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*Digital Demands: An Overview of the Journey Toward Access and Reimbursement in the German Statutory Health Insurance**

Simone von Hardenberg
(Professor at University of Applied Studies Munich)

Lauren Tonti
(Doctoral Candidate at Max Planck Institute for Social Law & Social Policy)

ABSTRACT Digitization is inherent to the technological innovation in the future of health care, and relatedly, health-insurance coverage. It also makes inherent demands upon healthcare systems. Germany has long sought to incorporate the ever-changing elements of digitization into its system services and structures. This paper explores the development and status of digitization in the German statutory health-insurance system. After first providing the context of the system in which digitization is occurring, the paper provides an overview of significant legislative efforts to promote digitization in the healthcare sector. It highlights the German experience with integrating digital health applications into the statutory health-insurance system as an example to illustrate the challenge of implementing new digital services in German healthcare, before offering considerations for the future.

1. *Introduction*

The future of healthcare is inherently linked with digitization. Systematic collection and analysis of medical data improves the detection of diseases, enables personalized therapies, and reveals new healing opportunities. Digitalized healthcare can also help address current access challenges facing elderly and chronically-ill patient populations, or patients located in geographically-remote or otherwise disconnected areas. Digitization enables easier communication between the many actors in the healthcare system who together make up and coordinate a patient's care. Digital technologies can strengthen patients' self-determination and health competency. Combined, these benefits contribute to maintaining and further developing high-quality care in face of rising healthcare costs.

Digitization also makes inherent demands upon healthcare systems that may hold varying degrees of readiness for integrating digital instruments and services. Digitization is seen as a potential instrument for optimizing healthcare processes and developments, which occur in nearly every country. While there exists no single uniform definition of digitization or e-Health, a term used equally as broadly and indiscriminately, there is a common understanding that systems should leverage the benefits and potential of digital-health technologies to the maximum possible.

The German experience of integrating e-Health activities has been prolonged and intentional. Often discussed in the media, debated in halls of the legislature, or even criticized in patient-exam rooms, the experience of the system's approach to digitalizing Germany's healthcare sector is useful to analyse, for examining the series of changes in pursuit of digitization, and the inherent challenges encountered in the pursuit thereof, offers valuable lessons. Insight gleaned from this journey can serve as a model and inspiration for other systems seeking to tackle the monumental task of incorporating e-Health and its many facets into their systems.

Accordingly, this paper provides a brief but broad overview of the actions toward developing e-Health in the German health system. With a focus on ambulant healthcare[1], it first explains the legal framework and the landscape in which digitization is occurring, then traces significant legislative action over the last two decades before highlighting prescription digital-health applications as an

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[1] The discussion excludes long-term healthcare and rehabilitative services.

example of digitization in practice in the German healthcare system.

2. *Digitization in the German Statutory Health Insurance System*

2.1. *Digitization in Context: The German Healthcare System*

The context of the system and environment in which digitization is intended is relevant not only because of the number of patients affected, but also because legal guarantees regarding the provision of healthcare must be observed. The technological capabilities enabled by digital innovations are integral to provide economic but high-quality care. Briefly explaining the statutory health-insurance (SHI) context helps explain the national journey toward digitization.

2.1.1. *Statutory health insurance*

Digitization can only fulfil its potential when it can be successfully integrated into the healthcare system, whether through existing channels or legislative reforms.

A statutory health-insurance (SHI) system that insures nearly 90 per cent of the population predominates the German healthcare landscape.[2] While private health insurance coexists and operates in the system, it covers a much smaller percentage of the population, and the insured cannot easily alternate between SHI and private insurance. Book V of the German Social Code ("Sozialgesetzbuch V", SGB V) contains the legal requirements that provide structure to and guide the system, which has traditionally been characterized by a strict separation of ambulatory and hospital care.

The SHI is a compulsory insurance. The SHI is obliged to cover participants who meet legal requirements and criteria.[3] As part of the welfare state,[4] the SHI is a solidarity-based insurance system,[5] where contributions are paid equally by employer and employee, and employee contributions are based on their income.[6] Regardless of the contribution amount or the duration of membership, insured persons can claim benefits under SGB V. The relevant factor is that the legal requirements are met, and the principle of economic efficiency is observed.[7] Regardless of contribution amount or duration of contribution, all insured persons are eligible for the same catalogue of benefits. The benefits are available as benefits-in-kind, which distinguishes SHI from the reimbursement of private health insurance. The principle of benefits-in-kind plays an important role in the system, as it separates the process of caregiving from the transactions related to payment for services rendered, and requires the care to be appropriate and economical with an eye toward modern standards of care.[8] It is therefore important that digital innovations find their way into the catalogue of benefits so that all insured persons have equal access and a quality, economic care is insured.

2.1.2. *Data protection in healthcare*

Digitization in healthcare depends on the use of sensitive data. Health data fall under the special protection of a complex system of data regulation at several legal levels.

The European General Data Protection Regulation (GDPR) applies to the use of health and care data in Germany. For processing personal-health data, Article 6 and Article 9 of GDPR must be met. According to these provisions, data processing is generally prohibited unless there is explicit consent or a legal basis for it.[9] Legal bases can be found not only in the GDPR directly, but also in national law. For the processing of genetic, biometric and health data, national legislators have the option of enacting their own rules under Article 9 (4) GDPR. Member States, therefore, could enact stronger protections. With health data, for example, Member States can require stricter conditions for processing health data for special purposes, such as research. The German legislature took advantage of the possibilities enabled by the GDPR to enact stricter and supplementary regulations in the German health sector. This affects, for example, genetic data and health-data processed by the SHI.

[2] For current figures and graphs, see www.gkv-spitzenverband.de/service/zahlen_und_grafiken.
[3] Sec. 5-10 SGB V.
[4] Article 20 GG.
[5] Sec. 1 SGB V.
[6] Sec. 3 SGB V.
[7] Sec. 2 SGB V.
[8] W. Rehmann and C. Tillmanns, *E-Health / Digital Health: Rechtshandbuch*, Munich, C. H. Beck, 2022, 69.
[9] If Article 9 (2) of the GDPR applies to processing in the healthcare sector, additional procedural and technical safeguards must be put in place given the sensitivity of the data.

Many provisions concerning data protection in Germany are spread across different areas and bodies of law, such as the Drug Act, the Infection Protection Act, and the Medical Devices Act. This holds true not only at the federal level but also at the state level, where several other data regulations (e.g., in the state hospital laws or cancer registry law) exist because states within Germany also maintain legislative competence in health care. Consequently, data protection in Germany, particularly in healthcare, is fashioned through a patchwork of provisions.

Despite the patchwork, protection is woven into a functional operation. Generally, in the German system, federal law pre-empts state law, and law specifically related to a topic takes precedence over more generally applicable provisions. This allows, for example, special regulations in the SGB V to take precedence over more-general regulations of the Federal Data Protection Act (Bundesdatenschutzgesetz – BDSG).[10] However, navigating data regulation remains a challenge, even if personal data are only exchanged in Germany (for research purposes, for instance), given many different state data-protection laws in effect, each of which may contain special, specific regulations. The result is a very complex regulatory system.[11] Absent complete European harmonization of data regulation, especially in the healthcare sector, the broad patchwork in Germany persists alongside European law.[12] This creates barriers to care and research.

2.2. *The German Digital Health Strategy*

The German Federal Ministry of Health published a new Digitalization Strategy in March 2023, which has been developed by a participatory process.[13] The development of the strategy required a common national understanding, and the willingness of all stakeholders to participate in implementation endeavours, especially because the new strategy is pursuing ambitious goals. The strategy is intended to help Germany become a pioneer in digitization. The German government has the ambitious goal of finally moving Germany up from the bottom of the international rankings in digitization. When it comes to digitization, especially in the health sector, Germany lags far behind similarly situated nations and healthcare systems.[14] This lag is attributed to conflicts of interest between relevant actors, self-administration, bureaucracy, high technology costs, security concerns, absence of as well as cumbersome regulations, and a lack of technical solutions to remedy interoperability challenges.[15] In light of these perceived stumbling blocks, central topics and core themes of the strategy are new processes in the areas of health and professional care, patient sovereignty, digital competencies, public and provider acceptance, regulatory frameworks, economic efficiency and data management. These diverse topics illustrate the range of variation required for optimal digitization and integration into the existing system.

Efforts to edit the existing system to include and support frameworks that will prove flexible enough to address the integration of future innovations remains the overarching goal, and simultaneous challenge, for health authorities. Indeed, the Ministry needed to develop a strategy that is "future-proof"[16]. The focus of the strategy is on the broader use of health data to improve healthcare and research by further developing already-existing digital applications, implementing new structures into the German healthcare system, and connecting to European and international concepts of data spaces. Despite the nation's experiences during the COVID-19 pandemic that shoved digitization deficits into the spotlight, momentum in the arena appears to have slowed, prompting Minister of Health Karl Lauterbach to undertake responsibilities not

[10] Sec. 1 (2) Sentence 1 BDSG.

[11] Deutscher Ethikrat, Big Data und Gesundheit. Datensouveränität als informationelle Freiheitsgestaltung, Stellungnahme, 2017, 145, in www.ethikrat.org/publikationen.

[12] J. Kühling, *Datenschutz im Gesundheitswesen*, in *Medizinrecht*, vol. 2019, 611-613.

[13] See www.bundesgesundheitsministerium.de/themen/digitalisierung/digitalisierungsstrategie.html.

[14] In the "Bertelsmann Foundation's international comparative study" of 2018, Germany ranked 16th out of 17 countries (www.bertelsmannstiftung.de/de/themen/aktuelle-meldungen/2018/november/digitale-esundheit-deutschland-hinkt-hinterher); Deloitte, Digitalisierung des Gesundheitsmarkts, 2019 (www2.deloitte.com/de/de/pages/life-sciences-and-healthcare/articles/digitalisierung-des-gesundheitsmarktes.html); Sachverständigenrecht Gesundheit & Pflege, Digitalisierung für Gesundheit, 2021 (www.svr-gesundheit.de/gutachten/gutachten-2021).

[15] Fraunhofer, *E-Health in Deutschland*, *Studie zum deutschen Innovationssystem*, No. 12, 2022.

[16] www.bundesgesundheitsministerium.de/themen/digitalisierung/digitalisierungsstrategie.

just as minister of health, but also as a "digitization minister".[17] Digitization in healthcare is a central topic of the current legislative period.

There is a consensus that digitization in Germany needs to move faster, matching the pace of current development and innovation, a pace which to date seems at odds with the rate of detailed integration efforts. While the strategy must inherently consider the complexity of the German healthcare system and data-protection laws, it should not let the complexity stymie progress.

3. *An Overview of the Legislative Pursuit of Digitization in Healthcare*

To ensure that the development of digitization in the healthcare sector in Germany progresses more quickly, the Federal Ministry has adopted several legal measures in recent decades. The following section briefly and chronologically describes the hallmarks of major legislative acts that have exerted a significant impact on the availability of digital technology and services in the public-health insurance system.

3.1. *2003: Initial Steps toward Digitization*

The GKV-Modernisierungsgesetz (GMG) of 2003[18] took initial steps toward digitization by introducing the Electronic Health Card (elektronische Gesundheitskarte - eGK) in January 2006 and the Telematics Infrastructure (TI) a few years later.[19] However, neither venture proved initially successful. The Electronic Health Card serves as proof of eligibility for benefits of the SHI. A microchipped Electronic Health Card contained an insured individual's photograph and personal information, including his or her name, date of birth, address, insurance number and insurance status. Only years later were more functions added to the Electronic Health Card.

The Telematics Infrastructure, the practical significance of which has increased over time, is the network of IT systems that enables links between information sources. In 2005, "Gematik" was founded as the operating company of the Telematics Infrastructure. It is the central platform for digital applications in the German healthcare system.[20] Because of only a partial connection between service providers and the Electronic Health Card's lack of added value, the effect of the law that instituted these innovations was very limited, and digital potential was not maximized. The impact of the unrealized vision and initial setbacks proved consequential, influencing subsequent legislative endeavours.

3.2. *2015/2016: A Digitization Booster*

More than ten years later, legislative action toward digitization in the healthcare sector recommenced with the "E-Health Act" of 2015, which came into force in January 2016.[21] This act initiated relevant developments to the Telematics Infrastructure, the data highway designed to connect all stakeholders in healthcare under a high level of protection. For the first time, the legislature introduced concrete deadlines and sanctions for connecting practices to the Telematics Infrastructure, while also naming specific digital applications. The provision of telemedicine services, such as online video consultations and online radiographic reporting, was encouraged by the new law. Documents like medication plans and provider letters were supposed to be integrated into the Electronic Health Card. Starting in 2018, it was planned to be possible to store emergency medical data on the card at the request of the insured person. Those data include, for example, important information about the blood group, existing vaccination protection or allergies and previous illnesses. The Electronic Health Card is intended to serve as a key that connects patients to the new infrastructure and provides them with easy access to their health data. However, the ambitious goals of the law have not been achieved in practice.

3.3. *2019: A Digital Rush*

A flood of legislation to provide a secure and practical framework for a digital healthcare system began in 2019. The TSVG[22]

[17] www.politico.eu/article/germanys-digital-health-efforts-are-flailing-is-a-lauterbach-strategy-the-ticket.

[18] Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GKV-Modernisierungsgesetz - GMG), 14 November 2003, in BGBl, 2003, 2190.

[19] Gesetz zur Organisationsstruktur der Telematik im Gesundheitswesen, 22 June 2005, BGB1. I 2005, 1720.

[20] www.gematik.de.

[21] Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen (E-Health-Gesetz), 21 December 2015, in BGBl, 2015, 2408.

[22] Gesetz für schnellere Termine und bessere Versorgung (Terminservice und Versorgungsgesetz - TSVG), 6 May 2019, BGBl. I 2019, 646.

obliged statutory health insurers to offer an Electronic Patient Record (elektronische Patientenakte - ePA) for insured persons by 2021. Patients should be able to access their treatment data easily, securely, and quickly, using only a smartphone or tablet. In addition, in 2021 the certificate of incapacity for work was supposed to be digitally exchanged between the doctor and the health insurance. Furthermore, the Federal Ministry of Health acquired majority decision-making power in Gematik to implement changes in the Telematics Infrastructure more quickly.

Just a few months later, the next piece of legislation, the Gesetz für mehr Sicherheit in der Arzneimittelversorgung (GSAV),[23] sought to make the drug supply easier and safer. GSAV obliged stakeholders to create the necessary regulations for the use of an Electronic Prescription (eRezept) within seven months after the law came into effect. In addition, prescription drugs could be dispensed by pharmacies after even exclusively-remote treatment.

Soon after, the legislature passed the Digitale-Versorgung-Gesetz (DVG).[24] The ongoing challenges within the Telematics Infrastructure and the patient's changing preferences were the main starting points for the new regulations.[25] The focus was on apps available via prescription, easy use of video consultations and secure access to the healthcare-data network for medical treatments. Prescription Digital Health Applications (Digitale Gesundheitsanwendungen - DiGA)[26] can be used to enhance the treatment of a wide range of illnesses by imparting information, providing context, or guiding patients through exercises. By including them in standard care, the legislator wanted to ensure health and privacy protections, but also to harness the potential of e-Health for the benefit of cost-effective health care.[27]

Moreover, the law made Electronic Patient Records compulsory for hospitals and pharmacies. Pharmacies were required to connect to the necessary digital infrastructure by the end of September 2020 and hospitals by January 2021, with the costs of voluntary connection to be reimbursed. Physicians who remained disconnected would face an increased fee deduction of 2.5%, raised from 1%, starting in March 2020. For midwives and physical therapists as well as nursing and rehabilitation facilities, connection to the Telematics Infrastructure remained voluntary. However, the pressure has been increased to join the digital system, as its success relies on the participation of all system actors. Though the exchange of paper should be overcome, additional premeditated regulations for the Electronic Patient Record were postponed in favour of specifically addressing them in subsequent legislative processes.

3.4. *2020: Focusing on Data Protection*

Less than a year later, in 2020, the Patientendaten-Schutz-Gesetz (PDSG)[28] built upon previous developments, particularly concerning Electronic Patient Records and Prescription Digital Health Applications. The act does not represent a fundamentally-new orientation of the legal concept, but rather ushers in various individual adjustments.[29] It focuses primarily, though not exclusively, on protecting sensitive health data. Every user of the Telematics Infrastructure is responsible for protecting processed patient data. With new and secure apps, insured persons can fill e-prescriptions at a pharmacy of their choice and providers can transfer specialist referrals digitally. Patients were also given the right to have their doctor fill out their electronic patient record. From 2022 on, insured patients can store their vaccination cards, maternity records, children's health booklets and the dental bonus booklet in their Electronic Patient Record, and patients can transfer data to new insurers if changing insurance providers. The record should be user-friendly and offer many different options to the user. The idea is that the patients manage the record themselves, and decide what happens to their data, especially what data are stored, deleted or accessible by others. After much debate,

[23] Gesetz für mehr Sicherheit in der Arzneimittelversorgung (GSAV), 9 September 2019, BGBl. I 2019, 1202.
[24] Digitale-Versorgung-Gesetz (DVG), 9 December 2019, in BGBl, 2019, 2562.
[25] J. Weyd, *Digitalisierung in der Gesetzlichen Krankenversicherung*, in *Medizinrecht*, vol. 38, 2020, 183.
[26] Details under 4.
[27] L. Münkler, *Health-Apps im gesundheitsrechtlichen Regelungsgefüge*, in *Neue Zeitschrift für Sozialrecht*, vol. 2, 2021, 43.
[28] Gesetz zum Schutz elektronischer Patientendaten in der Telematikinfrastruktur (Patientendaten-Schutz-Gesetz - PDSG), 14 October 2020, BGBl. I 2020, 2115.
[29] C. Dochow, *Das Patienten-Datenschutz-Gesetz (Teil 1): Die elektronische Patientenakte und Telematikinfrastruktur*, in *Medizinrecht*, vol. 38, 2020, 979-981.

every person with SHI receives the option to voluntarily make the data stored available to research as a "data donation", starting in 2023. The law strengthened patient sovereignty and patient autonomy, but also raised privacy concerns that led to subsequent improvements during the legislation process.[30]

3.5. *2021: Further development of digital applications*

In 2021, the Digital Supply and Care Modernization Act (DVPMG) was passed[31]. The law aimed at digital support for care, including more opportunities for telemedicine services and modernized networks in healthcare outside of direct medical treatment. Besides the introduction of Digital Care Applications (Digitale Pflegeanwendungen – DiPA) to support people in need of care[32], Prescription Digital Health Applications (DiGAs) were further developed. Data from DiGAs are supposed to be directly transferred to the Electronic Patient Record. Furthermore, data privacy and information security of DiGAs will be strengthened by introducing mandatory certificates for data privacy and information security. The possibility to reimburse DiGAs in an increasing range of fields is growing, as is the access to and range of reimbursable telemedical services. Provisions for updating the Telematics Infrastructure, for example, will allow insured persons and providers to receive digital identities for secure authentication in a video consultation or with DiGAs beginning in 2023.

3.6. *2023 and Beyond: Status and Prospects*

After a slow start in the early 2000s and a peak in 2019, legislative actions toward digitization in healthcare continue to expand and improve the many aspects of a digitized health system,[33] which reflects a consistent review and refinement towards Germany's digital goals. Some acts such as the DVG and the PDSG were specifically aimed at digitization in healthcare, while others, for example the TSVG, address several different innovations.[34] This reflects the experience that societal or system constraints may prevent immediate implementation of digital innovations in their totality, which results in an implementation that takes place over several incremental steps. These include major changes such as the Electronic Health Card and the Electronic Patient Record. For example, since January 2021, insured persons have been able to obtain an Electronic Patient Record, the functions of which are gradually being expanded, from their health insurers. But neither patients nor providers always embrace new care options. Voluntary use may not translate into high demand, as Germany's experience with the Electronic Patient Record reflects. Historically low Electronic Patient Record usage means that newly proposed regulations aiming to establish electronic records as defaults will bring Electronic Patient Records to 80 percent of SHI patients by 2025.[35] (Patients can still opt out if they wish). Both pieces of proposed digital-health legislation in 2023, the Digital Act (Digital-Gesetz – DigiG)[36] and the Health Data Use Act (Gesundheitsdatennutzungsgesetz – GDNG)[37] focus on the support and expansion of the Electronic Patient Record. While the Digital Act aims to simplify and streamline healthcare with digital solutions, the Health Data Use Act seeks to enhance opportunities to responsibly use health data for research.[38] Both new laws are intended to drive the exchange and use of health data and provide targeted support for care. E-prescriptions are anticipated as a mandatory standard as of January 2024. Existing health-care structures are to be better utilized and interconnected.

[30] BfDI (The Federal Commissioner for Data Protection and Information Security) very critical at the time: www.bfdi.bund.de/SharedDocs/Pressemitteilungen/DE/2020/20_BfDI-zu-PDSG.html.

[31] Gesetz zur digitalen Modernisierung von Versorgung und Pflege (Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz - DVPMG), 3 June 2021, BGBl. 2021 I, 1309.

[32] For more: www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiPA/_node.html.

[33] For an overview of milestones, https://gesund.bund.de/digitalisierung-im-esundheitswesen#einleitung.

[34] Acts such as the TSVG are called "Omnisbusgesetz" for this reason.

[35] www.bundesgesundheitsministerium.de/presse/pressemitteilungen/digitalisierungsstrategie-vorgelegt-09-03-2023.

[36] Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz - DigiG), Drucksache No. 435/23 (Gesetzentwurf der Bundesregierung); current consultation status: forwarded to the Bundesrat - not yet discussed (September 2023).

[37] Entwurf eines Gesetzes zur verbesserten Nutzung von Gesundheitsdaten (Gesundheitsdatennutzungsgesetz-GDNG) Drucksache No. 434/23 (Gesetzesentwurf der Bundesregierung); forwarded to the Bundesrat - not yet discussed (September 2023).

[38] www.bundesgesundheitsministerium.de/presse/pressemitteilungen/digitalisierungsstrategie-vorgelegt-09-032023.

Ease in linking data from multiple, different sources should enable greater data utilization. Through these laws, Germany wants to create the preconditions and infrastructure necessary to connect to a European health-data space.

It remains to be seen whether the announced legislative initiatives will resolve the longstanding issues related to implementation. The past has shown that neither the promise of financial incentives nor the threat of sanction has been entirely successful in achieving absolute digitization of the healthcare system nationwide. Nevertheless, regulators are again deploying deadlines and sanctions, and once again stakeholders are raising data protection and practical concerns.[39] Much scepticism about digital innovations remains. Even those willing to engage with new opportunities and offers are discouraged by technical problems that limit digital capabilities. For example, while nearly 100 percent of medical practices and pharmacies are connected to the Telematics Infrastructure, one in two medical practices complain of technical errors at least once a week.[40] As more stakeholders and patients are incorporated into the digital system by growing legal pressure, the system must deliver on its promises in practical terms, particularly in the domain of compulsory SHI. Creating the legal framework is only one part of the complex and long-term digitization process and must be flanked by technical guarantees.

4. *Prescription Digital Health Applications (DiGAs) – an Exercise in Innovation Integration*

The legislative efforts attempt to address the myriad aspects of digitization in its many possible mediums and modes. One digital innovation prompted a new design and structure to be built into the system – the digital health application. Digital health apps attest to the potential of digital technologies in health promotion and reflect the aspirations of system stakeholders to pursue health through technology capable of overcoming existing challenges. To practically leverage the technology quite literally at the fingertips of millions of patients, legislators sought to undertake the integration of health apps as one key component of digitizing the system, seeking to incorporate the prescription and reimbursement of health applications into the offerings of the public insurance system. Doing so required devising an original system, one that enabled insurers to select and reimburse effective health apps from the millions of health and wellness apps populating digital app marketplaces, while simultaneously empowering patients to play active roles in their health management.

The experience of integrating Prescription Digital Health Applications (DiGAs), the health apps and web applications that are made available by healthcare-provider prescription, into the SHI illustrates the influence of the previously-discussed legislative actions, and how they translate into the system. This section highlights DiGAs as a case study, as it sits at the intersection of healthcare delivery, technological innovation, and data protection. The subsequent section details the integration of DiGAs, therein illustrating not only the progress but also the challenges in implementing new digital services in the German healthcare system.

4.1. *Introduction*

The Digital Care Act of 2019 introduced DiGAs to patients in the SHI system. General regulations for DiGAs were established in Book V of the German Social Code.[41] With Sec. 33a SGB V, a new entitlement to benefit was incorporated into law. According to Sec. 33a (2) SGB V, a DiGA is a class I or IIa medical device according to Medical Device Regulation or Medical Device Directive.[42] Class I or IIa medical devices are products that have obtained CE-marking and pose a low risk of potential harm caused by a defect or functional failure of the medical device. DiGAs can support the treatment of a wide variety of conditions, such as migraines, tinnitus, various types of cancer, multiple sclerosis, diabetes, and depression. Some serve to detect or monitor symptoms that

[39] For different perspectives, see www.gkv-spitzenverband.de/gkv_spitzenverband/presse/pressemitteilungen_und_statements/pressemitteilung_1661504.jsp (GKV-Spitzenverband); www.kbv.de/html/1150_65129.php (KBV); www.kzbv.de/digitalisierung-des-gesundheitswesens.1778.de.html (KZBV).

[40] E-health Monitor 2022, available at www.mckinsey.de/news/presse/ehealth-monitor-2022.

[41] Supplemented by Digitale Gesundheitsanwendungen-Verordnung, 8 April 2020, BGBl. I 2020, 768.

[42] DiGA are to be extended to benefit medical devices in risk class 2b, BMG, *Digitalisierungsstrategie für Gesundheit und Pflege*, 2023, 30; Drucksache No. 435/23, 97.

require further investigation. Others promote the health competence of users and enable them to manage their health. Most DiGAs provide direct support for managing illnesses and relieving symptoms. However, software that serves purely to provide knowledge, enable communication, or store information is not considered a health app under the current legal definition.[43] DiGA classification does not include health apps that focus on wellness or fitness and are solely used for primary prevention.[44]

To be reimbursed for DiGA use, a physician's prescription or written proof of a relevant diagnosis is required. The prescription must indicate the name of the DiGA and its pharmaceutical registration number. The patient submits this documentation to the health-insurance provider. After the manufacturer and the SHI fund cross-check the anonymized data, the patient receives an activation code that he or she can enter in the DiGA interface or on the manufacturer's website in order to use the DiGA free of charge.

4.2. *Registry*

The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) provides an online registry that lists those DiGAs that have successfully passed an assessment for reimbursement.[45] The BfArM plays a central role in concretizing the entitlement to SHI benefits. This contradicts the usual SHI system practice, where the Joint Federal Committee (Gemeinsamer Bundesausschuss, G-BA)[46] is otherwise responsible for such decisions. In contrast to the G-BA, known for long and cumbersome decision-making processes, the BfArM promises faster access to digital innovation. The approval is designed as a fast track and takes a maximum of three months after the complete application of the manufacturer. After that, the manufacturer can enter price negotiations with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). Only DiGAs that have been classified for the official list by the BfArM are included in the SHI reimbursement system. Accordingly, this is a positive list with normative character. Such a registry, outside of G-BA review, is new and unusual in the healthcare system.[47] Germany, serving as an international pioneer in the process of establishing DiGAs as standard benefits in the SHI,[48] must nevertheless grapple with constitutional requirements and limitations[49] in their creation of this new path forward.

4.3. *Assessment*

The assessment by the BfArM ensures proof of security, functionality and quality including interoperability, data protection and data security and positive care effects.[50]

The BfArM has been criticized for examining complex data-protection issues as an external body without having to involve a data-protection authority.[51] From August 2024, a certificate in accordance with Article 42 GDPR is required as proof of compliance with data-protection requirements by the manufacturer.[52] Insured persons must be able to rely on the manufacturer's compliance with legal data-protection requirements, careful handling of their data, and implementation of measures to protect confidentiality, availability, and integrity. For this purpose, a regulation (Digitale Gesundheitsanwendungen-Verordnung – DiGAV) specifies and supplements the requirements from the GDPR and other data-protection requirements for the manufacturer's company, for the DiGA itself and for all

[43] V. Lücker, *Medizinprodukterechtliche Rahmenbedingungen für E-Health-Produkte im europäischen Wirtschaftsraum*, in *Bundesgesundheitsblatt*, vol. 3, 2018, 278.
[44] L. Münkler, *Health-Apps im gesundheitsrechtlichen Regulierungsgefüge*, in *Neue Zeitschrift für Sozialrecht*, vol. 2, 2021, 43.
[45] Sec. 139e SGB V; https://diga.bfarm.de/de/verzeichnis.
[46] Sec. 91, 92 SGB V.
[47] Sec. 33a (4) Sentence 2 SGB V.
[48] W. Lauer, W. Löbker, T. Sudhop and K. Broich, *Digitale Gesundheitsanwendungen (DiGA) als innovativer Baustein in der digitalen Gesundheitsversorgung in Deutschland – Informationen, Erfahrungen und Perspektiven*, in *Bundesgesundheitsblatt*, vol. 64, 2021, 1195.
[49] P. Axer, *Verfassungsrechtliche Fragen der Erbringung digitaler Gesundheitsanwendungen nach dem SGB V*, in *Medizinrecht*, vol. 40, 2022, 271.
[50] Sec. 139e (2) SGB V; Digitale Gesundheitsanwendungen-Verordnung-DiGAV; www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiGA/_node.html.
[51] See K. Schreiber and B. Gottwald, *Gesundheits-App auf Rezept*, in *Zeitschrift für Datenschutz*, vol. 8, 2020, 390, also for more data privacy issues.
[52] BfArM, Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 138e SGB V, Guidance, Version 3.3, 4 September 2023, 40 for further details.

systems in connection with the DiGA.

A special feature of DiGA assessment is the criterion of positive effects in the supply of healthcare, which includes both clinical benefit and structural and procedural improvements that are relevant to patients.[53] Examples are promoting health literacy, patient sovereignty and better coordination of treatment processes. The proof of positive effect is to be provided by quantitative comparative studies showing that using the DiGA is better than not using it.[54] The requirements for the proof are rather low compared to other SHI services. Furthermore, manufacturers have flexibility in terms of time. They may provide evidence for the benefits of their DiGAs either directly with the application for the fast-track process or generate it during a trial phase that includes temporary reimbursement.[55] All DiGAs in the register are reimbursable by the SHI, regardless of whether the listing is already permanent or initially only provisional. For manufacturers, the BfArM provides a range of support tailored to the requirements (for example, in the form of guidance).[56]

4.4. *Pricing*

DiGA pricing is determined in two stages, when it is included in the directory and one year after the inclusion (Sec. 134 SGB V). After the first year of open pricing, a price for a new DiGA is negotiated between the DiGA-manufacturer and the GKV-Spitzenverband.[57] To this end, the GKV-Spitzenverband has concluded a framework agreement with the top organizations of DiGA-manufacturers on the benchmarks for the agreements on remuneration amounts.[58] An expert committee is responsible for assigning DiGAs to ceiling price groups and for calculating ceiling prices. An arbitration board determined regulations on maximum amounts and thresholds, but there is still plenty of room for manufacturers to achieve high prices for their DiGAs.[59] Maximum amounts have been set for groups of comparable DiGAs, but the maximum amounts are based on the (high) prices of the listed DiGAs. Accordingly, pricing is complicated and can prevent abuse, but does not ensure a fair price from the SHI perspective.[60]

As with innovative drug pricing regulations[61], manufacturers can charge extremely-high prices in the first year of a DiGA's directory inclusion, during which time patients become accustomed to a DiGA. How the price is determined by the manufacturers in the first year and shown in the directory remains non-transparent.[62] Open pricing in the first year also applies to trial DiGAs, which must be reimbursed during this period, even if they have not yet provided evidence of positive-care effects. Limitations are necessary, because the SHI generally does not use the contributions of their insured persons to fund research by manufacturers. It is questionable whether the existing price limits are sufficient.

4.5. *Development*

At the beginning of October 2020, the register went online with the first two DiGAs – the tinnitus app "Kalmeda" and the web application "Velibra" for treatment support in anxiety disorders. From the opening of the application portal to September 2023, 186 applications were submitted.[63] Of these, 146 were requests for provisional admission for testing and 40 were requests for permanent admission. This reflects the increasing interest of manufacturers in provisional admission. The result of the applications is that 49 DiGAs have been added to the list, 16 applications have been negatively assessed and 98 applications have been withdrawn as of

[53] Sec. 139e (2) SGB V; Sec. 8 DiGAV; BfArM, Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 138e SGB V, 92.
[54] For details § 10 DiGAV; BfArM, Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 138e SGB V, 100.
[55] Sec. 139e (4) SGB V.
[56] https://diga.bfarm.de/de/diga-hersteller.
[57] The negotiations, their preparation, including the consultation documents and minutes of agreement on the amount of remuneration, are confidential. Sec. 134 (1) Sentence 5 SGB V.
[58] Rahmenvereinbarung nach Sec. 134 Absatz 4 und 5 SGB V, 16 December 2021, at www.gkv-spitzenverband.de/krankenversicherung/digitalisierung/kv_diga/diga.jsp.
[59] For more details, see www.gkv-spitzenverband.de/gkv_spitzenverband/presse/fokus/fokus_diga.jsp.
[60] For the different perspectives, T. Severin, Viel Konfliktstoff bei Gesundheits-Apps, in G+G, vol. 3, 2022, www.gg-digital.de/2022/03/viel-konfliktstoff-bei-gesundheits-apps/index.html.
[61] Sec. 35a SGB V.
[62] S. Stoff-Ahnis, *Digitale Gesundheitsanwendungen – Das erste Jahr aus Sicht der Gesetzlichen Krankenversicherung*, in *Medizinrecht*, vol. 40, 2022, 287.
[63] BfArM, 20 September 2023, www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiGA/_node.html.

September 2023. Seventeen applications are currently being processed, and six DiGAs were removed from the list. For data-protection reasons, the BfArM cannot provide information on application details, such as which manufacturers have submitted applications or to which DiGA they refer. Hence, detailed information on unsuccessful applications is not available. Potential bases for failure include, for example, deficiencies in data protection and information security, inability to demonstrate positive effects on the supply of healthcare, or the fact that the studies presented did not satisfy the principles of evidence-based medicine.[64] With time and with each application, manufacturers continue to gain experience and can better meet standards.

4.6. *Evaluation and Perspective*

In its first and second reports (September 2020 to September 2022), the GKV-Spitzenverband took stock of the uptake and development of care with DiGAs.[65] Both reports criticize the lax quality control and the high price in relation to the proven benefits. Even the maximum amounts that have been in force since October 2022 do not significantly limit the very high price level.[66] This contradicts the efficiency principle in the SHI system. According to the statement of the GKV-Spitzenverband, the relatively-low eligibility requirements for DiGAs are also inconsistent with other SHI benefits. Health insurers must provide their insured with DiGAs for which the medical benefit has not been proven and it is unclear whether and to what extent the DiGAs can help. In addition, the practice of the statutory health insurers in approving digital health applications is inconsistent, including the intensity of the review conducted. It is also not transparent whether and to what extent a patient uses the DiGA. However, this aspect should be considered when setting the price for the DiGA, as it is not just about downloads.

There is a consensus that DiGAs can improve healthcare, particularly complementing and supporting existing services, but the law needs to be amended. The planned Digital Act (DigiG) is intended to address this demand.[67] The proposed law requires the GKV-Spitzenverband to issue a guideline with uniform requirements for the approval process. The guideline must specify the scope of the examination and the type of proof of a medical indication as a prerequisite for approval. An exclusion of benefits is provided for products of DiGAs that are only intended for use with certain medical aids or medicines. Based on prior experience, the law will also clarify that it is impermissible for a DiGA to be deliberately created and designed as a result of agreements between various manufacturers that would make the application only suitable for accompanying a therapy with a specific drug, medicinal product, or medical device, thereby rendering the app's use with other suitable medical aids or medicines is impossible. This also applies to other agreements or concerted practices by manufacturers. The clarification is intended to safeguard the insured's freedom of choice and physicians' freedom to select therapies. It is also important to find the balance between proof of benefit and openness to innovation. The evolution of the benefit and its impact will continue to be examined using data on care-delivery patterns. Pending legislation, like the DigiG, underscores that it remains to be seen whether and to what extent DiGAs can be integrated and established in the growing digital-healthcare structure.

5. *Looking Ahead – Prospective Considerations*

Leading the historically complex German healthcare system into a digital age is a long, extensive process. The influx of legislation on digitization in the healthcare sector observed over the last decade is far from final, and stakeholders can anticipate more action as the system continues to build the frameworks that best leverage digital technologies' health benefits. Indeed, the coalition government

[64] W. Lauer, W. Löbker and B. Höfgen, *Digitale Gesundheitsanwendungen (DiGA): Bewertung der Erstattungsfähigkeit mittels DiGA-Fast-Track-Verfahrens im Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)*, in *Bundesgesundheitsblatt*, vol. 64, 2021, 1238 for a differentiated evaluation.

[65] www.gkv-spitzenverband.de/gkv_spitzenverband/presse/fokus/fokus_diga.jsp.

[66] About 600 to 900 Euro during the free pricing period in the first year; average price after one year about 215 Euro (DiGA-Bericht des GKV-Spitzenverbands, Berichtszeitraum: 1 September 2020 - 30 September 2022, in www.gkv-spitzenverband.de/krankenversicherung/digitalisierung/kv_diga/diga.jsp.

[67] Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz-DigiG), Drucksache No. 435/23, 98-99.

agreed on the digitization of healthcare as a shared priority,[68] and new digital laws are on their way. In addition to measures contained in DigiG and GDNG, proposed legislation includes action such as a messenger service for communication between care providers, and at least 300 research projects carried out or initiated using data from a research data center.[69]

With a basic infrastructure established, the system is entering a phase where it must more earnestly consider macro-level questions, beyond legal and technological aspects, related to the digitization process. Societal considerations about digital services and their support outside the healthcare sector must be considered, and that (social) factors external to the healthcare sector have a profound impact on digitization's success should be recognized. The process of digitalization has moved beyond theoretical options to binding practical steps toward nationwide digital coverage. Each participant in the healthcare system has its part to play, with the quality of patient care as the common goal that can be realized by using health data to a much greater extent. The more extensive the participation and the more seamless the system, the more successful digitization will be.

The exercise in DiGA incorporation should remind stakeholders of this in the progress toward flexible digital integration. DiGAs were meant to enhance patient voice, embodying, for example, patient-relevant components in the reimbursement considerations.[70] However, surveys post-implementation revealed preliminary provider reluctance toward DiGA prescription providing, citing lack of evidence and patient and provider education as some of the many reasons for their reluctance.[71]

Following innovation introduction, stakeholders should channel efforts into supporting uptake and integration, ensuring proficient usage of these tools, through actions such as continuing education for providers,[72] and enhancing patient digital literacy.[73] Evaluation of digital integrations will also serve as an instrumental tool in the evolution of digital products and services in the SHI. Looking ahead, reforms should make the system flexible enough to incorporate changes with ease and, ultimately, deliver optimal healthcare to all.

6. *Conclusion*

The potential of digitization in healthcare has not yet been fully realized in Germany, but important steps have been taken. This paper has illustrated how necessary legal frameworks have been implemented in the context of the existing system and are constantly being improved. Regulators must reckon with their role as system influencers, both at present and in the future. They must grapple with and balance inherent and frequently-conflicting interests in the pursuit of digitization. By setting the standards for digitally-enhanced healthcare, they necessarily shape innovation as well, influencing how high or low a standard must be for an innovator to become a player in the healthcare system, and accordingly for a patient to reap the benefits of digital innovation.

[68] Koalitionsvertrag 2021-2025, Zwischen der Sozialdemokratischen Partei Deutschlands (SPD), Bündnis 90, Die Grünen und den Freien Demokraten (FDP), *Mehr Fortschritt Wagen*, in *www.spd.de/fileadmin/Dokumente/Koalitionsvertrag/Koalitionsvertrag_2021-2025.pdf,* 83.

[69] For more, www.bundesgesundheitsministerium.de/presse/pressemitteilungen/digitalisierungsstrategie-vorgelegt-09-03-2023.html.

[70] Federal Institute for Drugs and Medical Devices, The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users, Bonn, 2020, 77 (available at www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf;jsessionid=437C9A1406E15C4B8D610B488FFC94D8.2_cid329?__blob=publicationFile&v=2).

[71] J. Wangler and M. Jansky, *Welche Potenziale und Mehrwerte bieten DiGA für die hausärztliche Versorgung? Ergebnisse einer Befragung von Hausärzt*innen in Deutschland [What potential and added value do DiGA offer for primary care? Results of a survey of general practitioners in Germany],* in *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*, vol. 65, No. 12, 2022, 1334-1343; M. Radić, I. Donner, M. Waack, C. Brinkmann, L. Stein and D. Radić, *Digitale Gesundheitsanwendungen: Die Akzeptanz steigern*, in *Dtsch Arztebl*, vol. 118, No. 6, 2021, 286-92.

[72] S. Sauermann, J. Herzberg, S. Burkert and S. Habetha, *DiGA - A Chance for the German Healthcare System*, *Journal of European CME*, vol. 11, No. 1, 2021, 2014047.

[73] Y. Goldwasser, W.J. Gordon, J.B. Brönneke and A.D. Stern, *On The Brink of a Digital Health Care Transformation: What Germany Can Learn From The United States*, Health Affairs Blog, 2021, in www.healthaffairs.org/content/forefront/brink-digital-health-care-transformation-germany-can-learn-united-states.

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*e-Healthcare in Hungary With the Help of ICT Tools**

Balázs Szabó
(Assistant professor, University of Miskolc, Faculty of Law, State Sciences Institutiones, Department of Public Administration Law)

ABSTRACT In addition to the smartphone applications, some specialized administrative bodies of the public administration have additional opportunities to facilitate the activities of the authorities. One of the important technical and development tools of the 21th century, is the big variety of drones, which were originally developed for military purposes. The another most important info-communication tools (hereinafter: ICT) are the smarth-phones. Undoubtedly, these equipments can be apostrophized as probably the most popular technical tools, based on the fact that in addition to their ever-expanding uses, they also provide excellent help for leisure activities and outdoor photo/video documentation. In addition, we can find their application in more and more fields of our Hungarian public administration system. In recent years, the use of smartphones and applications on them, has been successfully introduced in more and more administrative areas, which makes the work of the authorities more efficient and faster, which in many cases can lead to the saving of human lives too. After (?!) the Corona virus pandemic, I have no doubt about, that the health care, and the e-solutions, developements helped a lot till nowadays, and it will be just more important in the next years as well. I will highlighted some of the good practices that I consider to be most important and may give some positive expressions to implement them in other fields.

1. *Introduction*

The development of healthcare is one of the most important interests of society as a whole and one of the sectoral areas of greatest interest. In the life of a modern state, the service provider must be as efficient as possible and of the highest quality. This is especially true for the health sector, where citizens' health and possibly their lives are at stake. That is why the current Hungarian government must also do everything to be able to provide the most modern equipment for healthcare institutions.[1]

In this article, I tried to introduce the most important developements from the recent years, which were originated by the public administration developement programs of Hungary, especially focussing on the „smart-solutions". These developements, which are basically using and need smart phones are the best and necessary answers by the state for the new challgenges. Thanks to the covid-19 pandemic and the many official actions caused by it, the world and thus Hungary has learned that it is advisable to use as widely as possible the smart devices that are present in the largest number of citizens, which are smartphones.

Digital health and care cover the tools and services that use information and communication technologies to improve prevention, diagnosis, treatment, monitoring of health-related issues and as well as monitor and manage the interaction of health and lifestyle, such as artificial intelligence, blockchain, the interconnection of devices (IoT) or the 5G network. Innovative digital healthcare and care can improve the quality of care and access to care, as well as increase the overall efficiency of the healthcare sector or reduce administrative burdens. The topic is extremely difficult, as new projects, participants, or initiatives that "change everything" appear every day. In the following, I would like to briefly present the Hungarian developments.

1.1. *Developments in Hungary*

In connection with the present article, I did not of course wish to present the entire vertical of healthcare developments in Hungary, but specifically tried to present the topic of electronic solutions, software, and applications. In recent years, of course, many organizational changes and developments have taken place, as well as in the field of the development of applied medical technology devices. However, I do not want to address them in this study, not least because the series of organizational transformations does not

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[1] See more about this: Z. Árva, *The role of state bodies in health administration*, in A. Bencsik (ed.), *Public administrative legal knowledge: Study material for healthcare professionals - with special regard to the organization and administration of healthcare*, Budapest, Hungary, Health Registration and Training Center (ENKK), (2016), 18, 55-72.