitoring of patients suffering from certain forms of cardiac insufficiencies: the patient's medical data are regularly transmitted to a telemedical center where the data is clinically monitored and the attending physician of the patient is informed in case of any irregularities that require further clinical action.

Telehealth applications / technologies must be approved by the German Federal Office for Information Security ("BSI") and / or the Society of Telematics ("gematik"). Telehealth applications / technologies that are currently authorised in Germany include, inter alia, online audio-video appointments, remote diagnostics and monitoring (e.g. patients with cardiac resynchronisation therapy (CRT), implants or implantable cardioverter defibrillators (ICD)) and online video conferences for case-related discussions (e.g. conciliar discussions of X-rays, CT scans & MRI's) from various providers. In contrast to that, commonly used videoconferencing / teleconferencing apps and platforms like Skype, Zoom, etc. are not approved for telehealth services in Germany. In addition, the German Federal Framework Agreement for Physicians ("BMV-Ä"), inter alia, stipulates further requirements of the technical procedures for the provision for certain telemedicine services by physicians accredited by the Statutory Health Insurers ("SHI" – "GKV"), for example, video consultations (cf. BMV-Ä, Annex 31b).

Does the public health system include telehealth services, and if so, are such services free of charge, subsidised or reimbursed? Where the public health system does not include telehealth services, are such services covered by private health insurance?

In Germany, health insurance (either statutory or private) is compulsory. Approximately 90% of the population in Germany is covered by the Statutory Health Insurance ("SHI" – "GKV") and only about 10% (the gross income of which is above the income threshold for compulsory insurance) by the Private Health Insurance ("PHI" – "PKV").

The SHI provides for a number of reimbursable telehealth services. Generally, telehealth services must be listed in the German Uniform Value Scale ("EBM") of the SHI according to Sec. 87 para. 1 of the SGB V in order to be reimbursable as standard medical benefits by the SHI. Currently, inter alia, remote monitoring for patients with cardiac resynchronisation therapy (CRT) implants or implantable cardioverter defibrillators (ICD), conciliar case discussions of X-rays, CT scans & MRI's as well as online video appointments are listed in the EBM. Furthermore, the reimbursement of telehealth services may be subject to further limitations. The EBM is regularly amended and other telehealth services may be included in the standard benefits of the SHI in the future.

As regards to telehealth services covered by the PHI, as a general rule, the medical benefits provided by the PHI in Germany are more extensive than those provided by SHI. Therefore, benefits reimbursed by the SHI are generally also reimbursed by the PHI. In principle, this also applies to telehealth services.

Do specific privacy and/or data protection laws apply to the provision of telehealth services?

The processing of personal data in the context of the provision of telehealth services is primarily governed by the General Data Protection Regulation (EU) 2016/679 ("GDPR"), as well as the German Federal Data Protection Act ("BDSG").

Apart from that, the German Social Code Book V ("SGB V"), contains several regulations on the processing of personal data in connection with telehealth services and has only recently been subject to amendments as a result of the German Patients Data Protection Act ("PDSG"), which came into force in October 2020. Particularly, the provisions relating the use of the electronic health card ("*elektronische Gesundheitskarte*") have undergone substantial amendments (Sec. 291 et seq. of the SGB V). Additionally, the new chapter 11 of the SGB V (cf. Sec. 306 – 383 of the SGB V) which now comprehensively regulates the requirements for the telematics infrastructure received great attention among stakeholders, in particular, the extensive reorganisation of the electronic patient record ("*elektronische Patientenakte*") (cf. Sec. 341 et seq. of the SGB V). It should be noted, however, that the provisions of the SGB V primarily apply to service providers of the German Statutory Health Insurances ("SHI" – "GKV") and only in certain exceptional cases also to service providers of the Private Health Insurances ("PHI" – "PKV").

How should the cross-border transfer of personal information collected and processed in the course of telehealth services be carried out to ensure compliance

with applicable privacy laws?

The cross-border transfer of personal data processed in the context of the provision of telehealth services must comply with Art. 44 et seq. of the GDPR. It must be assessed on a case-by-case basis, if these requirements are met.

Are there any currently applicable codes of conduct on the use of telehealth systems and/or security of telehealth data in your jurisdiction?

The German Medical Associations ("BÄK") and the German Psychological Psychotherapists Association ("BPTK") have published the updated Model Professional Code for Physicians in Germany ("MBO-Ä") and the Model Professional Code for Psychological Psychotherapists and Child and Youth Psychotherapists ("MBO-P"), respectively, which now also include regulations relating to telehealth.

The German data protection supervisory authorities have not yet issued publications on the provision of telehealth services. The German Federal Commissioner for Data Protection and Freedom of Information ("BfDI") published two brief recommendations regarding telehealth services in the 28th Annual Activity Report on Data Protection (2019) of which only one is addressed to telehealth providers.

In the Activity Report, the BfDI recommends the implementation of a differentiated roles and rights management for electronic medical records. On a more general note, the BfDI comments that the processing of sensitive health data in large volumes in a digital environment requires a high level of data protection and data security and that patients must retain control of their own data. In his 29th Annual Activity Report, the BfDI expressed doubts about the lawfulness of some of the provisions of the German Social Code Book V ("SGB V") regarding the electronic patient record ("*elektronische Patientenakte*"), mainly due to the design of the access management and the access to the electronic patient record via mobile devices and the regulations on compulsory electronic medical prescriptions ("*elektronisches Rezept*"). The German Data Protection Conference ("*Datenschutzkonferenz*"), the coordinating body of all German supervisory data protection authorities, has already expressed similar concerns during the legislative procedures concerning the German Patients Data Protection Act ("PDSG").

Are any specific laws, regulations, or self-regulatory instruments expected to be adopted in the near future?

The telehealth initiatives of the German government have been highly dynamic very recently. According to the new German Patients Data Protection Act ("PDSG"), which came into force in October 2020, inter alia, from 1 January 2022, ePrescriptions shall be compulsory for physicians, dentists and clinics accredited by the Statutory Health Insurers ("SHI" – "GKV"), with certain exceptions. In addition, referrals to physicians and specialists as well as patients' medical records must be available in electronic form, too. Furthermore, the patients' comprehensive control over their personal data (including health data) and the requirements regarding the protection of the patients' data in the context of the processing by, e.g., physicians, clinics and pharmacies is regulated by the PDSG.

Additionally, the new Digital Supply and Care Modernization Act ("DVPMG") came into force in June 2021. The DVPMG, in particular, aims at digitizing healthcare in the area of nursing care. In addition to creating the possibility for patients in need of nursing care to use digital care applications on mobile devices or browser-based web applications to stabilize or improve their own state of health through exercises, e.g., fall risk prevention or personalized memory games for people with dementia, a new procedure will be created for reviewing the reimbursability of digital care applications. Furthermore, patients will be able to conveniently include data from telehealth applications into their electronic patient record ("*elektronische Patientenakte*"). Telemedicine services are now also available for other healthcare service providers than physicians and dentists, such as midwives. In addition, in the future, acute psychotherapeutic treatment can also take place in the form of a video consultation.

Besides that, the strict ban of advertisement for exclusive remote treatment under Sec. 9 of the German Act on Advertising in the Field of Healthcare ("HWG") has been lifted recently. Now, advertising for exclusive remote treatments is allowed, provided that in-person visits are not necessary according to recognised professional medical standards that apply in Germany.

In a recent decision, the German Federal Supreme Court ("BGH") emphasized that the current requirements for in-person visits prior to telemedicine consultations could no longer be upheld in view of the needs of modern healthcare (cf. BGH, decision of December 9, 2021, docket no. I ZR 146/20). This may prompt German lawmakers to further amend the current telemedicine legislation.

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