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HEALTHCARE AND LIFE SCIENCES

TELEMEDICINE ON THE RISE – THE LEGAL FRAMEWORK AND POTENTIAL FOR DEVELOPMENT

The events of 2020 have accelerated supply and demand for telemedicine services, and exponentially so. 2021 brought crucial changes to telemedicine healthcare in Germany: the obligatory electronic patient record (ePA), an increasing number of prescribable digital health applications (DiGAs), the new category of “digital care applications” as well as video consultations for non-physician therapists such as physiotherapists and ergotherapists as well as midwives. In 2022, patients and physicians have continued to connect by means of digital medical devices as well as real-time health data. This has expanded the treatment options using telemedicine without reducing quality compared with physical visits to a practice.

Enno Burk and Dilara Puls from the Gleiss Lutz Berlin Office, who focus on digital healthcare topics, summarize the current legal situation in Germany and look ahead to planned developments.

I. Online consultation hours now a fixed part of physicians’ work in Germany

Seldom performed in Germany prior to 2018, online consultation hours have since become a fixed part of the healthcare offered by physicians. Several providers have now established certified portals enabling physicians to conduct consultations with patients insured under either statutory health insurance or private schemes.

- ’ Since 2018, the Model Professional Code for Physicians in Germany (MBO-Ä) has allowed patients to be **treated remotely only**, without prior initial contact in person between physician and patient, though subject to certain conditions. Such treatment must be medically justifiable, physicians must continue to take due care, and the patient must be informed of how consultation and treatment only via communication media differ from conventional approaches (section 7(4) of the Code). Physicians may provide both private and SHI-accredited consultation hours online across Germany.
- ’ Fifteen of Germany’s sixteen medical associations have implemented the provision from the Model Professional Code. Only Brandenburg’s medical association continues to limit remote treatment to cases where patient and physician have had initial contact in person beforehand.
- ’ Since 1 April 2019, consultations conducted online have also been **billable** to the SHI funds.
 - ’ Currently, SHI-accredited physicians primarily bill their basic charge and flat charge per patient for video consultations. Depending on whether the relevant prerequisites are met, surcharges and further billable services may also be applied (e.g. for providing technical equipment or verifying the identity of new patients).
 - ’ Video case conferences, where physicians with different specialties discuss a case, have also been widely facilitated in SHI-accredited healthcare (section 87(2a) sentences 14 to 15 German Social Security Code, Book V). On 1 October 2020, the Committee for Rating SHI-Accredited Physicians’ Services (Bewertungsausschuss) decided to include and remunerate video case conferences in all medical areas in the Uniform Evaluation Scale (EBM), with patients attending such conferences in some cases.
- ’ Since 7 October 2020, it has also been possible for patients to obtain a doctor’s certificate via video consultations. Where certificates of incapacity to work are then issued, SHI-accredited physicians have had to send such certificates to health insurance funds digitally since 1 October 2021. At some point in the future,

- › the health insurance funds will be sending the relevant data direct to employers.
- › A further option now provided for is prescribing **digital health applications** (DiGAs: digital medical devices in Classes I and IIa).
- › Private health insurance schemes frequently conclude cooperation agreements with individual telemedicine portals, enabling their insureds to consult physicians free of charge by means of these portals (without requiring them to make later claims for reimbursement of costs).
- › [The diagram behind this link shows the main milestones in telemedicine to date.](#)

II. Focus remains on-site healthcare by SHI-accredited physicians in independent practice

- › Like out-patient healthcare on site, rendering telemedicine services within the SHI system **depends on SHI accreditation** (section 95 German Social Security Code, Book V). So for investors or telemedicine service providers who want to provide more than merely software, an online platform or corresponding technical services, the only remaining option will usually be to acquire a legal entity entitled to establish an ambulatory healthcare centre (MVZ), for example a certified hospital included in the Regional Hospital Plan (Plankrankenhaus).
- › On 09 June 2021, the Digital Healthcare and Nursing Care Modernisation Act (Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz) came into effect. For SHI-accredited physicians, telemedicine will remain a secondary activity even after this.
 - › If more than **30 %** of consultation hours billed in the SHI system are **online consultations**, then these will no longer be eligible for remuneration, pursuant to section 87(2a), sentence 30 German Social Security Code, Book V. So the SHI-accredited physician's work will continue to be centred around patient care on the spot, in the physician's practice.
 - › During the coronavirus pandemic, there was no limit to the number of online consultation hours that could be performed, as the Federal Association of SHI-Accredited Physicians (Kassenärztliche Bundesvereinigung) and the health insurance funds had suspended the relevant restrictions. **Since April 2022, however, the number of cases and volume of services have again been capped at 30 %**. Purely online practices do not exist at the current time, nor will they exist in the foreseeable future either.

III. Minimum technical requirements for telemedicine portals

Entry into the new market of telemedicine as a video consultation provider is also contingent on compliance with specific technical requirements:

- › Video service providers who facilitate video consultations as well as communication service providers who transmit data for physicians to confer on findings must be certified in accordance with the requirements of Annex 31a and 31b Federal-level Master Agreement on Physicians (Bundesmantelvertrag-Ärzte). Among other things, they must comply with **data protection and data security requirements**.
- › Requirements are also placed by the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the Federal Association of SHI-Accredited Physicians. Independent certifying bodies verify whether these requirements have been met, checking the relevant pieces of proof that must be provided. Currently, there are **62 certified video service providers** (as of 16 May 2022).

IV. How likely is competition between the Federal Association of SHI-Accredited Physicians and private telemedicine portals?

- › For SHI-insured patients, the Federal Association of SHI-Accredited Physicians is to set up a **new portal for assigning online consultation hours** with SHI-accredited physicians, as provided by section 370a German Social Security Code, Book V.
- › The private portals thus far established on the markets currently receive information directly from cooperating physicians. In future, however, they will only be able to access this information via the Federal

- › Association of SHI-Accredited Physicians and will be charged for doing so. SHI-accredited physicians may object to the Federal Association transmitting data to third parties. As far as we currently know, they need not pay a fee for offering their telemedicine consultation hours on the Federal Association's new portal. In 2022, the Federal Association is expected to present a concept for its own telemedicine portal. This may have a fundamental impact on private competitors.
- › Germany's federal government itself is active in digital health information. On 1 September 2020, the **national health portal** <https://gesund.bund.de/en> was set up. The portal provides information on health and nursing care, is worded in easily understandable language, is available to people with disabilities, and can be accessed via both the internet and the telematics infrastructure (section 395(1) German Social Security Code, Book V).

V. Advertising telemedicine treatment in public

In general, there is a ban in Germany on advertising for remote treatment (section 9, sentence 1 Health Products and Services Advertising Act (Heilmittelwerbegesetz). Telemedical treatment is exempted from this, however, where generally recognized professional standards do not dictate that a physician and patient meet in person (section 9, sentence 2 of the Act). To date, higher regional courts have interpreted this new provision unnecessarily strictly (see for example Munich Higher Regional Court, judgment of 9 July 2020 – 6 U 5180/19; Hamburg Higher Regional Court, judgment of 5 November 2020 – 5 U 175/19).

In a judgment of 9 December 2021 (I ZR 146/20), the Federal Court of Justice defined criteria for “generally recognized professional standards” in accordance with the requirements of section 9, sentence 2 Health Products and Services Advertising Act, thus setting Germany's first standard for whether it is permissible to advertise remote treatment. The latter includes video consultations.

- › For section 9, sentence 2 of the Act to be applied in a legally sound and consistent way, the Federal Court of Justice ruled, interpretation of the “generally recognized professional standards” must draw on the identical term in section 630a(2) German Civil Code (Bürgerliches Gesetzbuch) as well as the principles developed with regard to this term and a physician's duties under their contract with the patient for medical treatment (Behandlungsvertrag). In the Federal Court of Justice's view, drawing on section 630a(2) German Civil Code also facilitates recourse to extensive case law when interpreting the term. This, the Court holds, will enable the requirements of section 9, sentence 2 Health Products and Services Advertising Act to be applied in a consistent and legally sound way.
- › By contrast, the Court continued, section 9 of the Act does not depend on whether advertising for remote treatment is permissible under Germany's laws governing physicians as a profession.
 - › The Federal Court of Justice rejected the provisions of laws governing physicians as a profession as a basis for determining what constitutes “generally recognized professional standards”. Legislators, the Court held, intended to set an abstract and general standard for the permissibility of advertising remote treatment. The decisive rule in section 7(4) Model Professional Code for Physicians in Germany (MBO-Ä), new version, does not offer this abstract and general standard, however, but merely instructs the treating person with reference to a specific case. A further reason why the Model Professional Code for Physicians in Germany is unsuited to a standardized interpretation of section 9 Health Products and Services Advertising Act across Germany is that the country's various regional states do not implement the Code in a standard way.
 - › The Federal Court of Justice stressed that remote-only consultation has only recently become permissible and has been limited to individual cases. Only in a few cases, therefore, do remote treatment guidelines exist. But the Court also pointed out that legislators wish to further develop telemedical opportunities, and left the impression that as long as professional standards are complied with, it would not oppose such developments.

VI. Giving demand for telemedicine services a booster

Introducing video consultation hours directly enables telemedicine services to be rendered and remunerated. As part of digitalizing the German healthcare system, there are also a number of further projects to improve both information for physicians as well as prescribable treatment from the patient's perspective. Closer networking

between physician and patient enables a wider range of services to be offered than in the past. The following measures are noteworthy:

1. The electronic patient record

- › The electronic patient record constitutes a core element of digital networked healthcare and the telematics infrastructure. Since 1 January 2021, SHI funds have been **obliged** to offer their members the electronic patient record. Since 1 July 2021, all physicians and psychotherapists have been obliged to have the necessary equipment to transmit data to the electronic patient record via the telematics infrastructure. Digital patient data is now to be collected at one central point.
- › Currently, **medical information** is stored in the electronic patient record. From 2022, it will also be possible to implement certificates of vaccination, and from 2023 nursing care data and certificates of incapacity to work.
- › Currently, **patients have the right to decide** on how and for how long their electronic patient record can be accessed. By 2023, insurance representatives are to be provided with access accordingly. Insured patients are to be given the opportunity to make data from their electronic patient record available for research purposes as well.
- › To strengthen cross-border patient safety, the **National Contact Point for e-health** is to be established by mid-2023. This will enable insured persons to provide physicians in other EU countries with their health data, securely and in translation (section 219d(6) German Social Security Code, Book V).

2. E-prescription to be introduced across Germany

- › Obligatory use of the electronic prescription when prescribing drugs to SHI-insured patients was originally planned for 1 January 2022. It has, however, been postponed again, and this time indefinitely. Technical availability remains insufficient to meet the quality criteria agreed with the medical profession's self-governing bodies. A pilot phase has been running in Berlin and Brandenburg since July 2021, recently extended until the end of November 2021 by gematik (Germany's certification body for healthcare cards). This phase has now been extended again and extended to cover the whole of Germany.
- › On 3 November 2021, the Federal Association of SHI-Accredited Physicians issued a new guideline for SHI-accredited physician services. According to this guideline, the existing "Type 16" blank forms (used to prescribe drugs, surgical dressings and most medical aids) may continue to be used for a transitional period until 30 June 2022 as an alternative to the e-prescription format if physicians do not have the technical means to employ e-prescriptions. The same applies to the electronic certificate of incapacity to work. In the light of current e-prescription developments, the Federal Association of SHI-Accredited Physicians has called upon gematik GmbH to fulfil its statutory responsibility in the approval process and ensure that the components of the telematics infrastructure are in working order at SHI-accredited physicians' practices.
- › To use e-prescriptions, physicians must be linked to the telematics infrastructure and be in possession of an electronic health professional card, to enable an electronic signature. Patients need the e-prescription app to use e-prescriptions. Pharmacists must also be linked to the telematics infrastructure. [A diagram of the e-prescribing process can be found here.](#)
- › The obligation to use e-prescriptions will not apply to private insurees. Since 2020, however, Germany's Association of Private Health Insurers (PKV-Verband) has been a shareholder in gematik GmbH. Together with SHI players, the Association has been working to introduce a unified digital infrastructure for the healthcare system that links to the telematics infrastructure, thus providing patient and healthcare providers with the electronic patient record and prescriptions. Looking ahead, it can be assumed that private insurees and healthcare providers will also be able to use the telematics infrastructure in the near future.

3. Increasing number of prescribable digital health applications (DiGAs) and medical devices

Since Autumn 2020, digital health applications have been available under statutory health insurance as a new benefit package. These applications are Class I or IIa medical devices whose main function is based on digital technologies (see "Medical apps to become part of standard healthcare").

- › Before they become prescribable in statutory health insurance, digital health applications must be included in the directory of digital health applications by Germany's Federal Institute for Drugs and Medical Devices (BfArM), pursuant to section 139e German Social Security Code, Book V. This directory currently lists 30 digital health applications (as of 31 March 2022). The various areas of application range from treating depression to diabetes and multiple sclerosis through to migraines. According to a report issued in March 2022 by the National Association of Statutory Health Insurance Funds, over 51,000 digital health applications were prescribed between 1 September 2020 and 30 September 2021.

- › SHI insured patients are **entitled** to be provided with digital health applications. These can be prescribed by physicians and psychotherapists, and reimbursed by the health insurance fund. Insured persons who present proof of a corresponding indication to their health insurance fund receive the digital health application requested. This may also be possible without a physician's prescription if the health insurance fund's statutes provide for this.
- › In addition to purely digital health applications, health insurance funds also offer chronically ill insured patients the option of treating their illness by networking with their physician. This is done on the basis of **agreements for special care**. The physician remains informed of the patient's state of health at all times, using digital measuring devices, for example.
- › The law also **enables public healthcare entities to invest** in digital health. Such entities include SHI funds, regional associations of SHI-accredited physicians, the Federal Association of SHI-Accredited Physicians and the Federal Association of SHI-Accredited Dentists. Pursuant to section 68a et seq. German Social Security Code, Book V, these are entitled to promote digital innovations by assuming some or all of the costs. Digital innovations include telemedicine/networked healthcare and digital medical devices. Health insurance funds may also support or commission development by external providers. For this purpose, health insurance funds may invest up to 2% of their financial reserves as venture capital for developing digital innovations (section 263a German Social Security Code, Book V).
- › In the development and shaping of digital healthcare, this gives health insurance funds and regional associations of SHI physicians considerably more **scope for cooperation** with both established providers and start-ups in telemedicine services and digital medical devices.

VII. Conclusion and outlook

The foundation stones for the overdue expansion of telemedicine infrastructure in Germany have been laid since 2018. A large number of special rules continue to remain in force. Nevertheless,

- › the electronic patient record,
- › e-prescriptions,
- › increasing digital treatment options through networked medical devices and
- › increased opportunities for third-party payers to invest in and promote digital innovations

mean that telemedicine's share in healthcare in Germany will continue to rapidly rise over the next few years.

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