

17.05.2019

HEALTHCARE AND LIFE SCIENCES

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

On 15 May 2019, Germany's Federal Ministry of Health (*BMG*) presented a draft Act to Improve Healthcare Provision through Digitalization and Innovation (*Digitale Versorgung-Gesetz*). This Act will create the statutory basis for providing medical apps to those insured under Germany's statutory health insurance schemes.

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 insureds have under statutory health insurance (SHI)

- › With the new draft section 33a German Social Security Code, Book V (SGB V), SHI insureds 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

- › Insureds 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 (draft section 139e(3) of the 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 (draft section 73(2) sentence 1 German Social Security Code, Book V). SHI-accredited physicians may therefore prescribe the applications as medical aids or medicinal products.
- › The insureds then receive either a download option or a data carrier. Should this not be possible, insureds may also download the apps in app stores (draft section 33a(3) of the 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

- › In the first year, digital applications included in the directory under section 139e German Social Security Code, Book V, new version are to be remunerated by health insurance funds according to the sales price set by manufacturers. Subsequently, a standard price to be reimbursed will in future be agreed upon for all health insurance funds between Germany's Central Federal Association of the Health Insurance Funds (*GKV-Spitzenverband*) and the manufacturer, or set in an arbitration procedure.
- › Manufacturers will still be able to demand a higher sales price, going beyond the maximum sum set, to be borne by insurees themselves (draft section 134 of the 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). 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 (draft section 263(3) of the Code, Book V). Such holdings may comprise up to 2% 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.

Entry into effect

According to the Federal Ministry of Health's planning, as far as it is known, the Act to Improve Healthcare Provision through Digitalization and Innovation is due to enter into effect in early 2020.

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LAWYERS

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