

18.09.2019

## HEALTHCARE AND LIFE SCIENCES

### TELEMEDICAL CARE: REQUIREMENTS AND OPPORTUNITIES FOR TELEMEDICINE IN GERMANY

Accompanied by wide media coverage, German health minister Jens Spahn is pressing ahead with the digitalisation of the healthcare system with a host of legislative initiatives, with telemedicine services being seen as the key to improving the provision of healthcare, especially in rural areas. This is opening up new opportunities for telemedicine providers to enter a market that is hitherto relatively uncharted in Germany. Dr. Enno Burk (counsel) and Dr. Julia Hornung (associate) from our healthcare and life sciences practice in Berlin explain the recent developments and the new opportunities they bring with them for healthcare service providers.

#### Online consultations will become the order of the day within the statutory health insurance system

Offerings for online consultations with panel doctors will become part and parcel of the healthcare system and replace the small number of model projects hitherto available in Germany as well as offerings that patients had to pay for themselves.

- › The initial impulse came from the loosening of the ban on remote treatment by doctors at the 121st German Medical Assembly in May of 2018: The model professional code for doctors (Musterberufsordnung der Ärzte / MBO-Ä) now permits **remote treatment as a sole method of** treatment absent any initial personal contact between the doctor and the patient, if it is medically justifiable and if the mandatory duty of medical care is satisfied – especially as regards the manner in which the diagnosis is made, the medical advice, the treatment and the documentation – and the patient is informed as to the special features of the remote-only advice and treatment via communication media (section 7(4) model professional code for doctors).
- › With the exception, at the current time, of Brandenburg and Mecklenburg-Vorpommern, most of the professional codes of the federal states have either already been modified accordingly or are going to be in the near future. Patients have the right to choose freely which doctor to consult, which means that doctors can hold online consultations anywhere in Germany, i.e. also treat patients living in Brandenburg and Mecklenburg-Vorpommern.
- › Based on the amendment of section 87(2a) German Social Security Code, Book V (Sozialgesetzbuch V / SGB V) by the Act for Reinforcement of Nursing Staff (Pflegepersonal-Stärkungsgesetz / PpSG), the uniform assessment standard (Einheitliche Bewertungsmaßstab / EBM) was modified on 1 April 2019 and this now means that panel doctors can **bill for all kinds** of online consultations. Until then this was restricted to one purpose, namely follow-up checks for specific diseases and indications, but this restriction has now been dropped. Video case conferences between care-dependent patients and nursing staff are also billable. Panel doctors will also receive a flat-rate equipment and incentive subsidy for using the services of a certified service provider (maximum of approx. EUR 800/year).
- › In addition, at the end of August 2019 a start-up incentive for video consultations was added to the uniform assessment standard for the period 1 October 2019 to 30 September 2021, which can amount to up to EUR 500 per surgery and quarter.

#### Nationwide introduction of telemedical applications as legislator's declared target

The legislator also has various other new statutory provisions up its sleeve – some already approved, others still in the pipeline – to fast-track digitalisation in the healthcare system; these innovations will apply alongside online

consultations, among other things, and make them more attractive.

- › The **Act for Improved Safety in the Supply of Pharmaceuticals** (Gesetz für mehr Sicherheit in der Arzneimittelversorgung / GSAV), which passed into law on 15 August 2019, lifted the prohibition on the **dispensing of prescription drugs to patients** in the clear absence of personal doctor-patient contact (section 48(1), sentence 2 Medicinal Products Act, old version (Arzneimittelgesetz a.F. / AMG a.F.). Pharmacists may now dispense prescription drugs that a doctor has prescribed in a remote-only consultation.
- › At the same time the legislator is pushing ahead with the nationwide launch of **electronic prescriptions** on the basis of the Act for Improved Safety in the Supply of Pharmaceuticals by setting the self-governing bodies a 7-month deadline (which expires on 31 March 2020) to agree the necessary regulation for the use of electronic prescriptions (section 86 German Social Security Code, Book V).
- › The German government's draft **Act to Improve Healthcare Provision through Digitalization and Innovation** (Digitale-Versorgung-Gesetz / DVG) will also loosen – in line with the new professional code for doctors – the existing ban on advertising for remote treatment, e.g. on a doctor's website (section 9, sentence 2 Drug Advertising Act, Government Bill (Heilmittelwerbegesetz Regierungsentwurf / HWG RegE)). Once the Act to Improve Healthcare Provision through Digitalization and Innovation passes into law, **advertising for remote treatment will be permitted** if, based on generally accepted professional standards, personal doctor-patient contact is not necessary.
- › The Act to Improve Healthcare Provision through Digitalization and Innovation also provides for the possibility of **prescribing health apps** (for more information see Gleiss Lutz article "[Medical apps to become part of standard healthcare](#)") and for the expansion of **electronic medical records**. Hospitals and panel doctors have to be equipped – by 1 January 2021 and 30 June 2021, respectively – with the systems and services needed to give them access to electronic medical records; otherwise they risk having their fees reduced.
- › The intention is also to enable **teleconsultations** to be introduced and remunerated in the context of panel doctor and cross-sector medical services (section 87(2a), sentences 13 to 15 German Social Security Code, Book V in the version of the Act to Improve Healthcare Provision through Digitalization and Innovation, Draft Bill). Until now teleconsultations are only billable in certain isolated cases under the uniform assessment standard, e.g. teleconsultations for the diagnostic evaluation of X-rays and CT scans or in the area of specialised geriatric diagnostics. The enlarged evaluation committee must rule on the relevant adjustments to the uniform assessment standard within nine months after the Act to Improve Healthcare Provision through Digitalization and Innovation passes into law. As with video consultations, the intention is that the fees will include the costs incurred by the doctor who initiated the teleconsultation for the necessary certified service providers.

### Opportunities for telemedicine providers

- › Based on these developments the need for telemedical services and the acceptance of the use of telemedia in the healthcare sector will increase. This offers a wide range of market entry opportunities, including, in particular, for private providers from countries with already established telemedicine structures (e.g. Switzerland or Great Britain) as well as start-ups.
- › The demand of panel doctors and medical care centres for telemedical software and hardware as well as online platforms will likely increase significantly due to the existing extensive billability of online consultations, seeing as the catalogue of telemedical services will presumably continue to grow in the future.
- › In addition, there is a need for software and hardware as well as advice in connection with the technical implementation of teleconsultations, the introduction of e-prescriptions and e-health records.
- › The development and sale of prescribable health apps that could allow for communication with the doctor also represent an interesting component of telemedical care possibilities (for more information see Gleiss Lutz article "[Medical apps to become part of standard healthcare](#)").
- › Companies and investors are likely to carefully monitor the German market for this reason. This is because additional legislative changes that further open up the German healthcare market for digital care applications, in particular for improved care in economically weak regions, will not be long in coming.

### Regulatory requirements for the service providers for video consultations and teleconsultations

However, entry into the new market of telemedicine is contingent on compliance with specific requirements:

- › Video service providers who make video consultations possible as well as communication service providers who transmit data for the evaluation of findings by way of consultation must be certified in accordance with

- › the requirements of Annex 31a and 31b Federal Collective Agreement-Physicians (Bundesmantelvertrag-Ärzte / BMV-Ä) and comply with, among other things, data protection and data security requirements. With a view to the future, only communication service providers that have been certified by gematik – Gesellschaft für Telematikanwendungen der Gesundheitskarte mbh (limited liability company for telematic applications of the health card) established by the top-level organisations of the German healthcare system in accordance with their legal mandate – can be used to provide teleconsultations.

#### **The provision of telemedical services remains reserved for doctors with their own practices**

- › Anyone in the statutory health insurance system who wants to offer and bill for telemedical services of his or her own must be certified as a panel doctor (section 95 German Social Security Code, Book V), which in turn is only possible for doctors and medical care centres.
- › Therefore, in most cases the only remaining option for investors or telemedicine service providers who not only want to provide software, an online platform or corresponding technical services is to acquire a sponsoring company entitled to establish medical care centres, for example a certified hospital included in state hospital plans.

#### EXPERTISE

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