HEALTHCARE AND LIFE SCIENCES

MEDICAL APPS TO BECOME PART OF STANDARD HEALTHCARE – GERMANY’S FEDERAL MINISTRY OF HEALTH PRESENTS DRAFT ACT

On December 19, 2019, the Act for Improved Supply through Digitization and Innovation (DVG) entered into force (Federal Law Gazette I 2019, p. 2562). In particular, the DVG enables the provision of medical apps to persons with statutory health insurance.

Dr. Enno Burk, counsel in healthcare and life sciences, regularly advises healthcare providers and third-party payers on digital healthcare offers and summarizes the new options for offering medical apps under statutory health insurance schemes.

Medical apps are covered by the entitlement to healthcare that insurees have under statutory health insurance (SHI)

- With the new draft section 33a German Social Security Code, Book V (SGB V), SHI insurees are entitled to be provided with digital healthcare applications.
- These include medical devices in risk class I or IIa, whose principal function is based on digital technologies, primarily medical apps with medical device functions.

The German Federal Institute for Drugs and Medical Devices (BfArM) is responsible for quality control of digital offers, including positive healthcare effects

- Insurees are entitled to benefits in the form of medical device apps and other digital health applications. For insured persons to be entitled to such benefits, they need to be included by the Federal Institute for Drugs and Medical Devices in a new directory for digital health applications (section 139e German Social Security Code, Book V).
- For this purpose, the manufacturer must prove that the application meets basic requirements in safety, efficacy and quality. The application must also have positive effects on healthcare. Should it not yet be possible to prove that there are positive effects on healthcare, the application can be included in the directory on a preliminary basis (section 139e(4) German Social Security Code, Book V).

“App on prescription” and availability from manufacturer

- Digital applications will be added to the catalogue of treatment that a physician can prescribe, in accordance with the new entitlement to benefits (section 87(5c) German Social Security Code, Book V). SHI-accredited physicians may therefore prescribe the applications as medical aids or medicinal products.
- The insurees then receive either a download option or a data carrier. Should this not be possible, insurees may also download the apps in app stores (section 33a(3) German Social Security Code, Book V).
- Health insurance funds’ data processing options will also be adjusted to the new possibilities in digital offers.

Health insurance funds to bear costs of medical apps / digital health applications
The Central Federal Association of the Health Insurance Funds will agree remuneration amounts – applicable to all health insurance funds – for digital health applications with the manufacturers of such applications. A framework agreement is to be concluded beforehand in respect of the criteria for the agreements on the remuneration amounts.

The remuneration amounts will apply after the first year following the inclusion of the respective digital health application in the directory for digital health applications pursuant to section 139e.

If it is not possible to reach an agreement, an arbitration board formed at Federal level by the Central Federal Association of the Health Insurance Funds and the relevant central organisations of the manufacturers of digital health applications will decide on the remuneration amount (section 134(3) German Social Security Code, Book V).

Expanded options for health insurance funds to cooperate with software manufacturers and develop digital innovations

In future, health insurance funds will be able to actively shape and promote the development of digital innovations (draft section 68a German Social Security Code, Book V). Digital innovations are in particular

- digital medical devices,
- telehealth procedures or
- IT-supported procedures in medical care.

Either alone or in cooperation with third parties, they will be able to develop digital innovations, or have the third parties develop them. In particular, this will facilitate cooperation with the medical technology and software industries.

The new statute also provides for health insurance funds to acquire holdings in innovative companies (section 263a German Social Security Code, Book V). Such holdings may comprise up to 2 per cent of the companies’ financial reserves, and must be linked to content-based cooperation in a relevant area of expertise.

Special forms of healthcare with medical apps

- The new draft section 140a(4) German Social Security Code, Book V provides a basis for health insurance funds to conclude special healthcare agreements with medical device manufacturers on digital healthcare offers.
- Involving a physician in the healthcare is required where the respective digital offer goes beyond simple consultation and makes diagnoses. As a rule, it must be a physician who participates in SHI-accredited care. Correspondingly, exceptions are also conceivable in which the therapy proposals are reviewed by physicians who are not SHI-accredited.

Provision of health-oriented digital skills as non-statutory benefit

Health insurance funds will be obliged to provide services to promote digital health literacy. This establishes an individual entitlement to benefits for the insured persons. The quality requirements will be laid down by the Central Federal Association of the Health Insurance Funds.

The services are intended to provide the skills required for the use of digital or telehealth applications and procedures.

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