



International

## Telemedicine to the Rescue? Reviewing the Current Liability Picture in Germany

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The current global health crisis resulting from the coronavirus pandemic is shining a spotlight on the potential for “telehealth” to support, maintain and deliver key medical services. Media reports suggest that governments are already working to relax the current constraints on telemedical services to relieve strain on healthcare resources and minimise healthcare workers’ exposure to the virus.<sup>1</sup> This recent article from guest authors Dr. jur. Max Middendorf and Dr. jur. Carolin Wever of Bergmann & Partners provides an overview of the current regulations governing the use of telemedicine in Germany from a liability perspective.

Digitalisation marches on inexorably, not least in the health sector where the ongoing development of telemedicine is redefining how services can be delivered. Telemedicine is a collective term for a range of different medical care concepts whose principal approach is providing medical healthcare services (in the fields of diagnosis, treatment, rehabilitation, and counselling) to the public remotely, using information and communications technology.<sup>2</sup> Telemedicine is not a field in its own right, but rather is used in a variety of specialised healthcare disciplines.

### Updates to the Professional Code for Physicians in Germany

The most recent amendment to the (Model) Professional Code for Physicians,<sup>3</sup> adopted by the 121st German Medical Assembly in Erfurt (8–11 May 2018), represents an important step toward incorporating telemedicine into the everyday lives of physicians. The amendment of Article 7 (4) of the Code has toppled the dogma of “offline first” which required direct contact between the patient and the physician. Fundamentally, Article 7 (4) retains the principle of personal contact:

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### About This Newsletter

Gen Re’s *Casualty Matters International* reviews new liability developments.

*“Physicians provide medical consultation and treatment to patients through direct, personal contact. They may also use communications media to assist [...]”.*

However, in individual cases, professional regulations do permit treatment using telemedicine exclusively. The new regulation is as follows:

*“It is permissible in individual cases for medical consultation or treatment to be provided exclusively via communications media where it is medically justifiable and where the necessary medical care is ensured, particularly through the manner in which diagnostic assessment, medical consultation, treatment, and documentation are carried out, and where the patient is also informed about the particularities of receiving medical consultation and treatment exclusively via communications media.”*

In short, this allows decisions to now be made on a case-by-case basis, and the (previously) mandatory direct contact between the patient and the physician to be omitted, if doing so doesn't jeopardise the physician's duty of care to the patient.

As the (Model) Professional Code for Physicians is merely a regulatory model, the new regulation is not a directly applicable law, and must first be implemented by the region's respective Chamber of Physicians in order to become legally binding. However, given the nature of the regulation, we expect all 17 chambers to adopt a comparable regulation in the short term.

The paradigm shift toward enabling the remote provision of medical services also has significant implications in terms of liability law. Whereas a breach of professional standards

once implied a breach of duty of care under civil law (Section 276 (2) BGB: “A person acts negligently if he fails to exercise reasonable care.”), the way is now paved for cases to be assessed individually.

### How can telemedicine be applied?

The potential use cases for telemedicine are numerous, and include the following vital areas:<sup>4</sup>

- Remote diagnosis: The diagnosis of patients by a physician located far away (e.g., telecardiology)
- Telemonitoring: The remote monitoring of patients not situated in a hospital (e.g., foetal monitoring)
- Remote support: The use of remote monitoring data to examine patients from afar (e.g., diabetics)
- Telemedicine: The transmission of medical images between medical centres for remote diagnosis
- Home monitoring: Care services in the home of the patient (e.g., older patients and diabetics)
- Teleconsultation: Remote access to the knowledge or experience of a specialist (e.g., teleradiology)

### What problems does telemedicine pose in terms of liability?

The changes to the regulations mean that assessments will take on a new dynamic. Determining whether malpractice that renders a party liable exists must be considered within the framework of the medical field in question, on the date of treatment. To begin with, it will likely remain difficult to judge whether a certain approach can be considered professionally correct, or whether it

is beyond the boundaries of what is reasonable. Professional medical bodies urgently need to define the fields of application for telemedicine and issue statements to make it clear when direct contact with a physician can be waived.

Cases where professional regulation lags behind functional development could prove problematic, particularly in the transition phase. For example, even though amendments to the professional regulations have still to be implemented (e.g., at the time of writing the North





Rhine Chamber of Physicians was still to update its code of conduct), a professional body might consider an exclusively telemedical treatment to be admissible at a certain stage of a certain condition. In this situation, it seems questionable to assume there has been a breach in the duty of care, yet the conflict with professional regulations is obvious.

A lack of clarity regarding defined responsibilities could also lead to difficulties with reworking legal liability. Presently, there is no clear contractual structure between the primary service provider and a secondary (external) service provider concerning who must take responsibility for shortfalls (e.g., in teleradiology). In practice, we've observed that the liability insurance policies do not cover this question clearly. To eliminate gaps in cover in the event of a conflict, it's strongly advisable to identify the fields of application of telemedicine clearly and clarify the situation both internally and with the insurer providing cover.

Hospitals especially are advised to continuously monitor and identify how and where telemedical services are being used and whether corresponding contractual provisions exist to assign the fields of responsibility. Additional problems can also arise when foreign service providers are sued. In these cases, it's essential for the parties responsible for the damage to be identified right away.

If we categorise the liability risks, we can identify three core areas where precautions must be taken:

- Organisation: Safeguarding of the completeness and punctuality of the data transfer
- External contract management: Clarification and assignment of responsibilities with an external service provider

- Internal contract management: Clarification of sufficient cover, especially with regard to whether the risk at hand is covered by the insurance policy

### Can telemedicine be considered a "trial method"?

Besides liability stemming from malpractice, new liability questions are arising regarding clarification errors. In this context, certain parallels can be drawn with the case-law developed by the German Federal Court of Justice in connection with the use of trial methods (the "robotoc" judgement).<sup>5</sup> In that case, the Federal Court of Justice confirmed that the selection of the method of treatment is primarily the responsibility of the physician. However, if a trial method is used, it becomes necessary to observe the right of the patient to self-determine. Where multiple, equally effective, treatment options are available for a medically sensible and indicated treatment, the patient must be provided with information on all alternative treatments and their associated effects, risks and success rates.

Moreover, the Federal Court of Justice stated that if the physician does not want to use the generally recognised standard method, but rather a (relatively) new method with risks that may not yet have been identified conclusively, the physician must provide the patient with information about it in accordance with the case-law of the courts, indicating clearly, that unknown risks cannot be ruled out.

Given the complex nature of its application, there is no single right answer to whether these considerations also apply to telemedicine. However, since telemedical methods represent uncharted territory, it's conceivable that the considerations involved in case-law could come to bear with regard to their application in individual cases.

### Provision of patient information on treatment

The obligation to provide information on specific treatments must also be taken into consideration when using telemedicine. Under Section 630c (2) of the German Civil Code (BGB), the treating party is obliged to explain to the patient in a comprehensible manner all circumstances that are relevant to the treatment. This applies not only to the diagnosis and treatment itself, but also to the methods necessary to ensure that the treatment is successful. When there is no direct contact between the patient and the physician, this can mean a stronger instruction to attend a personal follow-up visit to compensate for the risks resulting from the lack of a direct examination of the patient. This obligation can also be derived from the amended Article 7

(4) of the (Model) Professional Code for Physicians which decrees a duty to provide the patient with information “about the particularities of receiving medical consultation and treatment exclusively via communications media”.

## Conclusion

The amendment of Article 7 (4) of the (Model) Professional Code for Physicians has paved the way for the more extensive application of telehealth methods in Germany – and not a moment too soon.

As the standard of liability is defined by medicine itself, it’s down to the respective medical professional bodies to define the fields of application of telemedicine as quickly as possible and determine the boundaries within which telemedicine can be used without it representing a failure to perform due diligence.

Regarding liability law, clear contractual arrangements must be in place to allocate responsibilities when external service providers are involved in treatments. Internally, service providers must ensure that their insurer is kept abreast of the use cases and ensure their insurance policy and its scope of cover fully reflect the actual development of telemedicine use in their company.

This article was originally published in German in October 2019 and has been updated to reflect the COVID-19 outbreak.

## Endnotes

- 1 <https://www.dlapiper.com/en/germany/insights/publications/2020/03/telehealth-update-covid-19-prompts-emergency-medicare-coverage-and-other-seismic-shifts-us>.
- 2 <https://www.bundesaerztekammer.de/aerzte/telematiktelemedizin/telemedizin>.
- 3 [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/MBO/MBO-AE.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE.pdf) – last amended 14.12.2018.
- 4 <https://www.dgtelemed.de/de/telemedizin/anwendungsbeispiele.php>.
- 5 BGH, ruling from 13.6.2006, VI ZR 323/04.

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