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HEALTHCARE AND LIFE SCIENCES

NEW FAR-REACHING DIGITAL HEALTHCARE ACT PASSES GERMAN BUNDESTAG

The Digital Healthcare and Nursing Care Modernisation Act (*Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz*) has passed the Bundestag. It is intended to exploit the potential of digitalization and marks the next step of the digitalization of the German statutory healthcare system following the Digital Healthcare Act (*Digitale-Versorgung-Gesetz*) and Patient Data Protection Act (*Patientendaten-Schutz-Gesetz*).

On 6 May, the *Bundestag* passed the Digital Healthcare and Nursing Care Modernisation Act, with the CDU/CSU, SPD and Green parties voting for it. A reversal of the changes that have now been decided is therefore very unlikely, this applies in particular against the backdrop of the upcoming federal election in September 2021. The Act provides for

- › further development of digital health applications,
- › the expansion of telemedicine, and
- › additional communication options within the telematics infrastructure (TI),
- › Health apps are to be used in nursing care (*Pflegebereich*).

Digital identities

From 1 January 2023, according to the new Act, health insurance funds are to provide insured persons with a secure and barrier-free digital identity within the healthcare system. This can be applied for upon request, in addition to the electronic healthcare card (*elektronische Gesundheitskarte*). These digital identities are to serve the purpose of authenticating the insured person within the healthcare system (such as video consultations) and as proof of insurance, in a similar way to the electronic healthcare card. The Act further states that a digital identity may take on a variety of forms, having different levels of security and confidentiality.

No later than 1 July 2022, health insurance funds are to make procedures available to authorized users to test the integration of the secure digital identity. Gematik [*Germany's governmental certification body for digital healthcare matters*] has to create the technical basis for introduction by 1 April 2022. In future, the electronic medication plan stored until now on the electronic healthcare card will be run solely in the corresponding application within TI. The electronic data for emergencies is to be further developed into an electronic patient summary.

Digital Care Applications (DiPAs)

The termed digital care applications [*abbreviated to "DiPA" in German, Digitale Pflegeanwendungen*] are intended to help stabilise patients' health with special training programmes or to facilitate communication with family members or nursing care professionals. For this purpose, the Federal Institute for Drugs and Medical Devices (*BfArM*) is setting up a new procedure for verifying reimbursability of digital care applications, including such applications in a corresponding directory. The Federal Ministry of Health has been empowered to issue a legal ordinance to structure the rules in more detail. Digital elements are also to be added to nursing care advice. There will also be modifications in digital health applications [*abbreviated to "DiGA" in German*]. In future, insured persons will be able to store their digital health application data in their electronic medical records. Services rendered by non-physician therapists such as physiotherapists and ergotherapists, or by midwives in connection with digital health applications are also to be remunerated. At the same time, an obligatory certificate will strengthen data

protection for digital health applications.

Telemedicine is to be used more than before. Such services are also to be offered by the on-call service, run by the federal association of physicians accredited for statutory health insurance (Kassenärztliche Bundesvereinigung – KBV) which might impact the market currently dominated by private service providers. In that regard, the introduction of the electronic prescription form will also boost telemedical treatment since it makes access to RX drugs much easier and convenient for all SHI patients.

Furthermore, non-physician therapists and midwives are able to render telemedicine services. According to the Digital Healthcare and Nursing Care Modernisation Act, providers of home nursing as well as intensive outpatient services must join the TI by 1 January 2024. Providers of psychotherapy must join in by 1 January 2025, while providers of non-physician therapy or medical aids must do so by 1 January 2026.

New digital communication procedures

Important functionalities are to be added to secure transmission procedures using the special TI service KIM (*Kommunikation im Medizinwesen*, "Communication in Medicine"). This is to justify the all-round needs for communication between insured persons, healthcare providers and third-party payers. In addition to the e-mail function, communication procedures are to also enable a video communication service – such as for video consulting hours – and offer a messaging service.

One point which will relieve physicians and other healthcare providers of their data protection responsibility when processing personal data in TI, is that data protection impact assessments will in future be made during the legislative procedure itself. There will be new tasks, however, for the Federal Association of SHI-Accredited Physicians (*Kassenärztliche Bundesvereinigung*). This organization is to prepare basic data and quality-related data from SHI-accredited care for the "National Health Portal".

The German legislature has thus significantly broadened the foundations for a wide range of digital applications to shape and modernise the German healthcare system in the coming years.

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Dr. Enno Burk