Draft Act

of the Federal Government

Draft Data and Digital Innovation Act for Health

A. Problem and aim

The consistent digitalisation of our health and care systems in line with users' needs is key to ensuring modern, efficient and future-proof care in Germany. The rapid, safe and complete provision of medical and nursing information and the expansion of digital technologies and infrastructure can optimise care, increase patient safety and thus improve healthcare in a sustainable way.

In recent years, we have seen great progress in Germany in digitalising our healthcare and care systems. Many legal and practical steps have been taken to make healthcare more efficient and patient-centred, using digital services and applications. The comprehensive introduction of the electronic health record (ePA) brings together the health data of insured persons in the hands of insured persons. With the introduction of applications such as the electronic prescription (e-prescription) and the electronic reporting of disability data from the medical office to the health insurance fund to the employer, important conditions have been created for digitalisation in care to reach its full potential. The law on the improved use of health data makes health data more extensively usable for care and research than before. And the digitalisation strategy for health and care also highlights the need for digitalisation to be optimally integrated into care processes.

This high pace of digitalisation in healthcare and care needs to be maintained. Building on past experience and achievements, there are many more opportunities to harness the potential of digital applications and data-driven processes, thus contributing to better and more cost-effective healthcare. In order to exploit these potentials and achieve the core objectives of digitalisation in healthcare and care – better care, more patient safety, less red tape for healthcare providers – this law aims to take action in almost all areas of our healthcare and care that are relevant to digitalisation.

For example, further development of the telematics infrastructure, the ePA and the Telematics Society is needed. The existing digital utility elements will be further developed in a more user-friendly way, integrated into good processes and linked to new digital opportunities. It is also necessary to promote the interoperability, but also the performance, stability and user-friendliness of service providers' information technology systems in order to ensure seamless and therefore user-friendly healthcare processes. The ePA will be continuously developed to make best use of it for supply-related purposes. The aim is to make existing data from the ePA fully usable, to increase competition for good and useful applications for insured persons and to promote innovation within the ePA. User-friendly usability and accessibility for specific patient groups and ePA users will be taken into account. Further development of access to the ePA by pharmacists is also needed to ensure a comprehensive review of drug therapy safety. The Act also aims to provide technical guidance on the planned primary care concept for the outpatient sector.

Potential in the secondary use of health data will also be better exploited, for example in the area of cross-sectoral research, improved governance of our health system and

care or the integration of innovative technologies. By further developing the legal framework, existing hurdles can be reduced and clear, workable rules can be put in place that not only enable the use of health data for medical research, but also serve the objective of sustainably improving patient care. This law continues the path towards an interconnected and interoperable health data infrastructure.

All these arrangements must take into account the new European law requirements of Regulation (EU) 2025/327 on the European Health Data Space (Regulation (EU) 2025/327). Regulation (EU) 2025/327 aims to establish a common framework for the use and exchange of electronic health data across the EU (European Health Data Space ('EHDS'). Regulation (EU) 2025/327 allows patients to better access and control their personal electronic health data (primary use). In addition, certain data can be re-used for purposes of public interest, support for public health policies and scientific research (secondary use). This Act serves to implement Regulation (EU) 2025/327 in a timely manner, both in the area of primary use and in the area of secondary use.

The purpose of this law is therefore, in particular, to:

- create essential technical conditions for the preparation of a digitally-supported primary care system;
- Harnessing health data for care, research and improving our health system;
- to strengthen the innovative use of data held by health and care insurance funds in a flexible and legally certain manner in the interests of insured persons,
- implement Regulation (EU) 2025/327 in Germany in a non-bureaucratic, timely and innovation-friendly manner;
- build a European-ready and interconnected health data ecosystem in Germany;
- further develop the interoperability process in health and care in a consistent and cross-sectoral manner;
- further develop the ePA for supply-related purposes to ensure the best possible and feasible use of the ePA;
- strengthen competition for applications that are well-managed and beneficial for insured persons with different levels of digital literacy and until old age, and promote innovation within the ePA;
- improve the operational resilience of the telematics infrastructure; and
- further advance the digitalisation of communication between healthcare and care providers.

B. Solution

In order to achieve the objectives outlined above, the following main measures will be added to the existing legislation.

Strengthening primary use of health data and care-orientation:

This Act makes the necessary adaptations to national law to implement Regulation (EU) 2025/327. In the area of primary use of health data (for care purposes), the future mandatory cross-border infrastructure MyHealth@EU will gradually transfer different

categories of electronic health data between EU Member States from 2029 onwards. The tasks of digital health bodies and market surveillance authorities implementing primary use rules and electronic health record systems (in short: EHR systems) are allocated to appropriate bodies within the German health system, with a particular focus on assigning tasks to the Society for Telematics (gematics). The role of gematics will also be further developed in the area of interoperability. The tasks of the Competence Centre on Health Interoperability shall be extended, in particular as part of the conformity assessment procedure. Reassigned tasks, including by defining qualitative and quantitative functions of information technology systems in healthcare, will ensure that they can not only communicate with each other at the technical, semantic and syntactic level, but can also be used in practice by users as intended. At the same time, this reduces the administrative burden on healthcare providers and further increases the quality and patient-centricity of healthcare. Both service providers and manufacturers of information technology systems will be required to further strengthen and implement the right to interoperability of patients. The former will have to keep health-related data of their patients in interoperable format. This corresponds to the obligation for manufacturers of information technology systems to make this interoperable data retention in the service providers' systems possible in the future. The Associations of Statutory Health Insurance Physicians will also provide service providers with digital advice on the digitalisation of practices and the expansion of competences, including on cybersecurity.

In order to provide advice and support to specific patient groups and users of the ePA more specific to the target group (e.g. (older) people with low digital skills, people with disabilities, children and young people, and taking into account gender-specific needs), further rights will be granted to the Ombudsperson bodies of the health insurance funds. First of all, it will be possible to set up, manage and delete representative arrangements via the Ombudsman's Office.

Strengthening secondary use of health data for care, research and innovation:

The requirements of Regulation (EU) 2025/327 are also being implemented in the area of secondary use of health data. This will create the legal framework for building an interconnected, European-ready health data ecosystem. First, the envisaged roles and tasks are distributed in the data access process in accordance with Chapter IV of Regulation (EU) 2025/327. A decentralised system with a coordinating access point and additional dome-specific access points are envisaged. In addition, the necessary arrangements will be made for the organisation of opposition proceedings and a register of the rights of interested parties will be set up. In order to enable the linking of data and the implementation of opposition rights in the EHDS secondary use process, a *unique research identifier* shall be established.

The EHDS data infrastructure will not be built as a silo, but will be interconnected with other data spaces. The research metric will be co-created as a tool for cross-cutting linkage. A regulation on linking health data with other data in line with EU law is planned and is to be enshrined in future horizontal research data legislation.

In addition to the EHDS secondary use process, the use of health data will also be further improved. In particular, the further use of data from health insurance funds will be strengthened. A legal basis for the establishment of regulatory sandboxes will allow health insurance funds to test innovative data use with legal certainty in the future. The existing rule on data-based identification of individual health risks by health insurance funds and long-term care funds will also be revised.

The Health Research Data Centre (FDZ) at the Federal Institute for Drugs and Medical Devices will also be further developed. In future, in certain cases, an application for access to data will also be made to the FDZ, in which individual health care providers will be identified. Such a request would be admissible, for example, if it serves to establish

contact between health care providers with similar cases, for example in order to allow for technical exchanges between health care providers.

Making health data of all genders available without discrimination reduces *the gender data gap*. The data thus available allow for more gender-sensitive assessments that can help identify gender differences in care, diagnostics and therapy. Research and development will also take better account of women's health needs and circumstances.

Adding value through digital applications and supply processes

Various rules create tangible added value for insured persons and relief for health care providers. The aim is to provide insured persons with user-friendly, digital pathways to outpatient care, which will also prepare for the introduction of the planned primary care system. An important tool is the e-transfer, which we intend to establish during this legislative term. We also want to create a digital start: Insured parties can be redirected nationwide via the ePA user interface (ePA app) to the nationwide standardised initial assessment by the appointment service points of the health insurance fund associations and then, if necessary, to a digital appointment booking, thus using a simple, digital route to outpatient care. In further steps, the standardised initial assessment is to be replaced by a more comprehensive digital needs assessment to assess the need for and urgency of treatment and to allocate treatment needs to the appropriate level of care. The Federal Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) and the Central Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen) are instructed to agree on the requirements and requirements necessary for the digital assessment of needs; the Federal Association of Statutory Health Insurance Physicians is also tasked with implementing and providing an electronic system for a uniform national digital needs assessment. In addition, we are making the necessary regulations to ensure that also digital appointment intermediation via private providers is carried out in a non-discriminatory manner and that the requirements of data protection and data security are complied with.

In addition, the legislative framework for digital health applications (Diga) is to be developed in a targeted manner, thereby reducing red tape.

In addition, the legal framework for the introduction of value-added applications by the health insurance funds in the ePA will also be made more accessible. In addition, existing data from the ePA will continue to be used. As a concrete added value application, digital vaccination documentation will be introduced as a preliminary step in the digitalised vaccination process, based on billing data. By expanding access for pharmacists, drug therapy safety is taken into account in other supply-related scenarios. The existing rules on e-prescription will be adapted to the new requirements in practice, including the implementation of new types of prescriptions. The scope of the e-invoice is extended to include direct billing for service providers and to allow its use by accident insurance. Secure methods of transmission in the health and care sectors will be further developed by consolidating and specifying the requirements. This will facilitate the use of secure transfer procedures.

The rules on the medical communication applications (KIM) and the instant messaging service of the telematics infrastructure (TI-Messenger – TI-M) will be bundled, clarified and supplemented. The aim is to ensure ubiquitous, interoperable and secure communication. Therefore, all service providers affiliated to TI will in future be obliged to use KIM for medical, nursing and administrative communication.

Gematics is intended to play a more steering role in order to improve the operational resilience of the telematics infrastructure. To this end, it should be able to centrally tender, bundle, operate or have operated components and services directly related to the telematics infrastructure and directly enforce operational obligations vis-à-vis the

operators actually responsible. In addition, comprehensive powers are granted to counter threats to the operational resilience of the telematics infrastructure and to remedy disruptions.

C. Alternatives

Absent. The objectives can only be achieved through legislative adaptation. Other alternatives are neither useful nor effective. The draft is intended, inter alia, to implement the directly applicable Regulation (EU) 2025/327.

D. Budgetary expenditure excluding implementation costs

(a) Federal Government

The establishment of a coordinating data access body, which serves in particular to implement the Regulation on the European Health Data Space, at the Federal Institute for Medicinal Products and Medical Devices incurs a one-off budgetary expenditure of approximately EUR 11.3 million. This appropriation is intended to be used in particular for the development of technical infrastructure. In addition, there are annual costs of up to EUR 2.3 million, which are needed in particular for the staff of the coordinating data access point, as well as ongoing material costs.

There are also one-off costs of EUR 0.65 million for the expansion of the Research Data Centre for Health at the BfArM. Increasing effort in setting semantic interoperability results in an additional annual effort of EUR 0.9 million for the BfArM.

The Federal Government also incurs one-off costs of around EUR 10 million for setting up and operating a register for the implementation of data subjects' rights, as provided for in Regulation (EU) 2025/327, and one-off costs of around EUR 10 million from the start of operations (vsl. 2029) annual costs of approximately EUR 5 million. These one-off costs for the deployment of the interconnected health data infrastructure will be funded by the Special Fund for Infrastructure and Climate Neutrality (SVIK).

The annual staff costs for setting up a complaint-handling body in the field of gematics amount to approximately 0.2 million. Euro. The cost of financing BSI expenditure as a market surveillance authority is approximately EUR 0.1 million.

The resulting additional annual needs of the Federal Government in terms of material and staff expenditure must be compensated for financially and in terms of (planned) posts in the relevant section of the budget. An agreement must be reached by 31 March 2034 on the financing of any additional annual needs of the Federal Government for material and personnel expenditure arising from the implementation of Chapter IV of Regulation (EU) 2025/327 on the basis of the evaluation pursuant to § 23 GDNG.

(b) Länder and municipalities

None

(C) Social security

Additional expenditure of around EUR 2.2 million per year is incurred on statutory health insurance as a result of the extension of the services of the Research Data Centre for Health. On the other hand, there is an annual reduction of around EUR 4 million as a result of the removal of the lump sum for the e-doctor's certificate.

E. Implementation costs

The change in the total annual implementing costs of approximately 0.17 million hours and minus approximately EUR 447 million is subject to the ‘one in, one out’ rule. Of this, 0.1 million hours and EUR 10.000 are due to the implementation of EU law.

E.1 Implementing costs for the public

Citizens incur an annual implementing cost of approximately 0.17 million hours and a one-off implementation cost of approximately 1.3 million hours.

E.2 Implementing costs for industry

The draft entails significant savings for service providers. The introduction of electronic remittances in the outpatient sector is expected to lead to significant efficiency gains in the care process, leading to savings in time and material costs. The annual relief for service providers is estimated at around EUR 445 million. At the same time, the relief concerns administrative costs arising from information requirements.

For the survey of the KVNR, one-off implementing costs of approximately EUR 0.3 million are estimated for the adaptation of specialist procedures in the economy. For the implementation of the pharmacy information system, a one-off implementation cost for service providers of approximately 0.3 is also estimated.

E.3 Implementation costs for the administration

The draft law creates a one-off additional implementing cost for the administration of approximately EUR 0.2 million.

In addition, the social security system incurs one-off implementing costs of approximately EUR 12.9 million.

Of this amount, approximately EUR 550.000 will be incurred in the form of non-recurring implementation costs.

This compares with an annual reduction of around EUR 3.1 million for social security.

F. Other costs

None

Draft Law of the Federal Government

Draft Data and Digital Innovation Act for Health[1]

From.....

The Bundestag has adopted the following Law:

Content overview

Artikel 1

Amendment of Volume V of the Social Code

Volume V of the Social Security Code – statutory health insurance – (Article 1 of the Law of 20 December 1988, BGBl. I p. 2477, 2482), as last amended by Article 1 of the Act of 26 June 2026 (BGBl. 2026 I No 195), is amended as follows:

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[1] Notified pursuant to of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

1. Section 25b is amended as follows:

a) In point (a), the first paragraph is replaced by the following:

(1) ‘ In order to protect the health of an insured person, the sickness and care insurance funds may carry out data-based evaluations and inform the insured person of the results of these evaluations, provided that the evaluations serve the following purposes:

1. the detection of rare diseases;

2. cancer detection;

3. the detection of serious cardiovascular diseases or an increased risk thereof;

4. the detection of serious health risks that may arise from the therapy of medicinal products;

5. the identification of an imminent need for care pursuant to Section 14 of Book Eleven,

6. the detection of similarly serious health risks, in so far as, from the point of view of the sickness and long-term care funds, this is in the overriding interest of the insured persons, or

7. the detection of the presence of vaccination indications for preventive vaccinations recommended by the Permanent Vaccination Commission pursuant to Section 20(2) of the Infection Protection Act.’

b) A (b)(2) is amended as follows:

a%6) The following sentences are inserted after the first sentence:

‘In addition to the personal data of insured persons held by the health and care insurance funds, the health and care insurance funds may also process data from an insured person’s electronic health record, provided that these data are made available to the health insurance funds pursuant to § 345 with the insured person’s consent and that these data are suitable and necessary for the purposes referred to in paragraph 1. Sickness and long-term nursing care funds may, with the consent of the insured persons, collect additional personal data from them in so far as such data are appropriate and necessary for the purposes referred to in paragraph 1. Data collected in accordance with the third sentence shall be transferred by the health insurance funds to the electronic health record and stored in accordance with § 341(2) No 20.’

b%6) In the new seventh sentence, the words ‘or processed by them in accordance with the second sentence or collected in accordance with the third sentence’ shall be inserted after the words ‘present’.

c%6) In the new eighth sentence, the words ‘fourth sentence’ are replaced by the words ‘seventh sentence’.

c) In the second sentence of paragraph 3, the words ‘, including public’ are replaced by the words ‘public’.

d) A bsatz 4 Sz 4 and 5 are replaced by the following sentences:

‘The information referred to in the first sentence shall be provided in writing, unless the insured person has consented to transmission in another form. With the information referred to in the first sentence, the health and care insurance funds may also provide information on individually appropriate care innovations and other individually appropriate care benefits in accordance with the first sentence of Section 68b(2). For the purposes of documentation and transparency, the health and care insurance funds shall transmit the information referred to in the first sentence to the electronic health record and store it in accordance with Section 341(2), point 20.’

e) In point 6, the second sentence is deleted.

2. § 31a is replaced by the following § 31a:

‘Paragraph 31a

Medication plan

(1) Insured persons who use at least three prescribed medicinal products at the same time are entitled to have a medication plan drawn up by a doctor participating in the statutory health insurance scheme. Each doctor taking part in the statutory health insurance scheme must update the medication plan as soon as they change the medication or receive a notification from the insured person of changes. The insured person is entitled to receive a paper copy of the medication plan from any doctor participating in the statutory health insurance scheme. The doctors participating in the statutory health insurance scheme shall inform the insured person of the entitlements referred to in the first and third sentences. The Federal Association of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds shall agree on the conditions for entitlement under sentences 1 and 3 as part of the Federal Sickness Insurance Contracts. When a medicinal product is dispensed, the pharmacy shall update the medication plan in accordance with Section 346(2) where necessary.

(2) The medication plan must be documented with instructions for use.

1. all medicinal products prescribed to the insured person;

2. Medicinal products used by the insured person without a prescription, and

3. References to medical devices, in so far as they are relevant to the medication referred to in points 1 and 2.

The specific needs of blind and visually impaired patients shall be taken into account when explaining the contents of the medication plan.

(3) If the insured person has an electronic medical record, the medication plan shall be stored there in accordance with § 347(1). If the insured person does not have an electronic health record or has objected under § 353(1) to the processing of data from the medication plan in the electronic health record or under § 353(2) to access to data from the electronic health record by the doctor who draws up or updates the medication plan, the doctor shall store the medication plan in the information technology system used by the doctor.

(4) In the case of the indication of finished medicinal products, the medication plan shall include, in addition to the name of the medicinal product, in particular the name of the active substance, the pharmaceutical form and the strength of the medicinal product. Uniform designations shall be used for this purpose and shall be made available in the reference database pursuant to § 31b.

(5) The content, structure and detailed rules for drawing up and updating the medication plan and the procedure for updating it shall be agreed between the Federal Association of Statutory Health Insurance Physicians, the Federal Chamber of Physicians and the relevant umbrella organisation of pharmacists set up for the protection of economic interests at federal level, in consultation with the Central Federal Association of Health Insurance Funds and the German Hospital Society, and, with regard to the technical design of the medication plan and the rules on storage and use in the electronic health record, in agreement with the Society for Telematics. The agreement shall establish a uniform format of the medication plan, independent of the place of storage. The organisations responsible for the protection of patients' interests and the self-help of chronically ill and disabled people at federal level must be given the opportunity to comment.

(6) The provisions of this provision shall be without prejudice to regional pilot projects pursuant to § 63.'

3. The fourth sentence of Section 31b(3) is replaced by the following sentence:

'Organisations responsible for the protection of patients' interests and the self-help of chronically ill and disabled people at federal level shall be given the opportunity to comment.'

4. Section 33a is amended as follows:

a) In the fifth sentence of the first paragraph, the following sentence is inserted:

'The entitlement referred to in the first sentence shall also include digital health applications used for the remote monitoring of the health status of insured persons using digital technologies.'

b) A (b)(2) is replaced by the following second paragraph:

(1) ' Low-risk medical devices within the meaning of the first sentence of paragraph 1 are those in risk class I or IIa within the meaning of the relevant provisions of medical device law which have already been placed on the market as such. Higher-risk medical devices within the meaning of the first sentence of paragraph 1 are those in risk class IIb within the meaning of the relevant provisions of medical device law which have already been placed on the market as such.'

c) Paragraphs 6 and 7 are replaced by the following paragraphs 6 and 7:

(1) ' The Central Federal Association of Health Insurance Funds shall provide the Federal Ministry of Health annually, by 1 April of each calendar year, with data on how and to what extent benefits under paragraph 1 are granted to insured persons at the expense of its members. To this end, the Central Federal Association of Health Insurance Funds shall determine the statistical information to be provided by its members on the benefits reimbursed and the nature and extent of the transmission. The Federal Ministry of Health may specify the content of the data to be transmitted in the statutory ordinance pursuant to § 139e(9).

(1) D The Central Federal Association of Health Insurance Funds shall forward to the Federal Ministry of Health for each calendar quarter no later than two weeks after the end of each calendar quarter:

1. the number of prescriptions per digital health application by the treating physician or psychotherapist;

2. the number of digital health applications made available on the basis of a regulation per digital health application;

3. the number of applications for authorisation submitted to health insurance funds per digital health application, including the number of applications approved and rejected; and

4. the amount of benefit expenditure incurred by its members in respect of the benefits referred to in paragraph 1.

The Federal Ministry of Health shall publish the data transmitted in accordance with the first sentence on the internet.'

5. Section 64e is amended as follows:

a) In paragraph 3, the seventh sentence is replaced by the following sentences:

'The Central Federal Association of Health Insurance Funds may specify the requirements referred to in sentences 1 to 5 and lay down further appropriate conditions for the participation of service providers under sentence 1 in the pilot project. If the Central Federal Association of Health Insurance Funds deviates from the recommendations under sentence 6, it shall justify the deviation to the German Hospital Association. The Central Federal Association of Health Insurance Funds shall publish on its website the requirements which it specifies and other appropriate conditions.'

b) In paragraph 4, fifth sentence, the following sentence is inserted:

'The Central Federal Association of Health Insurance Funds shall lay down the details of the application procedure referred to in the first sentence.'

c) In point 6, the second sentence is replaced by the following second sentence:

'The use of the data for the purposes referred to in point 1 of the seventh sentence of paragraph 9c and point 4 of the third sentence of paragraph 11 shall be subject to the prior written or electronic consent of the insured persons vis-à-vis the healthcare providers, in compliance with data protection requirements, in particular the rights of the data subject under Articles 12 to 22 of Regulation (EU) 2016/679.'

d) In the seventh sentence of paragraph 9, the first and seventh sentences of paragraph 9a and the first sentence of paragraph 9b, the words 'education and research' are replaced by the words 'research, technology and space'.

e) (A)(b)(9c) is amended as follows:

a%6) S atz 3 is amended as follows:

a%7%7) N ummer 4 is replaced by the following point 4:

1. ‘ to generate a random transaction number for a case identification referred to in point 1 of the seventh sentence in relation to the data transmitted to it in accordance with point 3 of the third sentence of paragraph 10 and to send it, together with the contact of the requested service provider and the operation number, to the requesting service provider via a data service,’;

b%7%7) In point 5 of the third sentence of paragraph 10, the words ‘the data communicated to it in accordance with point 2 of the third sentence of paragraph 10’ are replaced by the words ‘the operation number communicated to it in accordance with point 5 of the third sentence of paragraph 10’.

b%6) In the 11st sentence, the words ‘and the relevant pseudonyms’ are replaced by the words ‘together with the operation number’.

f) (A)(b)10 is amended as follows:

a%6) S atz 3 points 1 and 2 are replaced by the following points 1 to 5:

1. ‘ the requesting health care provider to a data service, the request criteria;

2. the data service at clinical data nodes or genomic data centres referred to in point 1, a project number together with the request criteria;

3. the clinical data nodes or genome data centres referred to in point 2 to the trusted entity, the operation number and a list of pseudonyms of the datasets they have identified based on the request criteria;

4. the requesting health care provider to the requested health care provider, the operation number and the operation number;

5. the requested health care provider to the trusted entity shall provide the operation number.’

b%6) In the fourth sentence, the words ‘relevant pseudonyms transmitted’ are replaced by the words ‘relevant operation number transmitted’.

g) (A)(11a), fifth sentence, is replaced by the following sentences:

‘Section 1(2) and (3) of the Obligations Act shall apply mutatis mutandis. The platform provider shall be the body responsible for the obligation of confidentiality pursuant to sentence 4. By way of derogation from the first sentence of Paragraph 1(2) of the Obligations Act, the obligation may also be performed by means of simultaneous transmission of images and sound.’

h) In paragraph 12, the words ‘education and research’ are replaced by the words ‘research, technology and space’;

6. In Section 73(9), the following paragraphs 9a and 9b are inserted:

“(9a) For the issuance of electronic credit transfers, from 1 September 2029, contracted doctors may only use electronic programs which contain the functions and information necessary to create, transmit and retrieve electronic credit transfers and which are authorised by the Federal Association of Statutory Health Insurance

Physicians to provide treatment under the statutory health insurance scheme. The details shall be agreed in the contracts referred to in Section 82(1).

(9b) As from 1 January 2028, contractual doctors may only use IT systems for the notification of appointments pursuant to § 75(1a), sentences 20 and 21, if, as from 1 March 2027, the Federal Association of Statutory Health Insurance Physicians has successfully completed a procedure to confirm the integration of the interface pursuant to § 370a(5) and are approved by the Federal Association of Statutory Health Insurance Physicians for the provision of statutory health care. The form and content of the procedure for confirming the integration of the interface pursuant to Section 370a(5), including the quality requirements for proper integration of the interface, shall be determined by the Federal Association of Statutory Health Insurance Physicians in consultation with the federal associations in the field of information technology in the health sector which are relevant for the protection of the interests of industry and with the Federal Commissioner for Data Protection and Freedom of Information. By 30 June 2027, the Federal Association of Statutory Health Insurance Physicians shall submit a report to the Federal Ministry of Health on the status of the procedures carried out to confirm the integration of the interface in accordance with Section 370a(5) and shall continuously publish a list of the IT systems approved by the Federal Association of Statutory Health Insurance Physicians.'

7. The first and second sentences of Section 86(1) are replaced by the following sentences:

'The Federal Associations of Statutory Health Insurance Physicians shall agree with the Central Federal Association of Health Insurance Funds, as part of the Federal Sickness Insurance Contracts, in consultation with the Society for Telematics, the necessary arrangements for the use of prescriptions in electronic form by contracted doctors. In consultation with the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products and Medical Devices), the provisions necessary for the use of regulations on narcotic drugs and medicinal products referred to in the first sentence of § 3a(1) of the Arzneimittelverschreibungsverordnung (Medicinal Product Prescription Ordinance) shall also be agreed in electronic form in accordance with the first sentence. The rules agreed pursuant to the first sentence shall be compatible with the provisions of the framework contract pursuant to § 129(4a), the contracts pursuant to § 125(1) and the framework recommendations pursuant to § 127(9).'

8. § 86a is replaced by the following § 86a:

'Paragraph 86a

Paragraph 86a Use of credit transfers in electronic form

By 1 November 2027, the Federal Associations of Statutory Health Insurance Physicians shall agree with the Central Federal Association of Health Insurance Funds, as part of the Federal Sickness Insurance Contracts, in consultation with the Competence Centre for Interoperability in Health Care, the necessary arrangements for the structured, interoperable and accessible use of credit transfers in electronic form. The agreements shall stipulate that the telematics infrastructure services are to be used for the transmission of the electronic credit transfer as soon as they become available.'

9. Section 87(2o), second sentence, point 3 is replaced by the following point 3:

1. ‘ the taking into account in care of electronic medical letters, electronic discharge letters and secure transmission procedures pursuant to § 363a(1), first sentence, point 2,’.

10. § 115f is amended as follows:

a) In point (a), first sentence, the sixth sentence is replaced by the following sentence:

‘At the request of the institute referred to in the first sentence of Paragraph 87(3b), the Central Federal Association of Health Insurance Funds shall, within two weeks, forward to the institute referred to in the first sentence of Paragraph 87(3b) the figures of the cases and the fees for the services paid by the health insurance funds pursuant to the fourth sentence of Paragraph 115b(2), available at the time of the request for the last four calendar quarters in respect of which the case numbers and fees have been communicated to it in full in accordance with point 3 of the first sentence of Paragraph 303b(1), indicating separately the material costs, and the amount of the material costs paid pursuant to the relevant collective agreement concluded pursuant to Paragraph 83 in relation to the services selected pursuant to point 2 of the first sentence of Paragraph 303b(1), broken down according to the codes of the operating and procedure key.’

b) In point 5, the first sentence is replaced by the following sentence:

‘The contracting parties referred to in the first sentence of paragraph 1 shall entrust the Institute referred to in the first sentence of Section 87(3b) and the Institute for the Hospital Pay System with the regular evaluation of the impact of the special sectoral equal remuneration on the care of insured persons, on the remuneration of service providers and on the expenditure of health insurance funds; to this end, the Central Federal Association of Health Insurance Funds shall forward to the institute referred to in the first sentence of § 87(3b) within four weeks, at its request, the data available to it pursuant to point 3 of the first sentence of § 303b(1) from the billing referred to in paragraph 3 of service providers participating in care pursuant to the first sentence of § 95(1) in a uniform pseudonymised form, on a practical, medical and case-by-case basis.’

11. Section 129(5h) is amended as follows:

a) In the ninth sentence, ‘one month’ is replaced by ‘three months’;

b) The 16th and 17th sentences are replaced by the following:

‘In so far as is necessary for the performance of the measures referred to in point 4 of the second sentence, pharmacies shall have access enabling data to be read, stored, used and deleted in accordance with Section 341(2). Access shall not be permitted for purposes other than those referred to in point 4 of the second sentence.’

12. In Section 137f(9), second sentence, point 3, the words ‘Section 311(6)’ are replaced by the words ‘Section 363a(1), first sentence, point 2’.

13. In Section 217f(4d), the following paragraph 4e is inserted:

“(4e) The Central Federal Association of Health Insurance Funds shall lay down, in a guideline, binding procedures for the treatment of electronic health records by health insurance funds in accordance with Section 341. In particular, the Directive shall contain provisions on the processing of objections pursuant to § 344, provisions

on the implementation of the statutory retention and deletion periods of the electronic health record, provisions on the procedure pursuant to § 342(2)(1)(o) and provisions on the handling of requests for rectification made by insured persons pursuant to § 342(2)(8). The guidelines shall be drawn up in consultation with the Federal Commissioner for Data Protection and Freedom of Information and the Federal Office for Information Security. The Directive shall be notified to the Federal Ministry of Health by... [insert: Date of the first day of the sixth calendar month following promulgation] for approval.'

14. § 219d is amended as follows:

a) Paragraphs 6 and 7 are replaced by the following paragraphs 6 and 7:

(1) ' In addition to the tasks referred to in paragraph 1, the Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland, shall establish and operate the organisational and technical liaison body for the provision of cross-border health data exchange services (national eHealth contact point) and further develop the national eHealth contact point into a national contact point for digital health pursuant to Article 23(2) of Regulation (EU) 2025/327 (national contact point for digital health) by 26 March 2029 and operate it. The Central Federal Association of Health Insurance Funds shall be the data controller for the data processing by the National Contact Point for eHealth and, from 26 March 2029, the data controller for the data processing by the National Contact Point for Digital Health pursuant to Article 4(7) of Regulation (EU) 2016/679. The Telematics Society assumes the tasks and coordination relating to the cross-border exchange of health data at European level and lays down the technical basis for the national eHealth contact point, on the basis of which the Central Federal Association of Health Insurance Funds, the German Liaison Body for Health Insurance – Abroad, establishes and operates the national eHealth contact point. The Telematics Society also establishes the technical basis for the national contact point for digital health, on the basis of which the Central Federal Association of Health Insurance Funds, the German Liaison Body for Health Insurance – Abroad, further develops and operates the national eHealth contact point as a national contact point for digital health. Through the establishment and operation of the national eHealth contact point and the further development of the national eHealth contact point as a national contact point for digital health by 26 March 2029, the Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland (German Liaison Body for Health Insurance – Abroad), shall coordinate continuously and to the extent necessary with the Gesellschaft für Telematictik (Society for Telematics). The Federal Institute for Medicinal Products and Medical Devices, taking into account the European semantic interoperability specifications and in consultation with the Federal Association of Statutory Health Insurance Physicians and the Society for Telematics, shall lay down the semantic interoperability specifications necessary for the cross-border exchange of data and shall coordinate these specifications at European level. The provisions shall be included on the platform in accordance with point 5 of the second sentence of Section 385(1) or the first sentence of Section 355(12).

(2) The Federal Ministry of Health shall determine the date of the start of operations of the national eHealth contact point after consulting the Central Federal Association of Health Insurance Funds, German Liaison Office for Health Insurance – Abroad. The eHealth National Contact Point and, from 26 March 2029, the National Contact Point for Digital Health shall use the services and applications of the telematics infrastructure as part of their activities pursuant to

the first sentence of paragraph 6 and Regulation (EU) 2025/327. The provisions of Chapter 11 shall apply.'

b) A (b)10 is replaced by the following paragraph (10):

(1) ' Private health insurance companies shall contribute 10 % of the financing of the national contact point for eHealth and the national contact point for digital health, which shall become operational by 26 March 2029 at the latest.'

15. Section 270(3) is deleted.

16. Section 283(2) is amended as follows:

a) S atz 1 is amended as follows:

a%6) In point 9, the words 'further training and' are replaced by the words 'further training,'.

b%6) In point 10, the words 'performance of duties' are replaced by the words 'performance of duties and'.

c%6) In point 10, the following point 11 is inserted:

1. ' on the digital data exchange of the medical services in consultation with the Central Federal Association of Health Insurance Funds.'

b) S atz 2 is replaced by the following sentence:

'By... [insert: Date of the last day of the twelfth calendar month following promulgation] a guideline pursuant to point 11 of the first sentence on communication with providers participating in the statutory health insurance scheme for which the use of the secure electronic mail service of the telematics infrastructure pursuant to point 2 of the first sentence of Paragraph 363a(1) is to be provided.'

17. § 284 is amended as follows:

a) In the first sentence of point (a), points (22) and (23) are replaced by the following points (22) to (24):

1. ' the fulfilment of the obligations pursuant to Section 342a(2) to (5) of the Ombudsperson Bodies pursuant to Section 342a;

2. the implementation of organised screening programmes pursuant to Section 25a; and

3. carrying out data-based evaluations and making reference to the results of these evaluations pursuant to § 25b.'

b) In paragraph 4, the following paragraph 5 is inserted:

(1) ' For the purposes referred to in points 13, 14, 16, 19, 23 and 24 of the first sentence of paragraph 1, the health insurance funds may, with the consent of the insured persons, collect additional personal data from their insured persons or from wellness applications within the meaning of Article 2(2)(ab) of Regulation (EU) 2025/327 that are appropriate for the fulfilment of their statutory tasks pursuant to the fourth sentence of § 1. The insured person's consent must

indicate for which or which of the purposes referred to in the first sentence the additional data collected may be processed. Data collected in accordance with the first sentence shall be transferred by the health insurance funds to the electronic health record and stored in accordance with Section 341(2), point 20.’

18. In Section 284, the following Section 284a is inserted:

‘Paragraph 284a

Health insurance regulatory sandboxes

(1) Health insurance funds may, with the approval of the supervisory authority, establish regulatory sandboxes in which innovative approaches to the use of personal data, including special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, for the performance of their tasks under this Book may be tested on a temporary basis. By way of derogation from Section 284(1), the health insurance funds participating in the regulatory sandbox may process the personal data of their insured persons in accordance with the authorisation referred to in paragraph 2 and to the extent of the testing determined in accordance with the first sentence of paragraph 4.

(2) The competent supervisory authority shall approve the establishment of a regulatory sandbox pursuant to the first sentence of paragraph 1 at the request of a health insurance fund, provided that:

1. the test project is in the public interest;

2. the purpose of the data processing in the sandbox corresponds to a task of the health insurance fund under this book,

3. the purpose for which the data are used is compatible with the purpose for which the data were collected;

4. the data to be processed in the sandbox are suitable and necessary for the specific testing project and its purpose;

5. the interests of insured persons worthy of protection are not prejudiced, and

6. Requirements of higher-ranking law or obligations under international treaties do not preclude this.

The application referred to in the first sentence may also be submitted jointly by several sickness insurance funds. On request, a health insurance fund may be authorised to participate in a regulatory sandbox that has already been set up. When examining the conditions under point 5 of the first sentence, account must also be taken of the possibility of conditions or further measures to minimise the risk to the interests of insured persons worthy of protection.

(3) The application referred to in the first sentence of paragraph 2 shall specify:

1. the health insurance fund or funds participating in the sandbox;

2. the purpose of the data processing, which corresponds to a task of the health insurance fund under this Book;

3. a description of the data to be processed in the sandbox;

4. a reasonable explanation that the scope and structure of the data to be processed in the sandbox are appropriate and necessary to achieve the intended purposes;

5. the methodological approach to data processing; and

6. the period for which the sandbox is to be established.

Before granting an authorisation pursuant to paragraph 2, the competent supervisory authority shall give the competent data protection supervisory authority the opportunity to comment on the application. In the absence of an opinion within two months, the authorisation may be granted by the competent supervisory authority.

(4) The competent supervisory authority shall specify in the authorisation referred to in paragraph 2 the extent to which, and the conditions under which, the testing of data processing in the regulatory sandbox is permitted and, where appropriate, the provisions of federal law which may be derogated from. In particular, the authorisation may provide that insured persons have the possibility to object to the processing of their data in the regulatory sandbox. The competent supervisory authority may only authorise the establishment of a regulatory sandbox for a limited period which shall not exceed six years. In justified cases, the competent supervisory authority may, upon request, extend the authorisation period once by up to three years.

(5) The health insurance funds participating in the sandbox shall publicly inform about the sandbox. They shall submit a report on the results to the competent supervisory authorities no later than six months after the termination of the sandbox. In the results report, the health insurance funds shall comment on whether the experiment made possible in the regulatory sandbox has been successful and whether further development of the provisions of this Act is necessary and necessary. Within six months, the supervisory authority shall submit to the Federal Ministry of Health and to the Federal Ministry of Economic Affairs and Energy the results report, together with an opinion on the results report.'

19. The fourth and fifth sentences of Section 290(3) are replaced by the following sentences:

'The register may be used only to exclude and correct multiple designations of the same health insurance number and to ensure the uniqueness of the health insurance number in the telematics infrastructure. In order to rule out or correct multiple awards of the same health insurance number, the health insurance funds and the payers referred to in § 362(2) using the fixed part of the health insurance number shall communicate the necessary social data to each other for the purpose of cross-checking data in accordance with the procedure set out in the third sentence; § 35 of Book I shall apply mutatis mutandis to the payers referred to in § 362(2). In addition, the register may be used for comparison with the health insurance numbers stored with the health insurance funds and with the payers referred to in § 362(2).'

20. § 291 is amended as follows:

a) In the second paragraph, point (3), '1 January 2026' is replaced by '1 June 2027';

b) In point 3, the second sentence is replaced by the following sentence:

'Health insurance funds shall:

1. Provide insured persons, at their request and without delay, with an electronic health card with a contactless interface and a personal identification number (PIN), where this has not yet been done;

2. Offer insured persons the use of electronic identification pursuant to Section 18 of the Identity Card Act, Section 12 of the eID Card Act or Section 78(5) of the Residence Act as a procedure for subsequent, secure identification pursuant to Section 336(4)(3) and for secure identification pursuant to Section 336(5); and

3. From 1 January 2027, as a procedure for subsequent, secure identification in accordance with Section 336(4), point 3, for secure identification in accordance with Section 336(5) and for secure identification in accordance with paragraph 8, also offer insured persons the use of electronic identification by means of a European Digital Identity Wallet as defined in Article 3, point 42, of Regulation (EU) No 910/2014, provided that the technical conditions are met.'

c) Paragraph 8 is amended as follows:

a%6) The following sentences are inserted after the third sentence:

'From the first December 2028, the European Digital Identity Wallet as defined in Article 3(42) of Regulation (EU) No 910/2014, in conjunction with corresponding electronic evidence in the wallet, shall serve as proof of insurance pursuant to § 291a(1) in the same way as the electronic health card. As soon as the technical conditions are met and at the latest from the first December 2030, the European Digital Identity Wallet as defined in Article 3, point (42), of Regulation (EU) No 910/2014, in conjunction with corresponding electronic evidence in the wallet, shall serve the authentication of the insured person in the health sector in the same way as the electronic health card.'.

b%6) In the new tenth sentence, the words 'seventh sentence' are replaced by the words 'ninth sentence'.

c%6) In the new 14th sentence, the words 'the 11st sentence' are replaced by the words 'the 13rd sentence'.

d%6) D new sentence 15 is replaced by the following sentence:

'In addition, the Telematics Company may, by binding decision pursuant to the first sentence of Paragraph 315(1), designate providers of other services or applications pursuant to point 2(a) of the second sentence of Paragraph 306(1) as eligible third parties in a non-discriminatory manner.'

d) In the first and second sentences of paragraph 9 of Section I, the words 'Section 311(6)' are replaced by the words 'Section 363a(1)'.

21. Section 291a(2) is replaced by the following paragraph 2:

(1) ' The following data shall be stored on the electronic health card:

1. the name of the issuing health insurance fund;

2. the surname and first name of the insured person;

3. the date of birth of the insured person;

4. the sex of the insured person;

5. the address of the insured person;

6. the insured person's health insurance number,

7. the status of insured person, for the categories of persons referred to in Section 264(2) and Section 151(1) of Book Fourteen, the status of care on a contract basis,

8. the co-payment status of the insured person;

9. the date of commencement of the insurance cover;

10. where the validity of the electronic health card is limited in time, the expiry date;

11. in the case of agreements pursuant to the second half of the third sentence of Paragraph 264(1), an indication that the person concerned is a recipient of health care services pursuant to Paragraphs 4 and 6 of the Law on benefits for asylum seekers,

12. the registration number of the association of health insurance physicians in whose district the insured person resides;

13. in the case of insured persons using the instant messaging service of the telematics infrastructure pursuant to point 1 of the first sentence of Section 363a(1), the unique identifier for the use of that service from 1 June 2027;

14. the identifier of any sign-related participation of the insured person in one or more structured treatment programmes pursuant to § 137f.

If the insured person's co-payment status pursuant to point 8 of the first sentence is not yet recorded on the electronic health card, storage must take place by... [insert: Date of the last day of the sixth calendar month following promulgation]. The storage of the label referred to in point 14 of the first sentence shall be carried out by... [insert: Date of the last day of the sixth calendar month following promulgation].'

22. The following paragraph 5a is inserted after § 291b(5):

"(5a) Providers of medicinal products, suppliers of medical aids, pharmacists and persons belonging to the pharmaceutical staff of the pharmacy may use the services referred to in the first sentence of paragraph 1 and access the information referred to in § 291a(2) and (3) in connection with the provision of care to insured persons.'

23. § 295 is amended as follows:

a) In Section 363a(1), first sentence, point 2, the words 'Section 311(6)' are replaced by the words 'Section 363a(1), first sentence, point 2'.

b) A (b)(1c) is replaced by the following paragraph (1c):

"(1c) Service providers under this Book and the Eleventh Book are obliged to receive and send electronic letters by means of the secure transmission procedure pursuant to § 363a(1), first sentence, point 2, as soon as the technical conditions for doing so are met.'

c) In paragraph 2a, the following paragraph 2b is inserted:

"(2b) The Federal Association of Statutory Health Insurance Physicians shall make available to the doctors and institutions participating in the statutory health insurance scheme the data required for drawing up the statement of medical services in accordance with the uniform assessment criterion pursuant to the first sentence of § 87(1) for medical services via a uniform, central interface for direct data retrieval. The Federal Association of Statutory Health Insurance Physicians shall also make available, via the interface referred to in the first sentence, the data required under the second sentence of Section 116b(6) to the doctors and institutions participating in the statutory health insurance scheme who are entitled under Section 116b(2) to participate in outpatient specialist health care for the purpose of drawing up the statement of the medical services provided by the outpatient specialist health insurance scheme. Where contracts pursuant to Paragraphs 73b, 132e, 132f and 140a have been concluded with the doctors and institutions participating in the statutory health insurance scheme, the Federal Association of Statutory Health Insurance Physicians shall also make available to them, via the interface referred to in the first sentence, the data necessary for drawing up the accounts for the medical services arising from those contracts. The data made available via the interface referred to in the first sentence shall be updated quarterly or, if necessary, by the Federal Association of Statutory Health Insurance Physicians. Any changes to these data must be indicated by the Federal Association of Statutory Health Insurance Physicians. The Associations of Statutory Health Insurance Physicians and the health insurance funds shall be authorised to retrieve the data referred to in sentences 1 to 3 via the interface referred to in the first sentence, in so far as such consultation is necessary in order to check the legality and plausibility of the statements in the statutory health insurance scheme pursuant to § 106d. The Federal Association of Statutory Health Insurance Physicians, in agreement with the Competence Centre for Healthcare Interoperability, shall submit details of the provision and retrieval of data via the uniform interface by... [insert: Date of the first day of the ninth calendar month following the promulgation] and publishes this on its website. The Federal Association of Statutory Health Insurance Physicians shall provide the uniform interface to the doctors and institutions participating in the statutory health insurance scheme by... [insert: Date of the first day of the 18th calendar month following the promulgation].'

d) In paragraph 4, the words '311(6)' are replaced by the words 'Section 363a(1), first sentence, point 2'.

24. Section 295a is amended as follows:

a) In point (a), second sentence, is replaced by the following sentences:

'Paragraph 80 of Book Ten shall apply. The requirements of § 393 shall apply mutatis mutandis to the use of cloud computing services by the delegated body.'

b) In point 3, the third sentence is replaced by the following sentence:

'The second to fourth sentences of paragraph 2 shall apply mutatis mutandis.'

25. In Section 302(2), seventh sentence, point 2, the words 'Section 311(6)' are replaced by the words 'Section 363a(1), first sentence, point 2'.

26. The following paragraph 5 is inserted after Section 303b(4):

(1) ‘ The Central Federal Association of Health Insurance Funds may extract and further process the data transmitted in accordance with paragraph 1 for the following purposes, in so far as the data are necessary for this purpose:

1. to replace data deliveries by the health insurance funds pursuant to the sixth sentence of § 115f(1) and the first sentence of § 115f(5), and

2. for the implementation of the reporting obligation pursuant to the first sentence of § 302(5).’

27. Section 303e is amended as follows:

a) In paragraph 1, the second sentence is replaced by the following sentence:

‘Natural and legal persons established in Germany or in another Member State of the European Union or in a State party to the Agreement on the European Economic Area shall be entitled to use the data in so far as they are authorised to process the data pursuant to paragraph 2.’

b) A (b)(2) is amended as follows:

a%6) Point 9 is replaced by the following point 9:

1. ‘ The development, evolution and monitoring of the safety of medicinal products, medical devices, examination and treatment methods, ancillary and curative products, digital health and care applications, as well as AI models and AI systems as defined in Article 3, point (1), of Regulation (EU) 2024/1689 in the health sector, including the training, validation and testing of those AI models and AI systems;’;

b%6) In point 10 of Annex I, the words ‘§ 130b.’ are replaced by the words ‘§ 130b,’.

c%6) In point 10, the following point 11 is inserted:

1. ‘ Establishing contact with certain service providers for the benefit of:

a) a Consultant, with the aim of networking Consultants with similar cases for the purpose of technical exchanges or the preparation of a consil,

b) the sponsor of a clinical investigation or an entity conducting a clinical investigation, with a view to identifying suitable subjects for that clinical investigation; or

c) the Joint Federal Committee pursuant to § 91 or the Institute for Quality Assurance and Transparency in Health Care pursuant to § 137a in each case for the performance of their statutory tasks in the field of quality assurance.’

c) In point 4, the fourth sentence is replaced by the following sentences:

‘Section 1(2) and (3) of the Obligations Act shall apply mutatis mutandis. The Research Data Centre shall be the body responsible for the obligation referred to in the third sentence. By way of derogation from the first sentence of Paragraph 1(2) of the Obligations Act, the obligation may also be performed by means of simultaneous transmission of images and sound.’

d) The following sentences are inserted after the second sentence of paragraph 4a:

‘The research data centre may, in accordance with the requirements of the beneficial owners, link the pseudonymised individual datasets referred to in paragraph 4 to pseudonymised data provided by the beneficial owners and make the linked datasets available to a beneficial owner for the purpose referred to in paragraph 2, point (11)(c). A link pursuant to the third sentence shall be permitted only if:

1. the conditions set out in paragraphs 4 and 5 are met;

2. the link is necessary for the performance of the statutory quality assurance tasks referred to in point (11)(c) of paragraph 2; and

3. legitimate interests of the data subject are not prejudiced or the public interest in the performance of the statutory tasks of the beneficial owners in the field of quality assurance outweighs the data subject’s interest in confidentiality and the specific re-identification risk in relation to the data to be linked has been assessed and minimised by appropriate measures, with due regard to the intended benefits.’

e) In paragraph 4a, the following paragraph 4b is inserted:

“(4b) The Research Data Centre shall carry out regular statistically aggregated evaluations of the data transmitted to it by the Central Federal Association of Health Insurance Funds and shall make the results of the evaluations available to the Federal Ministry of Health in machine-readable form for the purpose of monitoring and analysing the treatment and settlement process in the statutory health insurance and social care insurance schemes. The results of the evaluation must not relate to insured persons or service providers. By way of derogation from the first sentence of paragraph 1, no application to the Research Data Centre shall be required for data provision under this paragraph. The Federal Ministry of Health shall lay down requirements vis-à-vis the Research Data Centre regarding the type of evaluation, the scope of the results and the time of making available. The Research Data Centre shall publish information on the evaluations referred to in the first sentence in the public register of applications pursuant to Section 303d(1)(6).’

f) In the fourth sentence of paragraph 5, the following sentences are inserted:

‘By way of derogation from the fourth sentence, the processing of the data provided for the purpose of identifying health care providers shall be permitted in the cases referred to in paragraph 2(11). The identification of health care providers by removing the pseudonymisation of health care provider information is carried out by the trusted office. The Federal Ministry of Health shall lay down the details of the procedure for identifying service providers in the statutory instrument referred to in the second sentence of Paragraph 303a(1) and in Paragraph 303a(4).’

g) In point 6, the second sentence is replaced by the following sentence:

‘If the research data centre finds that the data made available pursuant to paragraphs 3 or 4 have been processed by the beneficial owner in a way that does not comply with the applicable data protection legislation or the requirements of the research data centre in this regard, it shall exclude the beneficial owner from access to the data for a period of up to two years.’

28. The words ‘, the Joint Federal Committee, the Institute for Quality Assurance and Transparency in Health Care pursuant to § 137a’ shall be inserted after the words ‘the Central Federal Association of Health Insurance Funds’.

29. Section 306 is amended as follows:

a) Paragraphs 1 and 2 are replaced by the following paragraphs 1 and 2:

(1) ‘ The Federal Republic of Germany, represented by the Federal Ministry of Health, the Central Federal Association of Health Insurance Funds, the Federal Association of Statutory Health Insurance Physicians, the Federal Association of Statutory Health Insurance Dentists, the Federal Chamber of Physicians, the Federal Chamber of Dental Practitioners, the German Hospital Society and the relevant umbrella organisation of pharmacists at federal level set up for the protection of economic interests, shall establish the telematics infrastructure. Telematics infrastructure is the interoperable and compatible information, communication and security infrastructure for the networking of health care providers, payers, insured persons and other health care, rehabilitation and care stakeholders, and in particular:

1. the use of the electronic health card, the applications of the telematics infrastructure and the secure transmission procedures pursuant to Section 363a(1) shall be subject to:

2. is suitable for:

a) for the use of telematics infrastructure services by other services and applications pursuant to § 327, and

b) for use for health and nursing research purposes.

The Federal Republic of Germany, represented by the Federal Ministry of Health, and the umbrella organisations referred to in the first sentence shall carry out the task referred to in the first sentence in accordance with Paragraph 310 through a company for telematics.

(2) The telematics infrastructure shall comprise in particular:

1. Components and services for authentication, electronic signature, encryption and decryption, secure access and processing of data in the telematics infrastructure (central and decentralised security infrastructure);

2. a central infrastructure consisting of services necessary for or supporting the applications of the telematics infrastructure and the secure transmission processes referred to in this Chapter, other than those referred to in point 1;

3. Interfaces for end-users in the applications of the telematics infrastructure, in the secure transmission procedures pursuant to this Chapter or in other telematics infrastructure services pursuant to § 327, provided that these are not information technology systems pursuant to § 371 or § 373; and

4. Services for the cross-border exchange of health data under Regulation (EU) 2025/327.’;

b) In point 4, the first sentence is replaced by the following sentence:

‘Applications and secure transmission methods within the meaning of subparagraph 2, point 2, are user-related functionalities based on health data processing services and components in the telematics infrastructure that have been authorised or mandated in accordance with Paragraph 325.’

30. Section 307 is amended as follows:

a) Paragraphs 2 to 4 are replaced by the following paragraphs 2 to 4:

“(2) The operation of the services specified and authorised or commissioned by the Telematics Society pursuant to Section 306(2)(2) shall be the responsibility of the respective service provider. The provider of a service pursuant to Section 306(2)(2) may process the personal data of insured persons solely for the purposes of setting up and operating its service. Section 3 of the Telecommunications-Digital Services-Data Protection Act shall apply accordingly.

(3) The Telematics Society shall issue a mandate pursuant to the first sentence of Section 323(2) for the sole responsible operation of the central security infrastructure pursuant to Section 306(2)(1), including the services necessary for its operation. The provider or providers of the central security infrastructure shall be responsible for the transmission of personal data, in particular health data of insured persons, between healthcare providers, payers and insured persons and for the transmission in the context of the applications of the electronic health card. The provider or providers of the central security infrastructure shall process the data solely for the purpose of data transmission. Section 3 of the Telecommunications-Digital Services-Data Protection Act shall apply accordingly.

(4) The operation of the services authorised or commissioned by the Telematics Society pursuant to Section 306(2)(3) is the responsibility of the respective service provider, which makes the service available to an end-user as part of an application or a secure transmission procedure based on an existing legal relationship with the end-user. Providers shall be responsible for the processing of personal data, in particular health data of insured persons, for the purpose of using the respective service in accordance with Section 306(2)(3).’

b) In the third sentence of paragraph 5, the following sentences are inserted:

‘In addition, the coordinating body shall examine the concerns of data subjects and service providers in connection with the electronic prescription pursuant to point 6 of the second sentence of Paragraph 334(1) and with the secure procedures for the transmission of medical and care data pursuant to Paragraph 363a(1) and, where appropriate, take appropriate measures within the scope of the competence of the Telematics Society. Upon request, the coordinating body shall provide data subjects with access to the log data of accesses and attempted accesses to data subjects’ personal data in an electronic regulation. Access by the coordinating body necessary for the fulfilment of the obligations under sentence 5 shall be limited to the log data of the electronic regulation. The Gesellschaft für Telematik is the controller of the processing of personal data in so far as it carries out tasks as a coordinating body in accordance with the third sentence.’

31. § 311 is amended as follows:

a) The first sentence of point (a) is amended as follows:

a%6) S atz 1 is amended as follows:

a%7%7) Points 4 and 5 are replaced by the following points 4 and 5:

1. ‘ The award of contracts to suppliers for the development, provision and operation of components and services of the telematics infrastructure and the approval of components and services of the telematics infrastructure, including the procedures for accessing those components and services;

2. Awarding contracts to providers for the development, provision and operation of secure services for procedures for the transmission of medical and nursing data via the telematics infrastructure and authorising secure services for procedures for the transmission of medical and nursing data via the telematics infrastructure;’;

b%7%7) Point 10 is replaced by the following point 10:

1. ‘ Making available, as services of general economic interest, the components of the telematics infrastructure enabling access to the application for the transmission of medical prescriptions pursuant to § 334(1), second sentence, point 6, in accordance with § 360(10),’.

c%7%7) In point 14, the following point 14a is inserted as follows:

‘14a. Support statutory pension insurance institutions with measures to enable rehabilitation institutions under the first sentence of Paragraph 32a(1) of Book Six and other service providers and statutory pension insurance institutions to use the telematics infrastructure for the performance of their tasks under Paragraph 32a of Book Six,’.

d%7%7) Points 16 and 17 are replaced by the following points 16 to 20:

1. ‘ the continuous conceptual evolution of the EHR towards a personal health data space, enabling privacy-compliant and secure processing of structured health data;

2. Support for the implementation and maintenance of the digitalisation strategy of the Federal Ministry of Health;

3. Performing the tasks of a digital health authority pursuant to Section 383a,

4. Transparency for users of the telematics infrastructure as regards compliance by the various providers of authorised services and components of the telematics infrastructure with the framework conditions laid down for the provision of operational services by the Telematics Society and with quality indicators; and

5. Piloting existing or planned telematics infrastructure applications and secure transmission procedures prior to their nationwide roll-out and their further development to improve digital healthcare.’

b%6) In the third sentence, the following sentence is inserted:

‘The second and third sentences shall apply mutatis mutandis to the statutory pension insurance institutions in so far as the Telematics Company performs tasks pursuant to point 14a of the first sentence.’

b) In the first sentence of paragraph 1a, the words ‘as well as the entrustment pursuant to point 2 of the second sentence of § 385(1) and the certification pursuant to point 7 of the second sentence of § 385(1)’ are replaced by the words ‘, the tasks and powers as a digital health authority pursuant to § 383a, the entrustment pursuant to point 2 of the second sentence of § 385(1) and the certification pursuant to point 7 of the second sentence of § 385(1)’.

c) (A)(b)(6) is deleted;

d) In point 7, the second sentence is replaced by the following sentence:

‘Section 55(2) of the Federal Budget Code shall apply mutatis mutandis.’

32. Section 312 is amended as follows:

a) The first sentence of the first subparagraph is amended as follows:

a%6) In point 4 of Section I, the words ‘Section 311(6)’ are replaced by the words ‘Section 363a(1), first sentence, point 1’.

b%6) In point 15 of Section I, the words ‘Section 311(6)’ are replaced by the words ‘Section 363a(1), first sentence, point 2’.

c%6) In point 17, the words ‘may and’ are replaced by the words ‘may,’.

d%6) In point 18, the words ‘shall’ are replaced by the words ‘shall’.

e%6) In point 18, the following points 19 and 20 are inserted:

1. ‘ take the necessary measures to ensure that authorised health care providers can access electronic credit transfers by means of the electronic health card or by using the digital identity of insured persons pursuant to § 291(8) or § 362 and in accordance with the conditions for access pursuant to § 361d, and

2. by 1 January 2030, take the necessary measures to ensure that providers involved in emergency care have access to the data contained in the electronic health record pursuant to § 341(2)(1)(c), irrespective of the temporal link with the treatment pursuant to § 339(1).’

b) (A)(b)(5) is replaced by the following paragraph (5):

(1) ‘ As part of its allocation of tasks pursuant to point 1 of the first sentence of Paragraph 311(1), the Gesellschaft für Telematik must carry out the measures to ensure that credit transfers can be transmitted in electronic form from 1 September 2028. When implementing the measures referred to in the first sentence, Gesellschaft für Telematik shall take particular account of the requirements of the Federal Cover Agreements pursuant to Section 87(1). When carrying out the measures referred to in the first sentence, the Telematics Society shall also take into account the ability to connect to applications and services of the telematics infrastructure, including the functions of digital access to care pursuant to Section 345a, and to the standardised initial assessment procedure for appointments in acute cases by the appointment service points of the

Associations of Statutory Health Insurance Physicians pursuant to Section 75(1a), third sentence, point 4.’

33. Section 313 is amended as follows:

a) In point (a), first sentence, the fourth sentence is replaced by the following sentence:

‘The data referred to in the third sentence shall include names, address data, technical address data, unique identification numbers and identifiers in accordance with the provisions of this book, the field of expertise and the public part of the technical identity of the user.’

b) A (b)(3) is replaced by the following paragraph (3):

(1) ‘ The directory service may be used only for the purpose of searching for, identifying and addressing the users referred to in the third sentence of paragraph 1 in the context of the use of applications and services of the telematics infrastructure and by the Telematics Society for testing measures to ensure the objectives referred to in the first sentence of paragraph 4, in particular with regard to the accuracy and usability of the directory service’s data. The results of the checks referred to in the first sentence, in particular errors and anomalies in the data from the directory service, may be evaluated by the Telematics Society and communicated to the data-providing bodies referred to in the first sentence of paragraph 5. For each user, the directory service shall indicate which applications and services can be addressed.’;

c) In paragraph 5, the fourth sentence is replaced by the following sentence:

‘Furthermore, in order to fulfil the obligations referred to in the first to third sentences, the relevant data may be updated and linked in a semi-automated manner, including registers and registers set up by the persons referred to in the first and third sentences in accordance with the provisions of this Book, for the purposes referred to in paragraph 3.’

34. Section 323(2) is replaced by the following paragraph 2:

(1) ‘ In order to carry out the operation of the telematics infrastructure, the Telematics Company shall award contracts or issue authorisations in a transparent and non-discriminatory procedure. It shall demonstrate that the availability, integrity, authenticity and confidentiality of the components and services are ensured. If individual partners or third parties have been appointed in accordance with § 311(5), the commissioners shall be responsible for awarding and granting approval; Section 311(7) shall apply mutatis mutandis. When awarding contracts for the operation of components and services of the central infrastructure pursuant to Section 306(2), point 2, which are essential to ensure the security or the maintenance of the functioning of the telematics infrastructure, the Telematics Society may stipulate that it acts as a supplier and operates individual components and services of the central infrastructure itself. In such cases, the functioning and interoperability of the components and services shall be ensured by the Telematics Society. Where the Telematics Society operates components and services itself, the safety of the components and services shall be demonstrated by an external security assessment. The verification procedures for the external security opinion are defined by the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik). The selection of the safety assessor is carried out as part of the examination procedure by the Gesellschaft für Telematictik in consultation with the Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information

Security). The external security opinion must be submitted to the Federal Office for Information Security for examination and confirmed by it. Only after confirmation of the external security opinion by the Federal Office for Information Security may the components and services be made available by the Telematics Society.'

35. Section 324 is replaced by the following Section 324:

§ 1'

Licensing of providers and operators of telematics infrastructure services and components

(1) Providers of telematics infrastructure components and services shall be entitled to authorisation where:

1. the components and services to be used are approved in accordance with Sections 363b or 325;

2. the provision of the services or components referred to in point 1 is subject to operator approval in accordance with paragraph 4;

3. the provider demonstrates that the availability and security of the components and services are ensured; and

4. the supplier undertakes to comply with the framework conditions for operating services of the Telematics Society.

Approval may be subject to ancillary conditions, in particular conditions relating to mandatory testing and deployment phases and to the mandatory performance of tests in the reference environment of the telematics infrastructure, in so far as this is necessary to ensure operational stability within the telematics infrastructure.

(2) The Telematics Society may limit the number of authorisations to the extent necessary to ensure functionality and the necessary level of safety.

(3) Publishes or publishes the Telematics Society or the organisations appointed by it;

1. the technical and material conditions which must be satisfied in order to prove compliance with point 3 of the first sentence of paragraph 1, and

2. a list of authorised and contracted suppliers and operators.

(4) The Telematics Society shall authorise operators of components and services. The Telematics Society shall determine the details of the authorisation procedure and the assessment criteria for operators. The authorised operator is obliged to comply with the framework conditions for operational performance of the Telematics Society and to provide evidence that the availability and safety of operational performance is ensured. The authorisation may be subject to ancillary conditions.'

36. Section 325(1) and (2) is replaced by the following paragraphs (1) and (2):

(1) ' The components and services of the telematics infrastructure shall be subject to approval by the Telematics Society. It shall demonstrate that the availability, integrity, authenticity and confidentiality of the components and services

are ensured. In the case of an invitation to tender for the components and services issued by the Telematics Society pursuant to points 4 and 5 of the first sentence of § 311(1), the safety of the components and services shall be demonstrated by means of an external security report.

(2) The Telematics Society shall approve the components and services of the telematics infrastructure at the request of the suppliers if the components and services are functional, interoperable and secure. The approval may be subject to ancillary provisions, in particular conditions relating to mandatory testing and deployment phases, in so far as this is necessary to ensure operational stability within the telematics infrastructure.'

37. Section 326 is replaced by the following Section 326:

§ 1‘

Prohibition of the use of telematics infrastructure without authorisation or confirmation

Providers and operators of components and services of the telematics infrastructure must have the authorisation required under § 323(2) and § 325(1) or the confirmation required under § 327(2), first sentence, before using the telematics infrastructure. By way of derogation from the first sentence, no approval or certification shall be required for components and services commissioned by the Telematics Society.'

38. The first sentence of Section 328(1) is replaced by the following sentence:

'The Gesellschaft für Telematik may charge fees and expenses for the authorisations and confirmations referred to in Paragraphs 324, 325, 327 and 374a(5), also in conjunction with Paragraph 363a(1), Paragraph 363b(1), the first sentence of Paragraph 362a and Paragraph 362b, and for measures referred to in Paragraph 329(3a).'

39. Section 329 is amended as follows:

a) In paragraph 1, the first sentence is replaced by the following sentence:

'Where there is a risk to the functioning or security of the telematics infrastructure or essential parts thereof, the Telematics Society shall be required to take, without delay, the necessary technical and organisational measures to counter that risk in accordance with the state of the art.'

b) The first sentence of the second sentence of paragraph (a) is replaced by the following sentence:

'Providers and operators of components or services approved or commissioned in accordance with Paragraphs 363b and 325, applications and services confirmed in accordance with Paragraph 327 and providers and manufacturers of information technology systems with the technical interfaces and modules necessary for the use of the telematics infrastructure in the health sector shall immediately report any significant disruption to the Telematics Society, notwithstanding any other legal obligations, and take appropriate measures to remedy the disruption without delay. In particular, disruptions that lead or may lead to the failure or compromise of the integrity, authenticity and confidentiality, functionality and operational resilience of parts of the telematics infrastructure or of the entire telematics infrastructure shall be significant.'

c) In paragraph 2, the following paragraph 2a is inserted:

“(2a) In the event of significant disruption, the Telematics Society shall have the right to request information from the providers, operators and manufacturers referred to in paragraph 2 on the possible causes of the disruption and the measures taken to remedy it. Suppliers and manufacturers shall be obliged to comply with a request for information pursuant to the first sentence without delay by providing comprehensive information.’

d) A (b)(3) is replaced by the following paragraphs 3 and 3a:

(1) ‘ In order to prevent threats to the operational resilience of the telematics infrastructure on a case-by-case basis and to avoid significant operational disruptions to the telematics infrastructure, the Telematics Society may in particular block components, services and information technology systems with the technical interfaces and modules necessary for the use of the telematics infrastructure in the health sector or individual users from accessing the telematics infrastructure. It may allow those users to continue to have access to the telematics infrastructure on condition that the security measures ordered by the Telematics Society are implemented. The Telematics Society may issue binding orders to providers and operators authorised in accordance with Paragraph 324 and to providers holding a licence for components or services of the telematics infrastructure in accordance with Paragraph 363a and Paragraph 325 or a certificate in accordance with Paragraph 327 in order to eliminate or avoid disruptions in accordance with subparagraph 2, in particular:

1. the notification of disruptions, identified vulnerabilities of a service and security incidents to the Telematics Society and the deadlines by which such notification is to be made;

2. the taking of measures to address or prevent disruptions, identified vulnerabilities of a service and incidents, and the deadlines by which those measures are to be implemented;

3. the taking of measures in the event of intended changes in the performance of operational services and the time limits within which such measures are to be taken; and

4. take measures to ensure the availability and stability of the service operated within the telematics infrastructure.

(3a) To the extent that, in the case of an order pursuant to point 2 of the third sentence of paragraph 3, the remedial action is not taken within the prescribed period, the Telematics Company may carry out the necessary measures itself or have them carried out by authorised third parties without further notice or have them carried out. This shall be indicated in the order. In so far as this is necessary for security within the meaning of the first sentence of paragraph 1, in particular in the event of imminent danger, the Telematics Society shall be entitled to carry out measures pursuant to the first sentence without the need for a prior order within the meaning of the third sentence of paragraph 3.’

40. § 330 is amended as follows:

a) In paragraph 1, the first sentence is replaced by the following sentence:

‘The Telematics Society and the providers and operators authorised pursuant to Paragraph 324 and providers holding a licence for components and services

pursuant to Paragraph 363a and Paragraph 325 or a certificate pursuant to Paragraph 327 shall be required to establish and keep up to date appropriate organisational and technical arrangements to avoid any disruption to the availability, integrity, authenticity and confidentiality of the information technology systems, components or processes of the telematics infrastructure.'

b) In the second sentence of paragraph 3, '§ 311(6)' is replaced by '§ 363b'.

41. Section 331 is amended as follows:

a) Paragraphs 1 and 2 are replaced by the following paragraphs 1 and 2:

(1) ' For components and services of the telematics infrastructure and for components and services using the telematics infrastructure but operating outside the telematics infrastructure, the Telematics Society shall, in consultation with the Federal Office for Information Security, take such measures to monitor operations as are necessary to ensure the security, availability and usability of the telematics infrastructure. In order to carry out its tasks under the first sentence, the Telematics Society may examine the relevant components and services. In doing so, it may rely on the assistance of third parties, unless this is contrary to the legitimate interests of the manufacturer, provider or operator of the components or services concerned.

(2) The Telematics Society shall determine the details to be disclosed to it by suppliers and operators of components and services and by suppliers of other applications and information technology systems in order for the monitoring referred to in paragraph 1 to be carried out.'

b) Paragraph 5 is replaced by the following:

(1) ' In so far as it is necessary for the implementation of the measures referred to in paragraph 1 and within the framework of the arrangements referred to in paragraph 3, the Telematics Society may use the components required for access to applications of the telematics infrastructure pursuant to the second sentence of Paragraph 334(1), applications for the verification and updating of information pursuant to Paragraph 291b and secure procedures for the transmission of medical data pursuant to Paragraph 363a(1) for identification and authentication in the context of audit user identities created for that purpose. As part of the process of creating and using the identity of the test user for insured persons, the Telematics Society is entitled to use a test health insurance number, which must be uniquely attributable to a fictitious insured person. This number is issued by the trust office in accordance with the second sentence of § 290(2) and must comply with the requirements of the guidelines in accordance with the first sentence of § 290(2) in so far as an unambiguous assignment to an audit user identity is guaranteed for the entire period of use of the audit health insurance number. The Deutsche Rentenversicherung Bund provides the Gesellschaft für Telematik with the test pension insurance number required to form the test-health insurance number, which must be clearly attributable to a fictitious insured person. The Telematics Society is entitled to use the audit pension insurance number in the context of the creation and use of the audit user identity. The audit user identities may only be used for audit purposes and the details shall be determined in consultation with the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information. It must be ensured that access to personal data of users of the telematics infrastructure who do not use audit user identities is excluded. The audit user identities may be used by a maximum of 20 employees of the Gesellschaft für Telematik who have been checked in accordance with the Security Clearance

Act. The access referred to in the first sentence must be logged and submitted annually or at the request of the Federal Commissioner for Data Protection and Freedom of Information. The log data shall indicate by whom and for what purpose the components referred to in the first sentence were used and shall be stored for three years. The components required under the first sentence, the numbers of persons with statutory health insurance required under the second sentence and the pension insurance numbers required under the fourth sentence shall be made available to the Telematics Company upon request by the body responsible for issuing them, in return for reimbursement of costs.'

42. Section 332a is replaced by the following Section 332a:

'Paragraph 332a

Prohibited restrictions by suppliers and manufacturers of information technology systems for panel dental care, panel dental care, nursing care, providers of medical care and aids, hospitals and pharmacies, and for preventive and rehabilitation facilities

(1) Providers and manufacturers of information technology systems for panel medical care, panel dental care, nursing care, medical and assistive devices providers, hospitals, pharmacies, preventive care facilities and rehabilitation facilities shall ensure the non-discriminatory integration of all components and services that are approved by the Telematics Society pursuant to Section 325(2) and (3) and that are necessary for the fulfilment of legal obligations when using applications of the telematics infrastructure, in so far as interfaces with the aforementioned information technology systems are specified or established by the Telematics Society for these components and services. It is not permissible to limit the involvement to specific manufacturers and suppliers.

(2) The integration of the components and services referred to in paragraph 1 shall be carried out at no additional cost to the users of the information technology systems, irrespective of the burden imposed by the manufacturer or provider. Direct or indirect costs related to the choice of a manufacturer or supplier shall not be allowed.'

43. Section 333 is amended as follows:

a) The first sentence of point (a) is amended as follows:

a%6) The words 'for evaluation' shall be inserted after the words 'two weeks'.

b%6) In point 1 of Section I, the words 'Section 311(6)' are replaced by the words 'Section 363b'.

b) Paragraphs 3 and 4 are replaced by the following paragraphs 3 and 4:

(1) ' The Telematics Agency shall be authorised to issue binding instructions to the suppliers and manufacturers referred to in Paragraph 329(2) to remedy the safety deficiencies identified by the Telematics Agency or the Federal Office for Information Security.

(2) The costs incurred by the Federal Office for Information Security for the assessment referred to in paragraph 1 shall be borne by the provider or manufacturer referred to in § 329(2) if the Federal Office for Information Security

has acted on the basis of evidence giving rise to reasonable doubts as to the safety of the authorised services and confirmed applications.'

44. Section 334 is amended as follows:

a) In paragraph 1, the second sentence is amended as follows:

a%6) In point 7, the words 'pursuant to § 358 and' are replaced by the words 'pursuant to § 358'.

b%6) In point 8, the words 'electronic invoice pursuant to § 359a.' are replaced by the words 'digital patient invoice pursuant to § 359a and'.

c%6) In point 8, the following point 9 is inserted:

1. ' electronic credit transfers.'

b) A (b)(2) is amended as follows:

a%6) In the second sentence of Section 342(1), the words 'the second sentence of Section 342(1)' are replaced by the words 'Section 342(1)'.

b%6) In the third sentence, the words 'period to be determined by regulation in accordance with Section 342(2b)' are replaced by the words 'period to be determined by the Telematics Society in accordance with Section 342(2b)'.

c%6) In the fourth sentence, the words 'date to be determined by regulation pursuant to § 342(2b)' are replaced by the words 'date to be determined by the company for telematics pursuant to § 342(2b)'.

45. In Section 335(3), the words 'the second sentence of Section 342(1)' are replaced by the words 'Section 342(1)'.

46. The second sentence of Section 336(1), the fifth sentence of Section 336(2) and the second and third sentences of Section 336(7) are deleted.

47. The fourth sentence of Section 337(2) is replaced by the following sentence:

'In so far as data sets and information objects pursuant to Section 342(2a)(1) or (2)(a) are concerned, they may be deleted only in their entirety.'

48. Section 338 is replaced by the following Section 338:

§ 1'

Components for the exercise of the rights of insured persons

The Gesellschaft für Telematik may assist the health insurance funds in carrying out the tasks referred to in § 342(7) in so far as the provision of accessible components for stationary terminal equipment is concerned.'

49. Section 339 is amended as follows:

a) In paragraph 1a, the words 'Sections 352 and 359' are replaced by the words 'Sections 352 and 352a'.

b) In paragraph 1a, the following paragraph 1b is inserted:

"(1b) By way of derogation from the third sentence of paragraph 1, health care providers with access rights pursuant to points 5 and 6 of the first sentence of § 352, also in conjunction with the second sentence, may also provide proof of the temporal link with the treatment by means of the access data pursuant to the first sentence of § 360(9) in the case of medical prescriptions pursuant to § 360(2). By way of derogation from points 5 and 6 of the first sentence of § 352, also in conjunction with the second sentence, where proof of the temporal link with the treatment pursuant to the first sentence is provided, access shall be limited to the processing of data pursuant to points 1(b) and 11 of § 341(2).'

50. Section 340 is amended as follows:

a) In the second paragraph, "points 33 to 37" is replaced by "points 33 to 38".

b) In the first sentence of paragraph 5, the words 'or a digital identity as referred to in paragraph 6' shall be inserted after the words 'electronic healthcare professional card or professional card'.

c) In paragraph 6, '1 January 2028' is replaced by '1 January 2029';

d) In paragraph 7, '1 January 2028' is replaced by '1 January 2029';

51. Section 341(2) is amended as follows:

a) In point 1(d), the words ' and electronic discharge letters' shall be inserted after the words 'electronic medical letters'.

b) Point 12 is replaced by the following:

1. ' the certificate of incapacity for work issued in accordance with point 9 of the first sentence of Paragraph 73(2) in the copy intended to remain with the insured person,'.

c) In point 14, the following point 14a is inserted:

'14a. Data on preventive medical services pursuant to Paragraphs 23 and 24 and on medical rehabilitation and aftercare services pursuant to Paragraphs 40 and 41 and Paragraphs 15, 15a, 17 and 31(1)(2) of Book Six,'.

d) In point 18 of Annex I, the words 'batch number and' are replaced by the words 'batch number,'.

e) In point 19 of Annex I, the words 'Section 48b(1) of the Medicinal Products Act' are replaced by the words 'Section 48b(1) of the Medicinal Products Act'.

f) In point 19, the following points 20 to 22 are inserted:

1. ' health data processed at health and care insurance funds;

2. Data on electronic credit transfers pursuant to Section 360a and information on the redemption of electronic credit transfers; and

3. Results of nationwide standardised digital initial assessment procedures for appointment mediation in acute cases by the appointment service points of

the sickness fund doctors' associations pursuant to § 75(1a), third sentence, point 4.'

52. Section 342 is amended as follows:

a) In point (a), the first paragraph is replaced by the following:

(1) ' The health insurance funds shall be obliged to make available to any insured person who, after giving prior information in accordance with Paragraph 343, has not objected to the establishment of an electronic health record to the health insurance fund within six weeks, an electronic health record approved by the Telematics Society in accordance with Paragraph 325(1) which complies in each case in good time with the requirements laid down in subparagraph 2 and in subparagraphs 2a to 2c.'

b) A (b)(2) is amended as follows:

a%6) Point 1 is amended as follows:

a%7%7) Before point (a), the words 'first or second sentence' are deleted.

b%7%7) Points (c) to (f) are deleted;

c%7%7) Point (h) is replaced by the following point (h):

a) ' through the user interface of a suitable terminal device, insured persons can object to access to data in the electronic health record in an accessible manner to individual authorised access persons pursuant to § 352 sentence 1 points 1 to 15 and 19, also in conjunction with sentence 2; it shall be possible to limit the appeal to all data in the electronic health record as a whole and only to datasets and information objects referred to in paragraph 2a, point (1) or point (a) of paragraph 2a;';

d%7%7) Point (j) is replaced by the following point (j):

a) ' through the user interface of a suitable terminal equipment, insured persons may give consent to individual authorised access in accordance with § 352 sentence 1 points 16 to 18, also in conjunction with sentence 2, to access data in the electronic health record in an accessible manner; it shall only be possible to extend consent to datasets and information objects referred to in paragraph 2a, points (1) or (2)(a), and to all data in the electronic health record as a whole;';

e%7%7) Point (l) is replaced by the following point (l):

a) ' by means of a corresponding technical default, the duration of the access authorisation by authorised service providers pursuant to § 352 sentence 1 points 1 to 4 and 7 to 15, also in conjunction with sentence 2, is by default limited to 90 days, the duration of the access authorisation by authorised service providers pursuant to § 352 sentence 1 points 5 and 6, also in conjunction with sentence 2, is by default limited to seven days, and the duration of the access authorisation by authorised service providers pursuant to § 352 sentence 1 points 16 to 19,

also in conjunction with sentence 2, is by default limited to three days;';

f%7%7) Points (o) and (p) are replaced by the following points (o) and (p):

a) ' in the event of a change of health insurance fund, the data referred to in Section 341(2) from the previous electronic health record may be made available in the electronic health record of the chosen health insurance fund;

b) representatives designated by the insured persons may exercise the rights referred to in points (b), (g), (h), (j), (m), (n), (s), (t), (u) and (v);';

g%7%7) Point (b)(s) is replaced by the following point (s):

a) ' the insured persons are able to object individually to the processing of datasets and information objects referred to in paragraph 2a, points (1) and (2)(a), in their electronic health record or to withdraw such objection in an accessible manner through the user interface of a suitable terminal equipment; in the event of an objection, the relevant datasets or information objects shall be deleted immediately and in full; to the extent that the respective datasets or information objects referred to in paragraph 2a, points (1) and (2)(a), process data that are automatically transferred to and stored in the electronic health record from telematics infrastructure applications services, they shall be exempted from complete deletion in the event of an objection to the respective datasets or information objects referred to in paragraph 2a, points (1) and (2)(a), respectively;';

h%7%7) Point (u) is replaced by the following point (u):

a) ' insured persons who do not use the user interface of a suitable terminal equipment in accordance with § 336 may exercise their rights under points (s) and (t) at the ombudsman office in accordance with § 342a and may request the establishment of a representative in accordance with point (p) or the deletion of a registered representative;';

b%6) In point 2 of Section I, the words 'Section 311(6)' are replaced by the words 'Section 363a(1), first sentence, point 1'.

c%6) Point 4 is replaced by the following points 4 to 8:

1. ' in addition, as soon as the necessary conditions are met, and at the latest by 30 October 2026, the data stored in the electronic health record pursuant to § 363a may be made available for research purposes,

1. in addition, by 1 February 2028 at the latest, insured persons or representatives designated by them may use the functional area for digital access to care pursuant to Section 345a in an accessible manner via the user interface of a suitable terminal equipment,

2. in addition, insured parties can access data on electronic credit transfers pursuant to Section 360a and information on the redemption

of electronic credit transfers in an accessible manner via the user interface of a suitable terminal device,

3. in addition, insured persons may declare an objection to the transmission and storage of the insured person's data pursuant to point 6 to be accessible to persons with access rights pursuant to § 352, and

4. in addition, at the latest by 1 January 2028, insured persons may, via the user interface of a suitable terminal equipment, request the correction of their personal data pursuant to Article 16 of Regulation (EU) 2016/679 from the relevant data processing bodies pursuant to § 341(4); This shall be without prejudice to § 308(1) and § 344(4).'

c) In paragraph 2a, the words 'in accordance with the second sentence of paragraph 1' are replaced by the words 'in accordance with paragraph 1';

d) Paragraph 2b is replaced by the following paragraph 2b:

"(2b) The Telematics Society shall, with the consent of the Federal Ministry of Health, by means of a binding decision pursuant to the first sentence of § 315(1) set the time limits for the implementation of the requirements under paragraph 2(6), paragraph 2a(2)(a) to (c) and (e) and § 351(2), and shall also determine other information objects and other data pursuant to § 341(2)(1)(a) and (d), (9), (10) to (14a) and (16); the deadline for the implementation of the targets referred to in paragraph 2a, point (2)(a), shall be no later than 26 March 2029 and the deadline for the implementation of the targets referred to in paragraph 2a, point (2)(b), shall be no later than 26 March 2031. If the data referred to in Section 341(2)(14) or (14a) fall within the competence of the Federal Ministry of Labour and Social Affairs, it must be included at an early stage in the procedures for setting the requirements. Decisions on § 341(2)(12) may relate only to the copy of the medical certificate of incapacity for work intended to remain with the insured person. The decisions shall be published in the Federal Gazette.'

e) In paragraph 2c, the second sentence is replaced by the following sentences:

'The Gesellschaft für Telematik shall, with the consent of the Federal Ministry of Health, by means of a binding decision pursuant to the first sentence of Paragraph 315(1), lay down the time limits within which the electronic health record must technically ensure that:

1. Data pursuant to § 341(2)(2) to (5) can be made available as information objects and used in accordance with the requirements and specifications pursuant to paragraph 2, and

2. the insured persons or representatives designated by them may, via the user interface of a suitable terminal equipment, declare an objection to authorised access pursuant to § 352 against the transmission and storage of the information objects and data referred to in point 1 in an accessible manner.

The decisions shall be published in the Federal Gazette.'

f) Paragraph 5 is replaced by the following:

(1) ' If a health insurance fund has failed to fulfil its respective obligations under paragraphs 2b and 2c, the Telematics Society shall immediately inform the Central Federal Association of Health Insurance Funds. The Central Federal Association of Health Insurance Funds shall set a grace

period of four weeks for the health insurance fund concerned. After that grace period has expired without success, the health insurance fund concerned must pay EUR 0.50 per insured member to the Central Federal Association of Health Insurance Funds, which is to be used by the latter in the context of the financing of the Telematics Society pursuant to Paragraph 316. The Central Federal Association of Health Insurance Funds shall issue a decision finding that the health insurance fund concerned has failed to fulfil its obligation under paragraphs 2b or 2c and shall determine the specific amount of the penalty in accordance with the third sentence. Actions brought against the decision shall not have suspensory effect.'

g) In paragraph 8, the words 'the second sentence of paragraph 1' are replaced by the words 'paragraph 1';

53. Section 342a is amended as follows:

a) In the first sentence, the third and fourth sentences are replaced by the following sentences:

'The Ombudspersons' Offices shall advise insured persons on all questions and problems relating to the registration procedure and the use of the electronic health record. They shall in particular provide information on the procedure for making available the electronic health record and the statement of objection pursuant to Section 342(1), on the rights and entitlements of insured persons under this Title and on the functioning and possible content of the electronic health record.'

b) A (b)(2) is replaced by the following second paragraph:

(1) ' The ombudsman bodies shall receive objections from insured persons pursuant to § 353(1) and shall technically ensure that the objection is enforced in the electronic health record pursuant to § 342(1).'

c) In paragraphs 3 and 4, the words 'Section 342(1), second sentence' are replaced by the words 'Section 342(1)'.

d) In paragraph 4, the following paragraphs 4a and 4b are inserted:

"(4a) At the request of an insured person, the ombudsman bodies shall establish in his electronic health record one or more representatives appointed by him and shall technically ensure that they can exercise the insured person's rights referred to in Section 342(2)(1)(p). The Ombudspersons' Offices shall delete a registered representative at the request of the insured person.

(4b) At the request of an insured person, the ombudsman bodies shall set up one or more representatives designated by the insured person for the purposes of digital access to care pursuant to Section 345a and shall technically ensure that they can exercise the rights of the insured person in connection with the use of the functional area for digital access to care by 1 February 2028 at the latest. The second sentence of paragraph 4a shall apply mutatis mutandis.'

e) In paragraph 5, the words 'Section 342(1), second sentence' are replaced by the words 'Section 342(1)'.

f) In the first sentence of paragraph 8, the words 'paragraphs 2 to 4' are replaced by the words 'paragraphs 2 to 4b'.

54. § 343 is amended as follows:

a) Point (a)(1a) is amended as follows:

a%6) In the first sentence of Section 342(1), the words ‘the second sentence of Section 342(1)’ are replaced by the words ‘Section 342(1)’.

b%6) The third sentence is amended as follows:

a%7%7) In point 10 w, the following point 10a is inserted:

‘10a. the transmission and storage of data in the electronic health record pursuant to § 350(5) and (6),’;

b%7%7) In point 11 of Section I, the words ‘data that may be processed as use cases in the electronic health record in accordance with Section 342(2a), (2b) and (2c)’ are replaced by the words ‘data sets and information objects in accordance with Section 342(2a)(1) and (2)(a)’.

c%7%7) In point 17 of Section I, the words ‘Section 350(4)’ are replaced by the words ‘Section 350(3)’.

d%7%7) Point 18 is replaced by the following:

1. ‘ the ombudsman bodies pursuant to § 342a(1) and the possibility, in addition to being exercised via the user interface of a terminal equipment, of declaring objections pursuant to § 342a(2), (3) and (4) also to the ombudsman body, as well as the possibility of requesting the ombudsman body pursuant to § 342a(4a), first sentence, to set up a representative to exercise the rights of the insured person referred to in § 342(2)(1)(p), or pursuant to § 342a(4a), second sentence, to delete a registered representative;’;

e%7%7) In point 23, the words ‘actually and’ are replaced by the words ‘actually,’.

f%7%7) N ummer 24 is replaced by the following points 24 and 25:

1. ‘ the possibility for insured persons, with their consent, to transfer data from their digital health applications pursuant to § 33a from the manufacturer of such an application to their electronic health record through the provider of the electronic health record or from the digital health application to their electronic health record, and

1. the possibility of requesting the rectification of personal data pursuant to Section 342(2)(8) via the user interface of a suitable terminal equipment.’

b) In paragraph 3, the words ‘not later than eight months before the date referred to in the second sentence of § 342(1)’ are deleted.

c) A (b)(4) is replaced by the following paragraph (4):

(1) ‘ Before data sets and information objects pursuant to Section 342(2a), (2b) and (2c) are processed in the electronic health record, the health

insurance funds shall provide insured persons with comprehensive and appropriate information in this regard in a concise, transparent, intelligible and easily accessible form, using clear and plain language and accessible. The information material shall inform about all relevant circumstances of data processing, about the transfer of the data to the electronic health record and about the possibility to object to the processing of datasets and information objects pursuant to Section 342(2a)(1) or (2)(a).'

d) In paragraph 5, the words 'pursuant to the Regulation' shall be replaced by 'pursuant to the provisions of the Telematics Association'.

55. In Section 344(6), the following paragraph 7 is inserted:

(1) ' The health insurance fund may process the objection status under paragraphs 1 and 3 for the purpose of taking account of the objection, store it in the electronic health record and transfer it to the insured person's new health insurance fund in the context of a change of health insurance fund. The competent health insurance fund after a change of health insurance fund is authorised to process the objection status for the purpose of taking into account the objection that has been made. If, at the time of the appeal, the electronic health record has not yet been transferred to the competent health insurance fund after a change of health insurance fund, the latter shall be entitled to take over the electronic health record and immediately delete it in order to implement the appeal.'

56. Section 345 is amended as follows:

a) In paragraph 1, the second sentence is replaced by the following sentence:

'Health insurance funds may process the data referred to in the first sentence for this purpose, with the consent of the insured person, in the health insurance funds' information technology systems or in the electronic health record and store them in the electronic health record.'

b) In paragraph 2, the words 'Section 343(1)' are replaced by the words 'Section 343(1a)'.

57. The following§ 345a and § 345b are inserted:

'Paragraph 345a

D igitarian start of care

(1) By 1 February 2028 at the latest, the health insurance funds shall offer their insured persons a functional area for digital access to care via the user interface of the electronic health record pursuant to Section 342(2)(1)(b). The functional area for digital access includes, in particular, the offer of:

1. booking treatment appointments referred to in Section 75(1a) using the electronic system operated by the Federal Association of Statutory Health Insurance Physicians in accordance with the first sentence of Section 370a(1);

2. the use of the nationwide standardised initial assessment procedure referred to in Section 75(1a), third sentence, point 4, and

3. the use of components of the telematics infrastructure that enable insured persons to access electronic credit transfers in accordance with Section 360a as soon as they become available.

(2) By integrating the available technical functions, the health insurance funds offer insured persons in the functional area for digital access to care an easy-to-use way of providing care that meets their needs. In particular, they shall ensure that the insured person:

1. once an appointment for treatment has been agreed and confirmed with a health care provider participating in the statutory health insurance scheme in accordance with the first sentence of Section 95(1), the health care provider can give access to its electronic health record and that access is withdrawn if the appointment is cancelled,

2. may, in the case of telemedicine, have proof of entitlement to treatment under the statutory health insurance scheme transmitted by its health insurance fund to a health care provider participating in the statutory health insurance scheme in accordance with the first sentence of § 95(1) via secure transmission procedures in accordance with § 363a(1) or via services in accordance with § 291b(1);

3. after an appointment has been arranged with a health care provider participating in the statutory health insurance scheme in accordance with the first sentence of Section 95(1), can provide that provider with information that he agrees to be contacted via the instant messaging service in accordance with point 1 of the first sentence of Section 363a(1) and that he wishes to use that instant messaging service for further communication, and

4. after using the nationwide standardised initial assessment procedure referred to in Section 75(1a), third sentence, point 4, can store the results of the initial assessment in its electronic health record.

The performance of the functions referred to in the second sentence shall be subject to the prior informed consent of the insured person. The insured person may choose whether the function is to be performed once or whether the function is to be performed permanently on an ad hoc basis. If the insured person consents to a permanent execution, he or she shall be informed, on an ad hoc basis and prior to the execution in question, of the forthcoming execution and shall be given the opportunity to withdraw his or her consent.

(3) Once the relevant technical possibilities are available, the health insurance funds offer to the insured persons to personalise the functions in the functional area for digital access to care. In particular, they shall enable the insured person to establish that:

1. its data, stored in its electronic health record or with the health insurance fund, are used in the nationwide standardised initial assessment procedure referred to in § 75(1a), third sentence, point 4, and for the provision of treatment appointments in accordance with § 75(1a), and

2. the data from an electronic transfer pursuant to Section 360a and after the use of the nationwide standardised initial assessment procedure referred to in Section 75(1a), third sentence, point 4, the results of the initial assessment are used to provide treatment appointments in line with needs pursuant to Section 75(1a).

The performance of the functions referred to in the second sentence shall be subject to the prior informed consent of the insured person. The insured person may choose whether the function is to be performed once or whether the function is to be performed permanently on an ad hoc basis. If the insured person consents to a permanent execution, he or she shall be informed, on an ad hoc basis and prior to the execution in question, of the forthcoming execution and shall be given the opportunity to withdraw his or her consent.

(4) By 1 February 2028 at the latest, health insurance funds shall offer insured persons the possibility of appointing representatives for the exercise of their rights in the context of the use of the digital health care entry facility.

(5) Upon agreement and confirmation of a treatment appointment of the insured person with a health care provider participating in the treatment under the statutory health insurance scheme in accordance with the first sentence of § 95(1), the information required in each case shall be automatically transmitted on an ad hoc basis, in particular:

1. the insured person’s health insurance number pursuant to § 290(1) to the Federal Association of Statutory Health Insurance Physicians and the Federal Association of Statutory Health Insurance Physicians to the health care provider,

2. the service provider’s establishment number and the unique identification number of its service provider organisation referred to in Section 313(1) to the Federal Association of Statutory Health Insurance Physicians and the Federal Association of Statutory Health Insurance Physicians to the insured person,

3. from the insured person to the Federal Association of Statutory Health Insurance Physicians referred to in point 3 of the second sentence of paragraph 2 and from the Federal Association of Statutory Health Insurance Physicians to the service provider.

The Federal Association of Statutory Health Insurance Physicians shall provide for the mandatory transmission of the identification numbers referred to in the first sentence and the mandatory transmission of the information referred to in point 3 of the second sentence of paragraph 2 in the specifications referred to in Section 370a(2) and (5). The Federal Association of Statutory Health Insurance Physicians shall delete the data referred to in the first and second sentences after the appointment has taken place or has been cancelled.

(6) From 1 February 2028 at the latest, the Federal Association of Statutory Health Insurance Physicians shall enable the health insurance funds to offer insured persons the use of the nationwide standardised initial assessment procedure referred to in § 75(1a), third sentence, point 4, in the functional area for digital access to care. To this end, it shall provide the health insurance funds with an interface for use free of charge by 1 November 2027 at the latest. After using the nationwide standardised initial assessment procedure referred to in Section 75(1a), third sentence, point 4, the interface provides for the results of the initial assessment to be transmitted in a standardised and structured form to the functional area for digital supply entry.

(7) By 1 February 2028 at the latest, the Federal Association of Statutory Health Insurance Physicians shall enable the health insurance funds to offer insured persons the booking of treatment appointments in acute cases in the functional area for digital access to care using the electronic system operated by the Federal Association of Statutory Health Insurance Physicians in accordance with the first sentence of Section 370a(1). The booking of treatment appointments in acute cases in the functional area for digital healthcare entry is subject to the condition that, following the

use of the nationwide standardised initial assessment procedure referred to in Section 75(1a), third sentence, point 4, an acute case and the level of care that is medically required have been identified and that these findings are transmitted, when the appointment is requested, from the functional area for digital healthcare entry to the electronic system operated by the Federal Association of Statutory Health Insurance Physicians in accordance with Section 370a(1), first sentence.

(8) The health insurance funds shall make the technical arrangements for the performance of their tasks under paragraphs 2, 3 and 4 in consultation with the Telematics Society. The Federal Association of Statutory Health Insurance Physicians shall draw up the technical specifications for the performance of its tasks pursuant to paragraphs 5, 6 and 7 in consultation with the Telematics Society.

Section 345b

D ate-based information on participation in clinical trials; Executive power

(1) Insured persons shall be given the possibility to view, via the user interface of a suitable device, information on clinical studies for which they could be individually suitable as participants on the basis of the data stored in the electronic health record.

(2) In order to identify suitable clinical studies, data from the EHR are processed with the consent of the insured persons to cross-check them with information on the requirements for participation in clinical studies.

(3) Study leaders conducting a clinical study may notify their clinical study to the body specified in the statutory ordinance referred to in paragraph 4(4) for participation in the matching procedure referred to in the previous paragraphs. With the notification, they shall provide information on the requirements for participation in their clinical study that are necessary for the purpose of the comparison referred to in paragraph 2.

(4) The Federal Ministry of Health shall be authorised to issue a statutory ordinance, without the consent of the Bundesrat, specifying:

1. the technical procedure for cross-checking data;

2. the procedure for the notification of a clinical study in accordance with the first sentence of paragraph 3;

3. the information to be provided with the notification on the requirements for participation in clinical studies; and

4. the designation of the place where study managers can register to take part in the matching procedure.’

58. Section 346 is amended as follows:

a) The words ‘and 1b’ shall be inserted after the words ‘Section 339(1)’.

b) In the second sentence of paragraph 5, the words ‘with effect on the date on which the electronic health record is made available in accordance with the second sentence of Section 342(1)’ are deleted.

59. Section 347 is amended as follows:

a) The first sentence of point (a) is amended as follows:

a%6) In the first sentence, the words ‘data of the insured person which may be processed as use cases in the electronic health record in accordance with Section 342(2a), (2b) and (2c)’ are replaced by the words ‘data sets and information objects in accordance with Section 342(2a), (2b) and (2c)’.

b%6) S atz 2 is replaced by the following sentence:

‘The obligation referred to in the first sentence shall apply in so far as:

1. in the context of statutory health care, these data are collected from the health care providers participating in the statutory health care and processed in a semantic and syntactically interoperable manner in the specific current treatment of the insured person,

2. the insured person has not objected to access by the providers referred to in the first sentence to the data in the electronic health record as a whole in accordance with Section 353(2); and

3. in the case of data sets and information objects pursuant to Section 342(2a)(1) or (2)(a), the insured person has not objected to their processing in accordance with Section 353(1).’

b) The first sentence of the second sentence of paragraph (a) is amended as follows:

a%6) In point 3, the words ‘measures and’ are replaced by the words ‘measures,’.

b%6) Point 4 is replaced by the following points 4 and 5:

1. ‘ electronic medical letters and electronic discharge letters pursuant to § 341(2)(1)(d), and

2. the copy of a certificate of incapacity for work in accordance with § 341(2)(12) intended to remain with the insured person.’

c) At the request of the insured person, the words ‘data of the insured person pursuant to § 341(2)(1) to (5), (10) to (14) and (16)’ shall be replaced by the words ‘data of the insured person pursuant to § 341(2)(1) to (5), (10) to (14a) and (16) in the context of their processing powers pursuant to § 352 at the request of the insured person’.

60. Section 348 is amended as follows:

a) In Section 342(2a), (2b) and (2c), the words ‘data of the insured person which may be processed as use cases in the electronic health record in accordance with Section 342(2a), (2b) and (2c)’ are replaced by the words ‘data sets and information objects in accordance with Section 342(2a), (2b) and (2c)’.

b) The first sentence of the second sentence of paragraph (a) is replaced by the following sentence:

‘The obligation laid down in paragraph 1 shall apply in so far as:

1. in the context of hospital treatment, these data are collected by health care providers in approved hospitals and processed in a semantic and syntactically interoperable form for the actual current treatment of the insured person,

2. the insured person has not objected to access by the providers referred to in paragraph 1 to the data in the electronic health record as a whole in accordance with Section 353(2), and

3. in the case of data sets and information objects pursuant to Section 342(2a) (1) or (2)(a), the insured person has not objected to their processing in accordance with Section 353(1).'

c) In the first sentence of paragraph 3, the words 'letters of discharge' are replaced by the words 'electronic letters of discharge pursuant to § 341(2)(1)(d)'.

d) At the request of the insured person, the words 'data of the insured person pursuant to § 341(2)(1) to (5), (10) to (14) and (16)' shall be replaced by the words 'data of the insured person pursuant to § 341(2)(1) to (5), (10) to (14a) and (16) in the context of their processing powers pursuant to § 352 at the request of the insured person'.

61. § 349 is amended as follows:

a) In the first sentence of the second paragraph, the words 'cases of use' are deleted.

b) In point 3, the first sentence is replaced by the following sentence:

'Persons with a right of access pursuant to Paragraph 352, first sentence, points 1 to 15 and 19, also in conjunction with the second sentence, shall, within the framework of their processing powers pursuant to Paragraph 352, at the request of the insured person, transmit and store in the electronic health record data of the insured person pursuant to Paragraph 341(2), points 1 to 5, 10 to 14a and 16, in so far as those data are collected and processed electronically as part of the actual current treatment of the insured person by those persons.'

c) In the first sentence of Section 342 (4), the words 'data on cases of use pursuant to Section 342(2a), (2b) and (2c) and data on insured persons pursuant to Section 341(2)(1) to (5), (10) to (14) and (16)' are replaced by the words 'data sets and information objects pursuant to Section 342(2a), (2b) and (2c) and data on insured persons pursuant to Section 341(2)(1) to (5), (10) to (14a) and (16)'.

62. § 350 is replaced by the following § 350:

§ 1'

Transfer of data stored by the health insurance fund to the electronic health record

(1) The health insurance fund shall transfer data on the benefits received by it pursuant to § 341(2)(8) to the insured person's electronic health record and store them there, unless the insured person has objected to this. Insured persons may object to the storage of data at any time thereafter. The objection may be made to the health insurance fund or via a user interface of a suitable terminal equipment.

(2) Details of the content and structure of the relevant datasets shall be agreed between the Central Federal Association of Health Insurance Funds and the Federal Association of Statutory Health Insurance Physicians in consultation with the Federal Association of Statutory Health Insurance Dentists, the Federal Chamber of Physicians, the Federal Chamber of Dentists and the German Hospital Society. They shall lay down the necessary structural requirements for semantic and syntactic interoperability of the relevant datasets pursuant to § 341(2)(8) by the end of... [insert: Date of the first day of the third calendar month following promulgation]. It must be ensured that the electronic health record makes it clear that the data are from the health insurance funds.

(3) At the request of the insured person, and by way of derogation from Section 303(4), the health insurance fund shall transmit and store in the insured person's electronic health record, in a corrected form, diagnostic data which have been communicated to it in accordance with Sections 295 and 295a and the inaccuracy of which is confirmed by medical evidence.

(4) On the basis of the data on the services received by the health insurance fund, the health insurance fund shall draw up and update an accessible digital vaccination overview for each insured person of the protective vaccinations received within the meaning of § 2(9) of the Infection Protection Act (Infectionschutzgesetz) and shall record this in the electronic health record referred to in § 341(2)(20). As part of the digital vaccination overview, the health insurance fund must inform the insured person of upcoming protective vaccinations, which are recommended to be carried out by the Permanent Vaccination Commission set up at the Robert Koch Institute.

(5) The health insurance fund may provide additional applications on the basis of the data on the services received by it and store the result in the electronic health record pursuant to § 341(2) No 20. If the insured person's data pursuant to Section 345(1) have been made available to the health insurance fund, they may also be used.

(6) The health insurance fund must inform the insured person in advance of the applications referred to in paragraphs 4 and 5. The insured person may object to the applications referred to in paragraphs 4 and 5 at any time.'

63. Section 350a is deleted.

64. Section 351 is amended as follows:

a) The heading is replaced by the following:

§ 1'

Transfer of data between applications pursuant to § 33a and the electronic health record; Making electronic health record data available for cross-border exchange'.

b) Paragraphs 1 and 2 are replaced by the following paragraphs 1 and 2:

(1) ' The health insurance fund shall ensure that:

1. With the consent of the insured persons, the data of the insured persons in digital health applications pursuant to § 33a can be transferred by the manufacturer of a digital health application pursuant to § 33a via the

provider of the electronic health record to the electronic health record of the insured persons pursuant to § 341(2)(9) and stored there,

2. from 1 February 2028, data from the electronic health record pursuant to § 341(2)(11) on medicinal product-related regulatory data and dispensing information and on over-the-counter medicinal products and food supplements may be processed by the manufacturer of a digital health application in digital health applications pursuant to § 33a with the consent of the insured persons,

3. from 1 February 2028, data from the electronic medication plan pursuant to Section 341(2)(1)(b) may be processed by the manufacturer of a digital health application in digital health applications pursuant to Section 33a with the consent of the insured persons.

(2) Within the period to be determined by the Telematics Association pursuant to Section 342(2b) in this regard, the Health Insurance Fund shall ensure that, in order to support specific treatment of the insured person with his or her consent in another Member State of the European Union, the following data stored in the insured person's electronic health record may be processed by the national eHealth contact point and, from 26 March 2029, by the national contact point for digital health pursuant to Section 352a via the provider of the electronic health record:

1. Data on findings, diagnoses, treatment measures taken and planned, screening tests and treatment reports and other medical information relating to testing and treatment pursuant to § 341(2)(1)(a),

2. Data contained in the electronic health record pursuant to Section 341(2)(1)(c);

3. Data on medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11); and

4. Data on electronic medical letters and electronic discharge letters pursuant to § 341(2)(1)(d).'

c) In paragraph 3, the words 'deadline laid down by regulation' are replaced by the words 'deadline to be determined by the Telematics Company'.

65. § 352 is amended as follows:

a) S atz 1 is amended as follows:

a%6) Point 5 is replaced by the following:

5. ' Pharmacists to the extent necessary for the provision of care to insured persons;

a) access allowing the retrieval, storage and use of data pursuant to Section 341(2)(1), (3) to (11), (17) to (19) and the processing of data pursuant to Section 341(2)(1)(b), (5), (11), (17) to (19), and

b) access which, as part of a measure referred to in point 4 of the second sentence of § 129(5h), enables assisted telemedicine to read data pursuant to § 341(2) and to erase such data at the request of the insured person;';

b%6) In point 18 of Section 341(2), the words ‘data referred to in point 5 of Section 341(2)’ are replaced by the words ‘data referred to in points 1(a) and 5 of Section 341(2)’.

b) In the second sentence, ‘pursuant to Book 7’ is replaced by ‘pursuant to Books 6 or 7’.

66. The following§ 352a is inserted:

‘Paragraph 352a

Access to EHR data in cross-border care

With the prior consent of the insured person to the use of the access procedure pursuant to Section 351(2), for the purpose of the cross-border exchange of health data to support specific treatment of the insured person, a healthcare provider who is authorised to access the data in another Member State of the European Union in accordance with the law of that Member State may access the following data stored in the insured person’s electronic health record via the national eHealth contact point and, from 26 March 2029, via the national contact point for digital health:

1. Data on findings, diagnoses, treatment measures taken and planned, screening examinations, treatment reports and other medical information relating to examinations and treatment pursuant to § 341(2)(1)(a),

2. Data contained in the electronic health record pursuant to Section 341(2)(1)(c);

3. Data on medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11); and

4. Data on electronic medical letters and electronic discharge letters pursuant to Section 341(2)(1)(d).

In addition, it is necessary that, at the time of treatment, the insured person technically releases access to the eHealth National Contact Point and, from 26 March 2029, to the national contact point for digital health of the Member State where the treatment takes place, by a clear affirmative action. With regard to the processing of data by a health care provider in another Member State of the European Union, the provisions of the Member State in which the health care provider is established shall apply.’

67. In the first, third and second sentences of § 353(1) and (4), the words ‘data that may be processed as use cases in the electronic health record in accordance with § 342(2a), (2b) and (2c)’ are replaced by the words ‘data sets and information objects in accordance with § 342(2a)(1) or (2)(a)’.

68. Section 354(1) is amended as follows:

a) Point 5 is replaced by the following:

1. ‘the ombudsman bodies pursuant to § 342a can technically enforce objections by insured persons pursuant to § 342a(2) to (4) and powers pursuant to § 342a(4a) and (4b) and can provide insured persons with the log data of the electronic health record pursuant to § 342a(5),’.

b) In point 6, the words ‘may’ are replaced by the words ‘may’.

c) In point 6, the following points 7 and 8 are inserted:

1. ‘ until the end of... [insert: The date of the first day of the third calendar month following the promulgation] evidence of the temporal link with the treatment pursuant to Section 339(1) can be provided by means of the access data pursuant to the first sentence of Section 360(9), thereby enabling access in accordance with Section 339(1b), and

2. the functional area for digital access to care pursuant to Section 345a(1) can be designed by the health insurance funds in such a way that it can be easily operated.’

69. Section 355 is amended as follows:

a) The first sentence of the first subparagraph is amended as follows:

a%6) In point 9, the words ‘health insurance and’ are replaced by the words ‘health insurance,’.

b%6) N ummer 10 is replaced by the following points 10 and 11:

1. ‘ the relevant associations for the accident insurance institutions, and

2. the Deutsche Rentenversicherung Bund (German Pension Insurance Association) for the pension insurance institutions.’

b) The second sentence of the third paragraph of point (a) is amended as follows:

a%6) In point 2 of Section I, the words ‘Section 31a(3a)’ are replaced by the words ‘Section 31a’.

b%6) In point 4, the words ‘may and’ are replaced by the words ‘may,’.

c%6) In point 5, the words ‘may’ are replaced by the words ‘may and’;

d%6) In point 5, the following point 6 is inserted:

1. ‘ the medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11) must also be suitable to support the cross-border treatment of the insured person pursuant to § 352a in another Member State of the European Union.’

c) In point 4 of the second sentence of paragraph 4, ‘§ 359(4)’ is replaced by ‘§ 352a’.

d) Paragraphs 4a and 4b are replaced by the following paragraphs 4a and 4b:

“(4a) The Federal Association of Statutory Health Insurance Physicians or a legal person within the meaning of point 2 of the second sentence of Section 385(1) shall, in the procedure provided for in paragraph 1, make the necessary arrangements for the semantic and syntactic interoperability of laboratory results as an information object of the electronic health record pursuant to point 1(c) of Section 341(2) in conjunction with point 2(b) of Section 342(2a), provided that the latter has been instructed to do so pursuant to point 2 of the second sentence of Section 385(1) and the third and fifth sentences of Section 385(4) and on the

basis of the statutory ordinance pursuant to the first sentence of Section 385(1). In the determinations pursuant to the first sentence, the Federal Association of Statutory Health Insurance Physicians shall take into account that laboratory findings pursuant to § 341(2)(1)(c) in conjunction with § 342(2a)(2)(b) must be suitable to support the cross-border treatment of the insured person pursuant to § 352a in another Member State of the European Union.

(4b) The Federal Association of Statutory Health Insurance Physicians shall, in accordance with the procedure laid down in paragraph 1, make the necessary arrangements for the semantic and syntactic interoperability of data processed in the context of structured treatment programmes pursuant to § 137f(9) as an information object of the electronic health record § 341(2)(13).'

70. In Section 356(3), first sentence, the words 'period to be determined in accordance with a statutory ordinance pursuant to Section 342(2b)' are replaced by the words 'period to be determined by the company for telematics pursuant to Section 342(2b)'.

71. In the first sentence of Section 357(4), the words 'by way of statutory instrument' are replaced by the words 'by the company for telematics'.

72. Section 358 is amended as follows:

a) In the third sentence of paragraph 2, the words 'the second sentence of § 342(1)' are replaced by the words '§ 342(1)'.

b) A (b)7 is replaced by the following paragraph 7:

(1) ' The electronic health record stored in the electronic health record pursuant to Section 341(2)(1)(c) pursuant to Section 334(1), second sentence, point 7, shall ensure the cross-border exchange of health data in accordance with the requirements laid down in Section 352a at the end of the period to be determined for this purpose by the Telematics Society pursuant to Section 342(2b).'

c) In the first sentence of paragraph 8 of Section I, the words 'the second sentence of Section 342(1)' are replaced by the words 'Section 342(1)'.

73. Section 359(4) is deleted.

74. Section 359a is replaced by the following Section 359a:

'Paragraph 359a

Digital Patient Invoicing

(1) As soon as the services and components required for the application pursuant to point 8 of the second sentence of § 334(1) are available in the telematics infrastructure, the providers and bodies referred to in paragraph 2 may invoice medical or other services which are not subject to the benefits-in-kind principle electronically using the digital patient invoice and process these invoice data for billing purposes with the consent of the insured person using the services and components of the application pursuant to point 8 of the second sentence of § 334(1). This shall be without prejudice to Section 360(13).

(2) With the consent of the insured person, only the following persons, bodies and institutions may access the data of the insured persons in the digital patient account referred to in the first sentence of paragraph 1 for billing purposes:

1. Doctors, as well as persons working for doctors as their professional assistants or in preparation for the profession;

2. Dentists and persons working as professional assistants or in preparation for the profession of dentist,

3. Pharmacists and persons forming part of the pharmaceutical staff of the pharmacy;

4. Providers of medical aids and appliances,

5. Nursing services, nursing homes, nursing insurance funds,

6. Hospitals,

7. Midwives and childbirth nurses;

8. Psychotherapists;

9. Billing agencies, in so far as they act on behalf of the service providers in accordance with points 1 to 3 for the settlement of accounts or in so far as they act on the basis of ownership of claims derived from those service providers, and

10. responsible payers.

(1) Insured persons may share the data of the digital patient invoice with the persons authorised to access it pursuant to paragraph 2 for the purpose of correcting incorrect data.

(2) Consent for access to the insured person’s data in the digital patient invoice pursuant to the first sentence of paragraph 1 shall be given via the user interface of a suitable terminal device and shall require a clear affirmative action.

(3) With the consent of the insured person, the data from the digital patient invoice referred to in the first sentence of paragraph 1 may be stored in the services of the application for a maximum period of 10 years.

(4) The Gesellschaft für Telematik is obliged, in consultation with the Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security) and the Bundesbeauftragte für Datenschutz und die Informationssfreiheit (Federal Commissioner for Data Protection and Freedom of Information), to take the necessary measures to ensure that the digital patient invoice is available using the telematics infrastructure.

(7) As soon as the services and components required for the application pursuant to § 334(1) sentence 2 point 8 are available in the telematics infrastructure, the providers and bodies referred to in paragraph 2 may also use the digital patient invoice pursuant to paragraph 1 sentence 1 for medical or other services subject to the benefit-in-kind principle and process these invoice data using the services and components of the application pursuant to § 334(1) sentence 2 point 8 for billing purposes. In this case, access to the data for billing purposes in accordance with paragraph 2 shall also be possible without the consent of the insured person.

(8) From... [insert: Date of the last day of the twelfth calendar month following promulgation] provide the necessary services for billing between pharmacies and health insurance funds free of charge using the digital patient invoice referred to in paragraph 7. The Central Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen) and the relevant umbrella organisation for pharmacists formed for the protection of economic interests shall regulate the details in the pharmaceutical billing agreement pursuant to § 300(3). If an agreement is not reached within six months of... [insert: The date of the last day of the sixth calendar month following the promulgation] shall be decided by the arbitration body in accordance with § 129(8).'

75. In Chapter Fifth Section, the heading of Title Six is replaced by the following heading:

'Sixth title

Transmission of medical prescriptions and referrals, digital needs assessment".

76. Section 360 is amended as follows:

a) Paragraphs 2 and 3 are replaced by the following paragraphs 2 and 3:

(1) ' Doctors and dentists participating in panel medical care or working in institutions participating in panel medical care or in approved hospitals, preventive care institutions or rehabilitation institutions shall be obliged to issue prescription prescriptions electronically and to use services and components referred to in paragraph 1 for the transmission of prescription prescription prescription prescription prescription prescriptions. The obligation laid down in the first sentence shall apply from 1 March 2028 to the electronic issuing and transmission of prescriptions of narcotic drugs or medicinal products referred to in the first sentence of Paragraph 3a(1) of the Arzneimittelverschreibungsverordnung. The obligations under the first and second sentences shall not apply if the electronic issue or transmission of prescriptions for prescription-only medicinal products or medicinal products referred to in the first sentence of Paragraph 3a(1) of the Arzneimittelverschreibungsverordnung is not possible in individual cases for technical reasons. The obligation laid down in the second sentence in conjunction with the first sentence to issue and transmit prescriptions of narcotic drugs issued under contract by electronic means shall not apply if, for technical reasons, it is not possible to issue or transmit these prescriptions electronically in individual cases or if narcotic drugs are prescribed in accordance with the first sentence of Section 8(6) of the Ordinance on the prescription of narcotic drugs to remedy an emergency. The obligation referred to in the first sentence shall not apply to prescription-only medicinal products ordinances which, on the basis of statutory provisions, may be assigned to a specific pharmacy or to a central purchasing body for medicinal products established by law or recognised by the competent authority in consultation with the Federal Ministry of Health. The Federal Association of Statutory Health Insurance Physicians and the Federal Association of Statutory Health Insurance Dentists shall report for each calendar quarter, no later than two weeks after the end of each calendar quarter, on the proportion of the number of electronic prescriptions issued by panel doctors in the total number of all prescription prescription prescription prescription prescriptions issued by panel doctors and the number of electronic dental prescriptions in the total number of all prescription prescription prescription prescription prescriptions issued by panel doctors. The health insurance funds shall transmit the non-personal data required for the report referred to in the sixth sentence to the

Central Federal Association of Health Insurance Funds, which shall transmit them to the Gesellschaft für Telematik. The Deutsche Krankenhausgesellschaft shall report to the Gesellschaft für Telematik on the first December 2026 and 1st December 2027 on the share of the total number of e-prescription prescriptions issued in hospitals out of the total number of prescription prescription prescription prescriptions issued in hospitals.

(2) Pharmacies shall be obliged to supply prescription-only medicinal products on the basis of medical prescriptions as referred to in paragraph 2 using the services and components referred to in paragraph 1. For the supply of narcotic drugs or medicinal products referred to in the first sentence of Paragraph 3a(1) of the Arzneimittelverschreibungsverordnung, the obligation under the first sentence shall apply from 1 March 2028. The obligations referred to in the first and second sentences shall not apply where, for technical reasons, electronic consultation of the medical prescription referred to in paragraph 2 is not possible in a particular case. The provisions of the Apothekenbetriebsordnung (Ordinance on the Operation of Pharmacies) shall remain unaffected.'

b) Paragraphs 5 to 8 are replaced by the following paragraphs 5 to 8:

(1) ' From 1 September 2028, the service providers referred to in the first sentence of paragraph 2 and the psychotherapists referred to in the first sentence of paragraph 4 shall be obliged to issue regulations of home nursing care pursuant to § 37 and, from 1 April 2031, regulations of non-clinical intensive care pursuant to § 37c electronically and to use services and components pursuant to paragraph 1 for their transmission. The obligation under the first sentence shall not apply if the electronic issuing or transmission of regulations under the first sentence is not possible in individual cases for technical reasons. Providers of home nursing services pursuant to § 37 shall be obliged from 1 September 2028 and providers of non-clinical intensive care services pursuant to § 37c shall be obliged from 1 April 2031 to provide the services using the services and components referred to in paragraph 1 also on the basis of an electronic prescription pursuant to the first sentence. The obligation under the third sentence shall not apply if electronic consultation of the Regulation is not possible in individual cases for technical reasons.

(2) From 1 September 2031, the providers referred to in the first sentence of subparagraph 2 and the psychotherapists referred to in the first sentence of subparagraph 4 shall be obliged to issue prescriptions of sociotherapy in accordance with Paragraph 37a electronically and to use services and components in accordance with subparagraph 1 for their transmission. The obligation under the first sentence shall not apply if the electronic issuing or transmission of regulations under the first sentence is not possible in individual cases for technical reasons. From 1 September 2031, providers of sociotherapeutic services pursuant to § 37a shall be obliged to provide the services using the services and components referred to in paragraph 1 on the basis of an electronic prescription pursuant to the first sentence. The obligation under the third sentence shall not apply if electronic consultation of the Regulation is not possible in individual cases for technical reasons.

(3) From 1 June 2029, the providers referred to in the first sentence of paragraph 2 and the psychotherapists referred to in the first sentence of paragraph 4 shall be obliged to issue prescriptions of medicinal products electronically and to use services and components in accordance with paragraph 1 for their transmission. From 1 July 2030, the providers referred to in the first sentence of paragraph 2 and the psychotherapists referred to in the first sentence of paragraph 4 shall be obliged to issue electronically prescriptions of assistive

devices, prescriptions of dressings pursuant to the first sentence of § 31(1), prescriptions of urine and blood test strips pursuant to the first sentence of § 31(1), prescriptions of medical devices pursuant to § 31(1) and prescriptions of balanced diets for enteral nutrition pursuant to § 31(5) and to use services and components pursuant to paragraph 1 for their transmission. The obligation referred to in the first or second sentences shall not apply if the electronic issuing or transmission of regulations referred to in the first or second sentences is not possible for technical reasons in an individual case. From 1 June 2029, providers of medicinal products shall be obliged to provide the medicinal products using the services and components referred to in paragraph 1 also on the basis of an electronic ordinance pursuant to the first sentence. From 1 July 2030, providers of assistive devices and providers of the other services referred to in the second sentence shall be obliged to provide the services using the services and components referred to in paragraph 1 also on the basis of an electronic ordinance pursuant to the second sentence. The obligation referred to in sentences 4 or 5 shall not apply if electronic access to the Regulation is not possible in individual cases for technical reasons.

(4) In order to be able to obtain prescriptions electronically pursuant to paragraphs 5, 6 or 7, providers of home nursing services pursuant to § 37, non-clinical intensive care services pursuant to § 37c and sociotherapy pursuant to § 37a shall connect to the telematics infrastructure pursuant to § 306 by 1 September 2030 and providers of medical aids and appliances and providers of the other services referred to in the second sentence of paragraph 7 shall connect to the telematics infrastructure pursuant to § 306 by 1 October 2027.'

c) In the second sentence of paragraph 9, '§ 311(6)' is replaced by '§ 363a(1), first sentence, point 1'.

d) (A)(b)10 is amended as follows:

a%6) S atz 1 is replaced by the following sentence:

'The Telematics Society shall be obliged to make available as a service of general economic interest the components of the telematics infrastructure which enable insured persons to have access to the electronic medical prescription referred to in point 6 of the second sentence of Paragraph 334(1).'

b%6) The following sentences are inserted after the ninth sentence:

'Provided that the necessary conditions are met, health insurance funds and the payers referred to in Paragraph 362(1) who make components available in accordance with the eighth sentence shall ensure that, through those components, insured persons can submit data on electronic prescriptions of prescription-only medicinal products to the national eHealth contact point and, from 26 March 2029, to the national contact point for digital health for the purpose of cross-border exchange. The transmission requires the prior consent of the insured person to the use of the transmission method and the technical release at the time of encashment of the Regulation with the health care provider authorised to access it under the law of the other Member State of the European Union.'

e) (A)(b)(11) is replaced by the following paragraph (11):

(1) ' Regulation data and dispensing information pursuant to paragraphs 2, 4, 6 and 7 shall be deleted upon the expiry of 100 days from the date of

dispensation of the Regulation. With the expiry of 100 days after the end of the selected regulatory period, in the case of electronic prescriptions of home nursing care pursuant to § 37 or of non-clinical intensive care pursuant to § 37c, the prescription data, the information on the provision of care services and the decision data of the sickness insurance funds shall be deleted.'

f) In paragraph 17, the fourth sentence is deleted;

77. The following§ 360a to § 360c are inserted:

'Paragraph 360a

Electronic transmission and processing of contracted electronic credit transfers

(1) The telematics infrastructure shall be used for the electronic transmission and processing of contracted electronic credit transfers as soon as the services and components required for this purpose are widely available.

(2) From 1 September 2029, doctors participating in panel medical care or working in institutions participating in panel medical care shall be obliged to issue and retrieve credit transfers electronically and to use services and components referred to in paragraph 1 for the electronic transmission of those credit transfers. The obligation under the first sentence shall not apply if the electronic issuing or transmission of electronic credit transfers is not possible in individual cases for technical reasons.

(3) Insured persons may choose from among the providers referred to in paragraph 2 whether to provide them with the access data necessary to access their electronic credit transfer in an accessible manner, either by means of a paper printout or by electronic means.

(4) The Telematics Association is obliged to make available, as a service of general economic interest, the components of the telematics infrastructure which enable insured persons to have access to electronic credit transfers. The functionality and interoperability of the components shall be ensured by the Telematics Society. The security of the components of the electronic credit transfer system, including the means of access for insured persons, shall be demonstrated by an external security opinion. The availability, integrity, authenticity and confidentiality of the components shall be demonstrated in a graduated manner in relation to the hazard potential. The verification procedures and the selection of the safety assessor for the external safety opinion shall be carried out by the Telematics Society in consultation with the Federal Office for Information Security. The external security opinion must be submitted to the Federal Office for Information Security for examination and confirmed by it. Only after confirmation of the external security opinion by the Federal Office for Information Security may the components be made available by the Telematics Society. By way of derogation from the seventh sentence, components pursuant to this paragraph for which an external security opinion has been obtained and confirmed in accordance with the sixth sentence by the Federal Office for Information Security may also be made available to insured persons by the health insurance funds and by the payers referred to in § 362(1) via the user interface of the electronic health record pursuant to § 342(2)(1)(b).

(5) Credit transfer data and information on the execution of the electronic credit transfer shall be deleted with effect from 100 days after the execution of the electronic credit transfer.

(6) Unless the insured person has objected, data on electronic credit transfers and, where technically possible, information on the redemption of the electronic credit transfer shall be automatically transferred to the electronic health record and stored in accordance with Section 341(2), point 21. The objection referred to in the first sentence may be declared or withdrawn via the user interface in the electronic health record pursuant to Section 342(2)(1)(b) and at the ombudsman's office pursuant to Section 342a.

(7) The health care providers referred to in paragraph 2 shall prove to the relevant association of statutory health insurance physicians that they are able to issue, retrieve and transmit the contractual health insurance transfers referred to in the first sentence of paragraph 2 electronically.

§ 360b

V Agreement on Digital Needs Assessment Requirements

(1) The Federal Association of Statutory Health Insurance Physicians shall agree with the Central Federal Association of Health Insurance Funds by... [insert: Date of the last day of the twelfth calendar month following the promulgation] the requirements for an electronic system for the standardised and structured collection of medical conditions, the assessment of the need for and urgency of the treatment and the allocation of treatment needs to the appropriate level of care (digital needs assessment). The digital needs assessment helps insured persons to access emergency, acute or outpatient care in a targeted manner. The agreement referred to in the first sentence shall comply with the rules and requirements laid down in Section 75(1a), third sentence, point 4, in conjunction with Section 75(7), first sentence, point 6, and with the provisions of the agreement referred to in Section 87(2o)(4). The Federal Ministry of Health shall be informed of the status of the agreement upon request. The agreement referred to in the first sentence shall be concluded in consultation with:

1. relevant medical societies;

2. D the Federal Chamber of Physicians,

3. D the Federal Chamber of Psychotherapists,

4. D he German Hospital Association,

5. D the Telematics Society;

6. joint Federal Committee,

7. organisations responsible at federal level for the protection of the interests of patients and the self-help of chronically ill and disabled people; and

8. the federal associations responsible for defending the interests of industry in the field of information technology in healthcare and medical technology.

(2) The agreement referred to in paragraph 1 shall provide that:

1. digital needs assessment is evidence-based and guidance-based;

2. digital needs assessment is non-discriminatory, accessible and usable in different languages;

3. the digital needs assessment can also be accessed by telephone;

4. D as an electronic system may consist of several modules; and

5. the use of digital needs assessment by different persons must be possible, in particular:

a) the insured person himself,

b) the representative appointed by the insured person in accordance with Section 342(2)(1)(p) and Section 342a(4b),

c) the specialist staff appointed for this purpose, and

d) I n of a Consultant Institution.

(3) The agreement referred to in paragraph 1 shall contain, in particular, provisions on:

1. technical and professional requirements for digital needs assessment, in particular to:

a) I informational and patient safety;

b) Accuracy, including sensitivity and specificity;

c) B equity,

d) Elasticity and reproducibility;

e) Intelligibility,

f) E explainability of the results;

g) I food-neutral; and

h) echnical high availability, redundancy, technical resilience and practicability; and

2. D the classification of the recommended time of treatment according to medical urgency (urgency level) and, in particular, to the following categories:

a) s ofort,

b) I within 24 hours,

c) I the next few days or weeks, with an indication of a time corridor for the treatment in question, or

d) g No need for treatment at present, and

3. D the classification and assignment of the supply event to an appropriate supply level, in particular:

a) m Emergencies,

b) N otdienst,

c) H dental care pursuant to § 73(1), second sentence, and (1a),

d) F paramedical care, including assignment to the relevant medical specialist group, or

e) Suitability for self-care by the insured person, supported by digital advice and information provision, and

4. D the suitability of the need for care for telemedicine;

5. D its suitability for the provision of care by specialised non-medical personnel;

6. requirements to ensure the quality of the digital needs assessment, in particular to:

a) I substantive validation of the digital needs assessment;

b) A custodianisation of the electronic system, and

c) F ongoing and transparent evaluation of the classification of insured persons at the appropriate level of care, and

7. requirements on the decision-making logics underlying the digital needs assessment, in particular on transparency and documentation, and ways to further develop them;

8. technical, technical and organisational requirements to ensure data protection and security;

9. requirements for planned interoperable data exchange, in particular with:

a) D he electronic health record pursuant to § 341,

b) the electronic system pursuant to Section 370a,

c) D electronic credit transfer in accordance with Section 360a;

d) information technology systems used in healthcare providers' institutions to document treatment; and

10. requirements to use international standards and to use the mandatory medical classifications, terminologies and nomenclatures made available by the Federal Institute for Medicinal Products and Medical Devices for these purposes to ensure semantic interoperability; and

11. requirements to ensure that the digital needs assessment result report:

a) is available and understandable to insured persons,

b) it contains the recommended level of urgency and care and is therefore suitable for obtaining a treatment appointment, and

c) is available and useful to the treating health care provider and is suitable for storage in the electronic health records of the insured persons pursuant to § 341 and in the information technology programmes used to document the treatment.

(4) The agreement referred to in paragraph 1 shall be submitted to the Federal Ministry of Health before publication. The Federal Ministry of Health may object to the agreement within three months and set a reasonable deadline for remedying the objections. If the objections of the Federal Ministry of Health are not remedied within the time limit set by it, the Federal Ministry of Health shall itself determine the content of the agreements complained of. If an agreement pursuant to paragraph 1 is not concluded in whole or in part, the parties to the agreement or the Federal Ministry of Health may refer the matter to the Federal Arbitration Office pursuant to § 89(2), which shall determine the content of the agreement pursuant to § 89(3).

(5) The agreement referred to in paragraph 1 shall be reviewed and updated on an ongoing basis, at least every 12 months, taking into account new scientific evidence and supply developments by the parties to the agreement referred to in paragraph 1, after its publication as from 1 July 2031. Paragraph 4 shall apply mutatis mutandis to the updates of the Agreement.

§ 360c

B Creation of an electronic system for digital needs assessment

(1) The Federal Association of Statutory Health Insurance Physicians shall, as part of its tasks pursuant to the first sentence of § 75(1), provide an electronic system for a digital needs assessment pursuant to § 360b from 1 January 2031. The electronic system referred to in the first sentence shall be made available to insured persons in a uniform manner throughout Germany.

1. by telephone or digitally via the appointment service points of the associations of statutory health insurance physicians pursuant to § 75(1a), and

2. as part of the digital switchover pursuant to Section 345a.

(2) The Federal Association of Statutory Health Insurance Physicians shall agree, for the first time by 1 July 2028 and annually thereafter, with the Central Federal Association of Health Insurance Funds on an equal amount to be provided by the Federal Association of Statutory Health Insurance Physicians, on the one hand, and the Central Federal Association of Health Insurance Funds, on the other, to finance the development, provision, updating and further development of the electronic system referred to in paragraph 1. By 1 June 2028 and every year thereafter at the latest four weeks before the start of the relevant negotiations on the agreement referred to in the first sentence, the Federal Association of Statutory Health Insurance Physicians shall submit a detailed calculation of the costs incurred to ensure the development, provision, updating and further development of the electronic system referred to in the first sentence. The amount of the last agreed amount under the first sentence and its use for the purpose for which it was intended shall be reviewed annually by the parties to the agreement referred to in the first sentence. If an agreement pursuant to the first sentence is not reached or not reached in part, the Federal Arbitration Office shall, pursuant to Section 89(2), determine the content of the agreement at the request of one of the parties to the agreement referred to in the first sentence. Section 89(3) shall apply mutatis mutandis.’

78. Section 361(1) is replaced by the following paragraph 1:

(1) ‘ Insured persons’ data contained in electronic prescriptions issued by contracted doctors may be accessed only by the following persons:

1. Doctors, dentists and psychotherapists involved in the treatment of insured persons, with access enabling the processing of data provided by them in accordance with § 360, in so far as this is necessary for the care of the insured person;

2. within the limits of the relevant access authorisation pursuant to point 1, also persons acting as professional assistants or in preparation for the profession, in so far as access is necessary in the context of the activities they are lawfully required to carry out and access is carried out under the supervision of a person pursuant to point 1,

   a) in the case of persons referred to in point 1,

   b) in a hospital, or

   c) in a preventive or rehabilitation facility pursuant to § 107(2), in a rehabilitation facility pursuant to § 15(2) of Book Six, in a provider of medical care, including medical rehabilitation, pursuant to § 26(1), first sentence, of Book Seven, or in home or institutional care pursuant to § 44 of Book Seven;

3. Pharmacists with access enabling data to be processed in so far as this is necessary for the provision of prescribed medicinal products to the insured person and they have the access data required for access pursuant to § 360(9);

4. persons belonging to the pharmacy's pharmaceutical staff within the limits of the relevant access authorisation pursuant to point 3, whose access

   a) is necessary in the course of the activities which they are authorised to carry out; and

   b) under the supervision of a pharmacist, in so far as supervision of the pharmaceutical activity associated with access is required under pharmaceutical law;

5. Nurses who are in each case involved in the medical or nursing care of the insured person with access that allows the processing of data, in so far as this is necessary for the provision of the medically prescribed care to the insured person or for the forwarding of the Regulation to another health care provider representing the insured person, and they have the access data required for access in accordance with § 360(9);

6. other providers of medically prescribed services pursuant to this book with access allowing the processing of data in so far as this is necessary for the provision of the medically prescribed service to insured persons and they have the access data required for access pursuant to § 360(9).

Only insured persons may access the dispensing information referred to in Section 360(11). The access rights referred to in the first sentence shall also apply to the authorised persons referred to therein if they access medical prescriptions pursuant to § 27(1) of Book Seven in the context of an activity under Book Seven and if they access medical prescriptions in the context of medical rehabilitation and follow-up care pursuant to §§ 15, 15a, 17 and 31(1)(2) of Book Six.'

79. The following sentence is added to Section 361a(1), second sentence:

‘The second sentence shall apply mutatis mutandis to providers of medical rehabilitation and after-care services pursuant to Paragraphs 15, 15a, 17 and 31(1)(2) of Book Six, in so far as this supports the attainment of the objective of participation.’

80. Section 361b(1) is replaced by the following paragraph 1:

(1) ‘ Health insurance funds and the other payers referred to in Section 362(1) may access and process the data of insured persons in electronic prescriptions issued by contracted doctors for the purpose of collecting electronic prescriptions from digital health applications pursuant to Section 360(4).’

81. The following§ 361c and § 361d are inserted:

‘Paragraph 361c

Prescriptions of medical aids and appliances, home nursing, non-clinical intensive care and sociotherapy in the telematics infrastructure

(1) For the purposes of advice, the examination of applications, the decision on benefits and the settlement of electronically prescribed remedies pursuant to § 32, aids pursuant to § 33, home nursing care pursuant to § 37, non-clinical intensive care pursuant to § 37c and sociotherapy pursuant to § 37a, health insurance funds, statutory accident insurance institutions and the payers referred to in § 362(1) may access and process the data of insured persons contained in the electronic prescriptions for these benefits.

(2) In the context of access pursuant to paragraph 1, the freedom of medical treatment or the freedom of choice of insured persons may not be interfered with.

(3) The payer may be authorised by the insured person to access the data referred to in paragraph 1 even without the access data referred to in Section 360(9).

Paragraph 361d

Electronic credit transfers in the telematics infrastructure under contract with a medical practitioner

Only the following persons may have access to the data of insured persons in electronic credit transfers under contract:

1. Doctors involved in the treatment of insured persons, with access enabling the processing of data provided by them in accordance with § 360a, to the extent necessary for the treatment of the insured person;

2. within the limits of the relevant access authorisation pursuant to point 1, also persons acting as professional assistants or in preparation for the profession, in so far as access is necessary in the context of the activities they are lawfully required to carry out and access is carried out under the supervision of a person pursuant to point 1;

3. Doctors with access allowing the processing of data, to the extent necessary for treatment on the basis of an electronic credit transfer from the insured person and to the extent that they have access data necessary for access.’

82. Section 362(1) is replaced by the following paragraph 1:

(1) ‘ Where electronic health cards or digital identities for the processing of data from an application pursuant to the second sentence of Section 334(1) are made available by private health insurance companies, the Postbeamtenkrankenkasse, the health care of federal railway officials, the Federal Police, the Land police, the Federal Armed Forces or free health care providers to their insured persons, police officers, other officers with health care responsibility or soldiers, the sixth sentences of Section 291(8), Section 291a(5) to (7), Sections 334 to 337, 339, 341(1) to (4), Section 342(2) (1), (3) and (4) and (3), Sections 342a, 343(1a) and (4), Sections 344, 345, 351(2), 352, 352a, 353, 356 to 359a and 361 shall apply mutatis mutandis. Section 342(2)(2) shall apply mutatis mutandis, with the proviso that the obligation shall apply from 1 January 2028. § 219d(6) to (9) and the ninth section of this Chapter shall also apply in the field of private health insurance, in particular to patients insured with private health insurance companies and providers treating them.’

83. In Section 363, the following title is inserted:

‘Ninth title

My methods of transmission

Section 363a

Establishing secure transmission procedures for medical and nursing data

(1) Secure means of transmission for the transmission of medical, nursing and care-related administrative data via the telematics infrastructure shall mean, in particular:

1. the instant messaging service; and

2. the secure email service.

In addition to the procedures referred to in the first sentence, the Telematics Society may, with the consent of the Federal Ministry of Health and in consultation with the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information, establish further secure transmission procedures by means of a binding decision pursuant to the first sentence of Section 315(1).

(1) For the secure transmission procedures referred to in paragraph 1, the Telematics Society shall take the necessary measures and measures, in particular the framework conditions for their content, use and accessibility. The Telematics Society shall adopt those provisions and measures that affect data security issues in consultation with the Federal Office for Information Security and those provisions and measures that affect data protection issues in consultation with the Federal Commissioner for Data Protection and Freedom of Information.

(2) The Telematics Agency shall publish the procedures laid down in accordance with the second sentence of paragraph 1 and the decisions and measures taken in accordance with paragraph 2 on its website.

(3) The costs incurred by the Federal Commissioner for Data Protection and Freedom of Information in the performance of tasks pursuant to paragraph 2 shall be reimbursed by the Gesellschaft für Telematik. The details of the reimbursement of costs shall be determined by the Gesellschaft für Telematik in agreement with the Federal Commissioner for Data Protection and Freedom of Information.

Paragraph 363b

Removal of telematics infrastructure components and services for secure transmission procedures

(1) The components and services of the telematics infrastructure required for the secure transmission procedures pursuant to Section 363a(1) shall be subject to approval in accordance with Section 325. In the case of a contract awarded by the Telematics Society for the development, provision, operation and approval of components and services pursuant to § 311(1), first sentence, points 4 and 5, the safety of components and services must be demonstrated by means of an external safety assessment. It shall demonstrate that the availability, integrity, authenticity and confidentiality of the components and services are ensured.

(2) The provider of a secure transmission procedure pursuant to Section 363a(1) must have the authorisation required under Section 324. The Federal Associations of Statutory Health Insurance Physicians may be providers of a secure transmission procedure, provided that the secure transmission procedure is made available only to Associations of Statutory Health Insurance Physicians and their members.

Paragraph 363c

V Mandatory use of secure means of transmission

(1) Health insurance funds are obliged to also use the instant messaging service pursuant to § 363a(1), first sentence, point 1 to communicate with insured persons. Service providers may also use the instant messaging service pursuant to point 1 of the first sentence of Section 363a(1) to communicate with insured persons.

(2) Health insurance funds are obliged to use the secure e-mail service pursuant to Section 363a(1), first sentence, point 2, to communicate with health care providers. If the secure email service pursuant to Section 363a(1), first sentence, point 2, is not available to service providers, other means of communication may be used for communication.

(3) Service providers connected to the telematics infrastructure shall use the secure e-mail service referred to in point 2 of the first sentence of Section 363a(1) for electronic communication with those connected to the telematics infrastructure. Electronic data transmission for billing purposes in accordance with Section 301(3) and Section 17c(5) of the Hospital Financing Act shall be exempted from the obligation under the first sentence.

(4) The transmission of medical and nursing data by fax shall be effective from... [insert: Date of the last day of the twelfth calendar month following promulgation] is no longer permitted for health care providers and payers. The first sentence shall not apply in cases where the secure transmission procedures pursuant to Section 363a(1) are not available either at the sender or at the recipient.

Paragraph 363d

I stop and use the secure means of transmission

(1) Providers of a secure transmission procedure authorised under Section 324 pursuant to Section 363a(1) shall be obliged to make the framework conditions relevant to their procedure pursuant to Section 363a(2) known to the users of the secure procedure at the current stage and to agree these as conditions for the use of the secure procedure with the users.

(2) Data from the directory service pursuant to Section 313 may not be used to send messages for advertising purposes in the context of the use of a secure transmission procedure. The provisions of the Unfair Competition Act shall remain unaffected.

(3) The Telematics Society may block a user's access to a secure transmission process if the user:

1. rejects the agreement referred to in paragraph 1;

2. accepts the agreement pursuant to paragraph 1 but infringes provisions of the framework conditions pursuant to Section 363a(2); or

3. contrary to paragraph 2, sends messages for the purpose of commercial advertising.

The provider of the service concerned for the transmission procedure shall assist the Telematics Society in clarifying the facts and blocking the user's access.

(4) Providers of a secure email service pursuant to Section 363a(1), first sentence, point 2, may use it not only to transmit medical and care data but also to send messages to users for business purposes.

Paragraph 363e

Use of specialised procedures in the context of secure transmission procedures

(1) An organisation may use a specific technical procedure, in agreement with the Telematics Society, to support healthcare or to support, process or document its medical or administrative processes. A specialised procedure is a standardised procedure that uses the secure transmission procedure pursuant to Section 363a(1), first sentence, point 2. The agreement referred to in the first sentence shall be published or made available to individual user groups at least three months before the specialist procedure for use under the secure transmission procedure pursuant to Section 363a(1), first sentence, point 2. This applies in particular to such specialised procedures;

1. laid down by law, or

2. which are expected to reach an average volume of ten thousand messages per day or at least one daily volume of data per terabyte and for which regular daily use can be predicted to stabilise.

(2) In order to reach the agreement referred to in the first sentence of paragraph 1, the Telematics Society shall be provided with information on:

1. the secure method of transmission used by the specialised method;

2. the expected number of messages per day and their expected average size;

3. the expected number of users; and

4. the planned start date of the offer.

The Telematics Society may lay down further requirements for the necessary information pursuant to the first sentence.

(3) The Telematics Company shall keep a register of the technical procedures referred to in the first sentence of paragraph 1 and publish it on its website. The register shall contain information on the provider, the name and intended purpose of the specialised procedure and a unique identifier to be determined by the Telematics Society for the specific specialised procedure. The identifier may also include subordinate components defined by the Responsible Organisations.

(4) For individual secure transmission procedures pursuant to Section 363a(1), the Telematics Society may stipulate, as part of its provisions pursuant to Section 363a(2), that the identifier referred to in the second sentence of paragraph 3 is to be used on a mandatory basis for the assignment of the identifier in the context of a specialist procedure.

Paragraph 363f

Transmission of medical and nursing data using appropriate private terminals

(1) Providers working in a hospital may use private terminals to transmit medical and nursing data, provided that the following conditions are met:

1. the transmission shall be carried out using a secure procedure for the transmission of medical and care data in accordance with Section 363a(1), whereby the services and components referred to in the first sentence of Section 363b(1) and the providers referred to in the first sentence of Section 363b(2) are authorised,

2. the framework conditions for content and use under Section 363d(1) applicable to the procedure under Section 363a(1) are complied with; and

3. the technical and organisational measures appropriate to the state of the art to ensure information security and data protection pursuant to Article 32 of Regulation (EU) 2016/679 when using private terminal equipment shall be taken.

(2) Technical and organisational measures to ensure information security when using private terminal equipment shall be deemed appropriate within the meaning of paragraph 1(3) in a hospital if the corresponding requirements of the sector-specific security standards for the information security of healthcare provided in a hospital pursuant to § 391(4) or equivalent requirements are met.

(3) The German Hospital Society, in consultation with the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information, shall lay down the conditions to be met by private terminal equipment for the transmission of medical and care data.’

84. In Section 367(1), the words ‘accident insurance’ are replaced by the words ‘accident insurance’.

85. In Section 369(3), the words ‘one month’ are replaced by the words ‘three months’.

86. Section 370a (1a)(3) is replaced by the following point (3):

    1. ‘ Support for the Instant Intelligence Service pursuant to Section 363a(1), first sentence, point 1,’.

87. In Section 370b, the following Section 370c is inserted:

‘Paragraph 370c

Agreement on technical procedures for the use of digital forward booking platforms

(1) The Federal Associations of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds shall agree by... [insert: Date of the last day of the ninth calendar month following promulgation] Requirements for digital appointment booking platforms that can be used by panel doctors and panel dentists to arrange appointments in the statutory health insurance scheme. The agreement shall specify in particular:

1. basic technical and procedural requirements for digital appointment booking platforms, including accessibility requirements, requirements for demonstrating state-of-the-art data protection and information security assurance, and requirements for the use of open and standardised interfaces;

2. Measures to ensure that insured persons have access, on a needs-based and non-discriminatory basis, to panel and dental care and to exclude appointments based on financial contributions from insured persons or providers or third parties or based on remuneration;

3. Measures to exclude commercial third-party use of the forward booking process, in particular advertising freedom and data use or sharing for marketing activities, as well as measures to publish the intermediation rules; and

4. the procedures for demonstrating compliance with the requirements set out in points 1 to 3 by the operators of digital appointment booking platforms to the Federal Association of Statutory Health Insurance Physicians.

(2) If the agreement referred to in paragraph 1 is not concluded in whole or in part, the Federal Arbitration Office shall, at the request of one of the parties to the agreement, decide in accordance with Section 89(2).’

88. Section 371(1)(4) and (5) is replaced by the following points (4) to (6):

    1. ‘ Interfaces for the connection of comparable supply-oriented information technology systems, in particular outpatient and clinical application and database systems in accordance with this book;

    2. Interfaces for the notification of appointments pursuant to Section 370a(5) and for the use of secure communication procedures pursuant to Section 363a(1); and

    3. Interfaces for electronic programmes authorised for the production of electronic credit transfers pursuant to the first sentence of Section 73(9a), with the exception of the IT systems of panel dentists and hospitals.’

89. Section 372(3) is replaced by the following paragraphs 3 to 5:

(3) ‘ Where service providers participating in panel or dental care use information technology systems which have not, or have not successfully, undergone a conformity assessment procedure pursuant to § 387, even though the system used is subject to binding provisions pursuant to § 385(2), first sentence, point 1, the remuneration for panel or dental care shall be reduced by up to 20 % on a flat-rate basis. The Central Federal Association of Health Insurance Funds and the Federal Associations of Statutory Health Insurance Physicians shall agree, for the first time by 31 October 2027 at the latest, on the details of the design and implementation of the reduction. The agreement referred to in the second sentence shall state in particular:

1. Rules on the amount and calculation of the reduction, with provision for a progressive increase in the reduction depending on the duration of use of a non-certified system and the number of requirements not complied with by the system, but which are laid down in a binding manner in accordance with point 1 of the first sentence of Section 385(2); the reduction shall be at least 5 % of the remuneration,

2. Rules on the settlement of the reduction, in particular the procedure and settlement arrangements;

3. Requirements relating to the provision of evidence to the associations of statutory health insurance physicians by means of the information technology system which they use for the provision of statutory health insurance and dental services;

4. an exception to the reduction that takes into account that service providers can use an information technology system certificate pursuant to the second or third sentence of Section 387(4) without penalty nine months after the publication of the withdrawal or revocation of the certification on the platform pursuant to point 5 of the second sentence of Section 385(1); and

5. Transitional periods and the conditions under which service providers participating in panel or dental care may continue to use a non-certified information technology system beyond the relevant period determined by the statutory ordinance pursuant to § 385(1), first sentence, in conjunction with § 385(2), first sentence, point 1, without the reduction applying; the transitional periods may not end more than six months after the deadline pursuant to point 2 of the first sentence of § 385(2).

If the agreement referred to in the second sentence is not concluded in whole or in part within the time limit, the arbitration office shall determine the content of the contract in accordance with Section 89(2). The time limits for assessment under Section 89(3), (4) and (9) for assessment under the second sentence shall be two months.

(4) The Contracting Parties referred to in the second sentence of paragraph 3 shall agree, at two-yearly intervals and for the first time by 31 October 2029, to adapt the Agreement if necessary. If an adjustment pursuant to the first sentence is not agreed within the time limit, the existing agreement shall continue to apply until an amendment pursuant to the first sentence is agreed.

(5) The funds resulting from the reduction in remuneration shall be used by the contracting parties in accordance with the second sentence of paragraph 3 to promote the digitalisation of panel and dental care, in particular to further develop digital care processes and digital practice organisation.’

90. Section 374a is replaced by the following Section 374a:

‘Paragraph 374a

Integration of open and standardised interfaces in assistive devices and implants

(1) From 1 January 2028, assistive devices or implants shall enable, free of charge, the data processed by the assistive device or implant to be transferred, in appropriate interoperable formats, to a digital health application entered in the register pursuant to § 139e(1) and to be further processed there, in so far as the data are required by the digital health application for the intended use of the same insured person. The transfer of the data is subject to the consent of the insured person. The first sentence concerns assistive devices and implants which are supplied to insured persons at the expense of the statutory health insurance scheme and which transmit the data on the insured person electronically to the manufacturer or associated undertakings via publicly accessible networks. The obligation to transmit data to digital health applications pursuant to the first sentence also includes data taken from assistive devices or implants of other manufacturers and data in aggregated form. For the transmission of data in accordance with sentences 1 to 4, manufacturers of the aids and implants referred to in sentence 1 shall offer interoperable interfaces in accordance with the provisions of paragraph 4 sentence 1 and open them for the digital health applications included in the list pursuant to § 139e. The obligation on manufacturers under the fifth sentence also includes the provision of suitable offers to provide technical assistance to manufacturers of digital health applications included in the list pursuant to § 139e in connection to the interface and in ensuring interoperability on a permanent basis. The influence of the digital health application on the aid or implant is prohibited and technically ruled out.

(2) The Federal Institute for Medicinal Products and Medical Devices shall establish and publish an electronic register of interoperable interfaces between assistive devices and implants. Manufacturers of assistive devices and implants shall notify the implemented interoperable interfaces referred to in paragraph 1 to the Federal Institute for Medicinal Products and Medical Devices for publication in the list referred to in the first sentence and shall provide confirmation in accordance with paragraph 5 to demonstrate the conformity of the interfaces. The notification shall be made within three months of the publication of the relevant application form by the Federal Institute for Medicinal Products and Medical Devices. If aids or implants are first supplied at the expense of the statutory health insurance scheme after that date, the declaration shall be made at the time of the first supply. Manufacturers of assistive devices and implants shall notify the Federal Institute for Medicinal Products and Medical Devices without delay of any changes to the interoperable interfaces used by the respective devices. The Federal Institute for Medicinal Products and Medical Devices shall make it possible to use the information in the list referred to in the first sentence for digital health applications included in the list pursuant to § 139e. The Federal Institute for Medicinal Products and Medical Devices shall make the information listed in the list referred to in Section 139e(1) available to manufacturers of assistive devices and implants on request in machine-readable and platform-independent form.

(3) By way of derogation from paragraph 1, care may be provided beyond 1 January 2028 with assistive devices or implants that do not meet the requirements set out in paragraph 1 if this is necessary for medical reasons or the regular provision of assistive devices or implants to insured persons would otherwise not be ensured.

(4) The competence centre for interoperability in the health sector shall, in consultation with the Federal Office for Information Security, the Federal Commissioner for Data Protection and Freedom of Information and the Federal Institute for Medicinal Products and Medical Devices, make the necessary technical and operational arrangements for the transmission of data pursuant to the first sentence of paragraph 1, in particular to ensure the mutual identification of products during data transmission. The Telematics Society may operate technical services for the secure mutual identification of products in accordance with the technical specifications referred to in the first sentence.

(5) Upon request to manufacturers of assistive devices and implants referred to in paragraph 1, the Telematics Society shall confirm that the technical and operational specifications referred to in paragraph 4 have been implemented and shall establish a confirmation procedure for this purpose. The Telematics Company shall establish and publish on its website the details of the confirmation procedure and the assessment criteria necessary for that purpose.

(6) The Central Federal Association of Health Insurance Funds, in consultation with the Federal Institute for Medicinal Products and Medical Devices, the Telematics Society and the relevant umbrella organisations formed for the protection of economic interests of manufacturers of assistive devices and implants and manufacturers of digital health applications, shall lay down, at federal level, the details of the checks to be carried out by the health insurance funds on the implementation of the obligations under paragraphs 1 and 2 by manufacturers of assistive devices and implants. In particular, the Directive must regulate the proof of implementation of the interface and the procedure to be followed in the event of indications of non-compliance with technical and operational requirements by manufacturers of assistive devices and implants.

(7) Contracted doctors and hospitals may use digital data platforms holding data on the insured person from assistive devices and implants supplied to insured persons at the expense of the statutory health insurance scheme for the treatment of the insured person, provided that the providers of the digital data platforms have implemented and notified interoperable interfaces in accordance with paragraphs 1 and 2.';

91. Section 380 is amended as follows:

a) In paragraph 4, point 5 is replaced by the following point 5:

1. ' until 1 January 2023, for the service providers referred to in paragraph 2, point 4, the Central Federal Association of Health Insurance Funds and the associations of care institutions at federal level, with the involvement of the relevant central organisations for hospice work and palliative care at federal level.'

b) In paragraph 4, the following paragraph 5 is inserted:

(1) ' In the absence of an agreement pursuant to paragraph 3 or 4, the content of the agreement shall be determined within three months by an independent arbitrator to be appointed by the respective parties to the agreement. If the parties to the agreement do not agree on an arbitrator, the latter shall be appointed by the Federal Social Security Office within one month of receipt of the information necessary to identify the arbitrator. Objections and actions brought against the appointment of the arbitrator by the Federal Office for Social Security and actions brought against the determination of the content of the agreement by the latter shall not have suspensory effect. Actions against the

determination of the content of the agreement shall be brought against the other party to the agreement. The costs of the arbitration procedure shall be borne equally by the parties to the agreement.’

92. Section 381(1), point 2, is replaced by the following point 2:

1. ‘ the statutory pension insurance rehabilitation institutions approved in accordance with Paragraph 15(2) of Book Six shall be compensated by the statutory pension insurance institutions.’

93. Section 383 is replaced by the following Section 383:

§ 1‘

Transmission of electronic letters from doctors in the statutory health insurance scheme

(1) The Federal Association of Statutory Health Insurance Physicians, in consultation with the Central Federal Association of Health Insurance Funds, the Gesellschaft für Telematik (Society for Telematics) and the Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security), shall lay down in a guideline details of the requirements for a secure electronic procedure and information technology systems for the transmission of electronic medical certificates in statutory health care between participating health care providers, as well as details of:

1. the content and structure of the electronic medical certificate; and

2. in order to avoid an unnecessarily large increase in quantities.

(2) The Directive shall stipulate that the secure procedures laid down pursuant to § 363a(1) shall be used for the transmission of the electronic medical certificate as soon as they are available. The guidelines are to be submitted to the Federal Ministry of Health for examination. When examining the Directive, the Federal Ministry of Health shall give the Federal Commissioner for Data Protection and Freedom of Information and the Federal Office for Information Security the opportunity to comment. The Federal Ministry of Health may set a reasonable deadline for comments. The Federal Ministry of Health may object to the Directive within one month and set a deadline for remedying the objections.

(3) The Federal Association of Statutory Health Insurance Physicians confirms, at the request of a provider of an information technology system for health care providers participating in the statutory health insurance scheme, that its system meets the requirements of the Directive. The Federal Association of Statutory Health Insurance Physicians shall publish a list of those IT systems for which providers have received confirmation in accordance with the first sentence.

(4) Paragraphs 1 to 3 shall not apply to panel dentists.’

94. In Section 383, the following ninth section is inserted:

‘Ninth section

D Implementing Regulation (EU) 2025/327

Section 383a

Telling for digital health; central Complaints Board

(1) Digital health tellens as referred to in Article 19 of Regulation (EU) 2025/327 are:

1. D as Federal Ministry of Health with regard to the tasks referred to in Article 19(2), points (a), (c) and (f), of Regulation (EU) 2025/327; and

2. D ie Telematics Society for the tasks referred to in Article 19(2), points (b), (d), (e), (g), (h) and (j) to (m), of Regulation (EU) 2025/327.

(2) The Telematics Society shall perform the tasks of the coordination body between several digital health authorities referred to in the third sentence of Article 19(1) of Regulation (EU) 2025/327 and the tasks of the digital health authority responsible for the activity report referred to in the first and second sentences of Article 20 of Regulation (EU) 2025/327. Prior to publication of the activity report, agreement must be reached with the Federal Ministry of Health.

(3) B Efforts with regard to the provisions of Chapter II of Regulation (EU) 2025/327 may, without prejudice to the provisions of Article 21 of Regulation (EU) 2025/327, be submitted to the coordinating body set up at the Gesellschaft für Telematik as the central appeal body pursuant to the second sentence of Section 307(5).

Section 383b

Act monitoring authority

(1) The market surveillance authority within the meaning of Regulation (EU) 2025/327 is the Federal Office for Information Security.

(2) The costs directly incurred by the Federal Office for Information Security for the performance of the tasks referred to in paragraph 1 shall be borne by the Telematics Society. The Telematics Association shall determine the details of the reimbursement of costs in agreement with the Federal Office for Information Security.

Paragraph 383c

European Health Data Space Board groups; Steering Groups

The German representatives in sub-groups of the European Health Data Space Board referred to in Article 92(6) of Regulation (EU) 2025/327 and in the steering groups referred to in Article 95 of Regulation (EU) 2025/327 shall, as far as material matters are concerned, reach an agreement with the Federal Ministry of Health before voting.’;

95. The first sentence of Section 384 is amended as follows:

a) Point 7 is replaced by the following:

1. ‘ Specifications defined, standardised and documented requirements for technical, semantic and syntactic interoperability and for the qualitative and quantitative functions of information technology systems in the form of standards, profiles, guides, information models, reference architectures or software components;’;

b) In point 8, the words ‘interoperability requirements’ are replaced by the words ‘requirements’;

96. Section 385 is amended as follows:

a) In paragraph 1, the second sentence is amended as follows:

a%6) In point 7, the words ‘Interoperability requirements of this Book, of Book 7 and of Book 11’ are replaced by the words ‘Requirements of this Chapter’;

b%6) Point 9 is replaced by the following:

1. ‘ support the Federal Government in the context of projects and bodies to promote interoperability in the health sector at federal level, in the European Union and in the context of bilateral and multilateral consultations, as well as in the implementation and maintenance of an interoperability agenda for the health sector, and carry out the task referred to in points 1 to 4 and 6 on the basis of international standards.’

b) A (b)(3) is amended as follows:

a%6) In point 16 of Annex I, the words ‘interoperability requirements’ are replaced by the words ‘mandatory requirements laid down in accordance with point 1 of the first sentence of paragraph 2’.

b%6) In point 17 of Annex I, the words ‘mandatory interoperability requirements’ are replaced by the words ‘mandatory requirements laid down in accordance with point 1 of the first sentence of paragraph 2’.

97. In Section 386, the following Sections 386a to 386c are inserted:

‘Paragraph 386a

Interoperability obligation

(1) Manufacturers within the meaning of point 3 of the second sentence of § 384 shall provide service providers who use an information technology system of that manufacturer, upon their request, with their patients’ personal health data and the interfaces laid down in mandatory terms in accordance with point 4 of the first sentence of § 385(2) in an interoperable format without delay and free of charge, and shall enable service providers to have access to patient data in accordance with this book in an interoperable format. This shall be without prejudice to Section 630f(3) and Section 630 g of the Civil Code.

(2) The applicable interoperable format is set out in the statutory ordinance pursuant to Section 385(1), first sentence, in conjunction with Section 385(2), first sentence, point 1; the applicable interoperable format for transmission from and to

digital health applications results from the interoperability requirements under Section 5(1) in conjunction with Section 6 of the Digital Health Applications Regulation.

(3) The purpose of associations of health insurance funds shall be to assist health care providers in pursuing their claims under paragraph 1. The support of the associations of health insurance funds referred to in the first sentence shall include, in particular, requesting, with the consent of the health care providers, the personal health data of the health care providers' patients from the manufacturers on behalf of the health care providers.

(4) If, contrary to paragraph 1, the manufacturer does not provide the information requested, does not provide it in a timely manner or does not provide it in an interoperable format, he shall be obliged to compensate the service provider for the resulting damage.

Paragraph 386b

D igital consultation

The aim of the Associations of Statutory Health Insurance Physicians is to provide contractual health care providers with advice and support on the digitalisation of care processes and practice organisation, as well as on improving cybersecurity.

Paragraph 386c

U Prohibition of stocking

(1) Producers within the meaning of § 384(2)(3) may not take or refrain from taking measures that are likely to prevent, impede or delay the exercise of the rights under § 386(2) and § 386a(1). In particular, the following shall not be permitted:

1. the collection of charges, fees or other indemnities for making data available in an interoperable format;

2. agreeing contractual restrictions on the disclosure of data to healthcare providers or insured persons;

3. technical limitations on the speed or scope of data extraction, in so far as they go beyond what is technically necessary;

4. the provision of data in a format that prevents complete semantic reconstruction by another information technology system approved under this Book; and

5. the withholding of data elements which are not laid down in a binding manner pursuant to Section 385(2), first sentence, point 1, but which are necessary in order to be able to ensure the obligations incumbent on healthcare providers to document and archive patient data.

(2) Manufacturers pursuant to point 3 of the second sentence of § 384 shall inform service providers using an information technology system of that manufacturer, no later than three months before the date on which a requirement pursuant to point 1 of the first sentence of § 385(2) is made binding, of the following:

1. whether the information technology system will meet the relevant requirement under the first sentence at the time it is made binding or the expected state of implementation at that time;

2. the planned date of the conformity assessment pursuant to § 387; and

3. in the event of non-compliance, a reference to the possibility of exercising a right of termination in accordance with the second sentence.

If a manufacturer informs a service provider that the information technology system referred to in the first sentence will not meet the relevant requirement at the time it is made binding, the service provider may terminate the contract concluded with that manufacturer without notice and at no cost within three months of receipt of the information.'

98. In Section 387(1) and (2), first and second sentences, (3) and (4), first sentence, the words 'interoperability requirements' are replaced by the words 'requirements'.

99. Section 388(1) is amended as follows:

a) In point 2 of the first sentence, the words 'interoperability requirements of this Book' are replaced by the words 'requirements of this Chapter';

b) In the second sentence, the words 'their interoperability' are replaced by the words 'the mandatory requirements laid down in accordance with point 1 of the first sentence of § 385(2)'.

100. Section 393(1) is replaced by the following paragraph 1:

(1) ' Providers within the meaning of Chapter 4 and sickness and long-term care funds and their respective processors may also process social data and health data through the cloud computing service, provided that the conditions laid down in paragraphs 2 to 4 are met. Access for maintenance and support purposes shall not be considered to be processing within the meaning of the first sentence if state-of-the-art technical measures, in particular encryption, ensure that the data cannot be accessed or otherwise processed during such access.'

101. Section 396 is replaced by the following Section 396:

§ 1'

Cooperation to prosecute and punish administrative offences

(1) In order to prosecute and punish administrative offences, the health insurance funds shall cooperate in particular with the Federal Employment Agency, the authorities of the customs administration, the pension insurance institutions, the social assistance institutions, the authorities referred to in Section 71 of the Residence Act, the tax authorities, the authorities responsible under Land law for prosecuting and punishing administrative offences under the Undeclared Work Prevention Act, the accident insurance institutions and the Land authorities responsible for health and safety at work, if specific indications emerge in the individual case of:

1. Infringements of the Undeclared Work Prevention Act;

2. employment or activity of foreigners

a) without the required residence permit pursuant to the first sentence of Section 4a(5) of the Residence Act,

b) without a permit or authorisation pursuant to Section 4a(5), second sentence, in conjunction with Section 4a(4) of the Residence Act,

c) without a residence permit or acquiescence entitling them to work, or

d) without an authorisation pursuant to § 284(1) of Book Three,

3. Breaches of the duty to cooperate under Section 60(1), first sentence, point 2 of Book I vis-à-vis a department of the Federal Employment Agency, a statutory accident or pension insurance institution or a social assistance institution, or breaches of the duty to notify under Section 8a of the Asylum Seekers Benefits Act,

4. Infringements of the Temporary Employment Act;

5. Infringements of the provisions of Books 4 and 7 on the obligation to pay contributions, in so far as they relate to the infringements referred to in points 1 to 4;

6. Breaches of tax laws;

7. Infringements of the Residence Act;

8. Infringements of the law on safeguarding workers' rights in the meat sector;

9. Breaches of the Minimum Wage Act; or

10. Infringements of the Posted Workers Act.

The health insurance funds shall inform the authorities responsible for prosecution and punishment, the social assistance institutions and the authorities referred to in Section 71 of the Residence Act. The information may also include information on the facts necessary for the collection of sickness and pension contributions. The transmission of social data collected from insured persons in accordance with Sections 284 to 302 and Chapter 11 shall be prohibited.

(2) The Telematics Society shall inform the Federal Office for Information Security of facts known to it which could give rise to a suspicion of an administrative offence under Section 397(2a)(2), (3) or (4).

(3) If, in proceedings concerning an administrative offence under Section 397(2a)(2), (3) or (4), the Federal Office for Information Security is involved in accordance with Section 76(1) or (3) in conjunction with the first sentence of Section 63(3) of the Administrative Offences Act, the Federal Office for Information Security shall request an opinion from the Gesellschaft für Telematictik (Society for Telematics). If, in accordance with Paragraph 76(4) of the Gesetz über Ordnungswidrigkeiten (Law on Administrative Offences), the Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security) becomes aware of the judgment or of other decisions concluding the proceedings, it must immediately inform the Gesellschaft für Telematictik (Telematics Society) thereof.'

102. Section 397 is amended as follows:

a) A (b)2a is replaced by the following paragraph 2a:

"(2a) An offence shall be committed by any person who, intentionally or negligently:

1. uses the telematics infrastructure without authorisation or confirmation in accordance with the first sentence of § 326;

2. contrary to Section 329(2), first sentence, fails to make a notification, or fails to do so correctly, completely or in good time, or fails to take a measure referred to therein, or fails to do so in good time;

3. contrary to the second sentence of Section 329(2a), fails to comply with a request referred to therein or fails to do so in good time;

4. contravenes an enforceable order pursuant to the third sentence of Section 329(3) or Section 333(3),

5. contrary to § 360(16) sentence 1, provides or operates a system referred to therein,

6. contrary to the first sentence of Section 386(2), fails to release data, or fails to do so correctly, completely, in the manner provided for or in good time,

7. contrary to Section 386a(1), first sentence, fails to provide the data or an interface referred to therein, or fails to do so correctly, completely, in the prescribed manner or in a timely manner, or fails to provide access referred to therein, or fails to do so correctly, completely, in the prescribed manner or in a timely manner; or

8. contrary to the first sentence of Section 388(1), also in conjunction with the second sentence, places an information technology system on the market.'

b) A (b)(4) is replaced by the following paragraph (4):

"(4) The administrative authority within the meaning of Section 36(1)(1) of the Administrative Offences Act shall be the Federal Office for Information Security in the cases referred to in subparagraph 1, point 2, and subparagraph 2a, and the Federal Commissioner for Data Protection and Freedom of Information in the cases referred to in subparagraph 1, points 3 to 5.'

103. The second sentence of Section 399(3) is replaced by the following sentence:

'The data subject, the controller within the meaning of Article 4(7) of Regulation (EU) 2016/679, the Federal Commissioner for Data Protection and Freedom of Information and the competent data protection supervisory authority shall be entitled to make an application.'

104. Annex 2 to Section 307(1), third sentence, is amended as follows:

a) In section 2.1.2 of the table, in the row 'Scope of processing', in the column 'Description', the words 'Electronic medical letters' are replaced by the words 'Electronic medical letters, electronic discharge letters'.

b) In Section 2.2, the table is amended as follows:

a%6) In the row ‘Appropriateness and relevance of processing, limitation of processing to the necessary level’, in the column ‘Description’ under Category 3, in the second indent, the words ‘agree’ are replaced by the words ‘take part’.

b%6) In the row ‘Information to be provided to the data subject’, in the column ‘Description’, in the paragraph following the second indent in the fourth sentence, the words ‘§ 342(1), second sentence’ are replaced by the words ‘§ 342(1)’.

Artikel 2

Further amendment of Volume V of the Social Security Code

Volume V of the Social Security Code, as last amended by Article 1 of this Law, shall be amended as follows:

1. § 219d is amended as follows:

a) Paragraphs 6 to 8 are replaced by the following paragraphs 6 to 8:

(1) ‘ In addition to the tasks referred to in paragraph 1, the Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland, shall set up and operate the national contact point for digital health pursuant to Article 23(2) of Regulation (EU) 2025/327 (national contact point for digital health). The Central Federal Association of Health Insurance Funds is the controller of data processing by the national contact point for digital health pursuant to Article 4(7) of Regulation (EU) 2016/679. As part of its tasks as a digital health authority pursuant to Section 383a(1)(2), the Gesellschaft für Telematik assumes the tasks and coordination relating to the cross-border exchange of health data at European level and lays down the technical basis for the national contact point for digital health, on the basis of which the Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland, operates the national contact point for digital health. The Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland (German Liaison Body for Health Insurance – Abroad), continuously coordinates with the Gesellschaft für Telematik (Society for Telematics) to the extent necessary with regard to the operation of the national contact point for digital health. The Federal Institute for Medicinal Products and Medical Devices, taking into account the European semantic interoperability specifications and in consultation with the Federal Association of Statutory Health Insurance Physicians and the Society for Telematics, shall lay down the semantic interoperability specifications necessary for the cross-border exchange of data and shall coordinate these specifications at European level. The provisions shall be included on the platform in accordance with point 5 of the second sentence of Section 385(1).

(2) The national contact point for digital health shall use the services and applications of the telematics infrastructure as part of its activities pursuant to the first sentence of paragraph 6 and Regulation (EU) 2025/327. The provisions of Chapter 11 shall apply.

(3) Where, for the purpose of cross-border exchange of health data for the treatment or redemption of a Regulation in another Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a third country whose national contact point for digital health has been included by the European Commission in the list referred to in Article 24(3), third subparagraph, of Regulation (EU) 2025/327 (connected third country), the insured person has consented to the use of the procedure for the transmission of his or her data from the electronic health record, the electronic prescription or the dispensation information, the national contact point for digital health may transmit those data for that purpose to the national contact point for digital health of the other Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country where the treatment takes place or the Regulation is redeemed, provided that, at the time of the treatment or redemption of the Regulation, the insured person technically releases the transmission by a clear affirmative action to the national contact for digital health. Technical measures shall be taken to ensure that the Central Federal Association of Health Insurance Funds (Deutsche Verbindungsstelle Krankenversicherung – Ausland) and the national contact point for digital health do not become acquainted with the data or have access to them.'

b) In paragraph 10, the words 'the national contact point for eHealth and the national contact point for digital health, which shall become operational no later than 26 March 2029' are replaced by the words 'the national contact point for digital health';

2. Section 351(2) is replaced by the following paragraph 2:

(1) ' Within the period to be determined by the Telematics Association pursuant to Section 342(2b), the Health Insurance Fund shall ensure that, in order to support specific treatment of the insured person with his or her consent in another Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a connected third country, the following data stored in the insured person's electronic health record may be processed by the national contact point for digital health pursuant to Section 352a via the provider of the electronic health record:

1. Data on findings, diagnoses, treatment measures taken and planned, screening examinations, treatment reports and other medical information relating to examinations and treatment pursuant to § 341(2)(1)(a),

2. Data contained in the electronic health record pursuant to Section 341(2)(1)(c);

3. Data on medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11); and

4. Data on electronic medical letters and electronic discharge letters pursuant to § 341(2)(1)(d).'

3. § 352a is replaced by the following § 352a:

‘Paragraph 352a

Access to EHR data in cross-border care

With the prior consent of the insured person to the use of the access procedure pursuant to Section 351(2), for the purpose of the cross-border exchange of health data to support specific treatment of the insured person, a healthcare provider who is authorised to access the data in another Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a connected third country under the law of that State may access the following data stored in the insured person’s electronic health record via the national contact point for digital health:

1. Data on findings, diagnoses, treatment measures taken and planned, screening tests and treatment reports and other medical information relating to testing and treatment pursuant to § 341(2)(1)(a),

2. Data contained in the electronic health record pursuant to Section 341(2)(1)(c);

3. Data on medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11); and

4. Data on electronic medical letters and electronic discharge letters pursuant to Section 341(2)(1)(d).

In addition, it is necessary that the insured person, at the time of the treatment, technically releases access to the national contact point for digital health of the other Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country where the treatment takes place by a clear affirmative action. As regards the processing of data by a health care provider, the provisions of the State in which the health care provider is established shall apply.’

4. In Section 355(3), second sentence, point 6, (4), second sentence, point 4, (3), point 6, and (4a), second sentence, the words ‘Member State of the European Union’ shall be replaced by the words ‘Member State of the European Union, a State party to the Agreement on the European Economic Area or a connected third country’.

5. The words ‘in another Member State of the European Union’ in the first sentence of Section 358(1a) shall be replaced by the words ‘in a Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a connected third country in accordance with Section 352a’.

6. Section 360 is amended as follows:

   a) In point 10, the 11st and 12nd sentences are replaced by the following sentences:

      ‘Provided that the necessary conditions are met, health insurance funds and payers pursuant to § 362(1) who make components available in accordance with the eighth sentence shall ensure that insured persons can use these components to transmit data from electronic prescriptions pursuant to the first sentence of paragraph 2 to the national contact point for digital health for the purpose of cross-border exchange. The transfer shall require prior consent to the use of the transfer procedure and technical clearance at the time of redemption of the Regulation with the provider authorised to access it under the law of the other

Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country.'

b) In paragraph 12, point 2 is replaced by the following:

1. ' create the conditions for insured persons to be able, through the components referred to in the first sentence of paragraph 10, for the purpose of the cross-border exchange of data from the electronic prescription, subject to prior consent to the use of the transmission procedure and technical release at the time of the redemption of the prescription, to transmit data from electronic prescriptions referred to in the first sentence of paragraph 2 to the national contact point for digital health with the provider authorised to access data under the law of the other Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country.'

7. Section 361(3) is replaced by the following paragraph 3:

(1) ' The transmission of data from the electronic prescription pursuant to Section 360(2) for the cross-border exchange of health data for the purpose of supporting the insured person's treatment to a health care provider authorised under the law of another Member State of the European Union, a State party to the Agreement on the European Economic Area or a connected third country to access data from the prescription via the respective national contact points for digital health shall require the insured person's prior consent to the use of the transmission procedure. In addition, at the time of the enforcement of the Regulation, the insured person must technically release the transmission to the national contact point for digital health of the other Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country in which the Regulation is implemented by a clear affirmative action. By way of derogation from paragraphs 1 and 2 and Paragraph 339, the provisions of the State in which the Regulation is implemented shall apply to the processing of data by a provider in another Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a connected third country. This will take into account the joint European arrangements for the cross-border exchange of health data. The Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland (German Liaison Body for Health Insurance – Abroad), shall inform insured persons of the conditions and procedure for the transmission and use of data from the electronic ordinance on the cross-border exchange of health data via the national contact point for digital health.'

Artikel 3

Further amendment of Volume V of the Social Security Code

Volume V of the Social Security Code, as last amended by Article 2 of this Law, shall be amended as follows:

The first sentence of Section 219d(8) is replaced by the following sentence:

'Where, for the purpose of the cross-border exchange of health data for the treatment or redemption of a regulation in another Member State of the European Union, in a State party to the Agreement on the European Economic Area or in a third country whose national contact point for digital health has been included by the European Commission in

the list referred to in Article 24(3), third subparagraph, of Regulation (EU) 2025/327 (connected third country), the insured person has consented to the use of the procedure for the transmission of his or her data from the electronic health record, the electronic prescription under contract, dispensation information, his or her data on medical findings from imaging diagnostics, his or her data on laboratory findings and on findings from invasive or surgical measures, as well as from non-invasive or conservative measures, or his or her data on discharge letters, the national contact point for digital health may, for that purpose, transmit those data to the national contact point for digital health of the other Member State of the European Union, of the State party to the Agreement on the European Economic Area or of the connected third country where the treatment takes place or where the Regulation is complied with, provided that the insured person technically releases the transmission by a clear affirmative action to the national contact point for digital health at the time of treatment or receipt of the Regulation.'

Artikel 4

Amendment of Book VI of the Social Security Code

Volume VI of the Social Security Code – statutory pension insurance – in the version published on 19 February 2002 (BGBl. I, p. 754, 1404, 3384), as last amended by Article 2(10) of the Act of 12 May 2026 (BGBl. 2026 I, No 143), is amended as follows:

1. In the table of contents, the following entry is inserted after the entry for § 32:

   'Seventh title

   Telematics infrastructure

   § 32a Telematics infrastructure'.

2. In Section 32, the following seventh title is inserted:

'Seventh title

Telematics infrastructure

§ 32a

Telematics infrastructure

(1) Doctors, dentists, psychotherapists and approved rehabilitation facilities pursuant to Section 15(2) and rehabilitation facilities providing follow-up care pursuant to Section 17 shall be required to connect to the telematics infrastructure from 1 January 2029. The first sentence shall also apply to the obligation to receive and send electronic letters pursuant to Section 295(1c) of Book Five.

(2) In the case of the provision of medical rehabilitation and aftercare services pursuant to Sections 15, 15a, 17 and 31(1)(2), Sections 31a, 347, 348 and 374a of Book Five shall apply mutatis mutandis, provided that the service provider referred to in the first sentence of paragraph 1 or the rehabilitation facility is connected to the telematics infrastructure.

(3) Sections 360, 363c and 363e of Book Five shall apply mutatis mutandis to rehabilitation institutions and other service providers within the meaning of the first sentence of subparagraph 1 and to pension insurance institutions as soon as the rehabilitation institution or other service provider is connected to the telematics infrastructure.'

Artikel 5

Amendment of Volume 7 of the Social Code

Volume 7 of the Social Security Code – Statutory Accident Insurance – (Article 1 of the Act of 7 August 1996, BGBl. I, p. 1254), as last amended by Article 3 of the Act of 12 May 2026 (BGBl. 2026 I, point 140), is amended as follows:

1. § 27A(b)(1) is amended as follows:

   a) The second sentence is replaced by the following sentence:

   'For doctors, dentists, institutions and other service providers involved in the provision of medical care pursuant to the first sentence, who provide statutory accident insurance services and for whom it is not yet possible to connect to the telematics infrastructure on the basis of the provisions of Book Five, an obligation to connect shall apply from 1 January 2027; providers of sociotherapy services shall be required to connect to the telematics infrastructure within the period laid down in Paragraph 360(8) of Book Five.'

   b) The fourth sentence is deleted.

2. Section 27a is amended as follows:

   a) In paragraph 2, the words '§ 27(1)(4) and (5)' are replaced by the words '§ 27(1) sentence 1(4) and (5)'.

   b) (A)(b)(3) is deleted;

   c) Paragraph 4 becomes paragraph 3.

Artikel 6

Amendment of Volume 11 of the Social Code

The Eleventh Book of the Social Security Code – Social Care Insurance – (Article 1 of the Act of 26 May 1994, BGBl. I p. 1014, 1015), as last amended by Article 8 of the Act of 16 April 2026 (BGBl. 2026 I No 107), is amended as follows:

1. In the table of contents, the following entry is inserted after the entry for § 106c:

   '§ 106 Mandatory use of secure transmission procedures'.

2. Section 53d(3) is amended as follows:

a) S atz 1 is amended as follows:

a%6) In point 6, the words ‘services and’ are replaced by the words ‘services,’;

b%6) In point 7, ‘Statistics’ is replaced by ‘Statistics and’.

c%6) In point 7, the following point 8 is inserted:

1. ‘ digital data exchange between medical services.’

b) S atz 4 is replaced by the following sentence:

‘The guidelines referred to in points 1 to 6 and 8 of the first sentence shall be binding on the medical services and care funds.’

3. In § 94(1)(12), the words ‘and a reference to the results of these evaluations’ shall be inserted after the words ‘evaluations’.

4. In Section 105(3), first sentence, point 2, the words ‘Section 311(6)’ are replaced by the words ‘Section 363a(1), first sentence, point 1’.

5. Section 106c is replaced by the following Sections 106c and 106d:

‘Paragraph 106c

E Involvement of medical services in telematics infrastructure

In performing the tasks assigned to them under this Book, the medical services referred to in Section 278 of Book Five and the care funds or the provincial associations of the care funds shall use the secure transmission procedure of the telematics infrastructure referred to in Section 363a(1), first sentence, point 2, of Book Five for the mutual transfer of data in accordance with the guidelines referred to in Section 53d(3), first sentence, point 8, provided that the respective medical service and the care fund or the respective provincial association of the care fund are connected to the telematics infrastructure. § 114(1a) shall remain unaffected.

§ 106d

V Mandatory use of secure means of transmission

(1) Care funds shall also use the instant messaging service pursuant to Section 363a(1), first sentence, point 1 of Book Five to communicate with insured persons. Providers may use the instant messaging service pursuant to Section 363a(1), first sentence, point 1 of Book Five to communicate with insured persons.

(2) Care funds are obliged to use the secure e-mail service referred to in Section 363a(1), first sentence, point 2, of Book Five to communicate with service providers. If the secure email service pursuant to Section 363a(1), first sentence, point 2, is not available to service providers, other means of communication may be used for communication.

(3) Service providers connected to the telematics infrastructure shall use the secure e-mail service referred to in point 2 of the first sentence of Section 363a(1) of Book

Five for electronic communication with those connected to the telematics infrastructure. § 114(1a) shall remain unaffected.

(4) The transmission of medical and nursing data by fax shall be effective from... [insert: Date of the last day of the twelfth calendar month following promulgation] is no longer permitted for health care providers and payers. The first sentence shall not apply in cases where the secure transmission procedures pursuant to Section 363a(1) of Book Five are not available either at the sender or at the recipient.

(5) Sections 363a, 363b, 363d to 363f of Book Five shall apply mutatis mutandis.'

6. Section 121(1) is amended as follows:

a) In point 6, the words 'equipment' are replaced by the words 'equipment'.

b) Point 7 is deleted;

Artikel 7

Act on the Use of Health Data for Public Interest Purposes and Data-Based Development of Health Care

(Health Data Usage Act – GDNG)

Content overview

Abschnitt 1

A general provisions

§ 1

The corner of the law; Scope

(1) The purpose of this Act is to regulate the further use of health data for purposes in the public interest and for the further development of health care as a learning system based on data. The objectives of the use of health data are to ensure safe, better and

quality-assured healthcare and care, to foster research and innovation and to further develop the digitalised health system based on a solid data base.

(2) This Act shall apply to the processing of health data for further use, in particular for research purposes, for the improvement of health and care and for other purposes in the public interest.

(3) This Act governs the implementation of Regulation (EU) 2025/327 in so far as it concerns secondary use within the meaning of Article 2(2), point (e), of Regulation (EU) 2025/327.

(4) The provisions of this Act shall take precedence over those of Book Five and Eleven of the Social Security Code and the Genetic Diagnostics Act in so far as they regulate the same facts.

(5) In administrative proceedings under this Act, the relevant Administrative Procedure Act shall apply, unless otherwise provided for in this Act.

§ 2

B Definitions

In addition to the definitions in Article 2 of Regulation (EU) 2025/327 and Article 4 of Regulation (EU) 2016/679 (General Data Protection Regulation), for the purposes of this Act:

1. ‘Research projects’ means projects that process health data for the scientific research purposes referred to in Article 9(2), point (j), and Article 89(1), first sentence, and (2) of the General Data Protection Regulation; these health data may also be social data pursuant to Section 67(2) of Book Ten of the Social Code;

2. ‘Health and care research’ means research aiming at the promotion of health, the prevention, cure and reduction of the impact of diseases, the improvement of health care provision and prevention, and the development of public health, including basic research in the field of life sciences;

3. ‘data-processing health institution’ means an institution in which data are processed by, or under the responsibility of, a health professional, for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, for medical diagnosis, or for the purposes of health or social care or treatment, which requires training regulated by the State in order to exercise the profession or use the professional title.

§ 3

F is the index number; Executive power

(1) A unique, pseudonymous identifier for natural persons (research identifier) shall be introduced for the linking of health data of different health data holders for re-use and for the enforcement of the right to object referred to in Article 71(1) of Regulation (EU) 2025/327.

(2) The coordinating health data access body referred to in Section 7(1) shall establish, in consultation with the Federal Office for Information Security and the Federal

Commissioner for Data Protection and Freedom of Information, a technical procedure by which the research code referred to in paragraph 1 can be generated from the unalterable part of the health insurance number referred to in the second sentence of Section 290(1) of Volume V of the Social Security Code and cross-referenced or linked to other, sector-specific or cross-sector identification characteristics or codes. It must not be possible to infer from the research code the unchangeable part of the health insurance number. The coordinating health data access body shall make the technical procedure referred to in the first sentence available free of charge for use by health data holders and other bodies involved in re-use. The coordinating health data access body shall submit to the Federal Ministry of Health by 31 December 2027, a blueprint to further develop the research metric.

(3) G Health data holders shall generate and store research metrics for the datasets of personal electronic health data they hold. To this end, health data holders may process the unmodifiable part of the health insurance number pursuant to the second sentence of Section 290(1) of Volume V of the Social Security Code to generate the research code.

(4) Further processing of the research metric by health data holders and other entities involved in re-use is allowed;

1. where the linking of data of different health data holders or the linking of health data with other data is permitted under this Act or pursuant to another legal provision of the Federal Government or the Länder or pursuant to directly applicable legal acts of the European Union, and

2. to the extent that it is necessary to process the research metric to link it.

(5) The Federal Ministry of Health, in consultation with the Federal Ministry of Research, Technology and Space and the Federal Ministry of Digital and State Modernisation, is hereby authorised to issue a statutory ordinance, with the consent of the Bundesrat, specifying:

1. technical requirements and design of the research metric;

2. the technical method of production of the research identifier referred to in the first sentence of paragraph 2; and

3. D enabling cross-sector reconciliation of the research metric with other, sector-specific or cross-sector identification metrics or metrics.

§ 4

V Preparation of data on deceased persons

(1) Insofar as the processing of personal data is permitted under this Act, data relating to persons who have already died may also be processed to the same extent.

(2) E In opposition lodged pursuant to Article 71(1) of Regulation (EU) 2025/327, continues to apply after death. The right to object may not be exercised by the heir or heirs.

§ 5

D Nuclear safety supervision of cross-border health research projects

(1) Where a health and care research project involving the processing of health data involves, as controllers, one or more public or non-public bodies in such a way that more than one data protection supervisory authority of the Federal Government or the Länder is competent under Chapter VI of the General Data Protection Regulation, and those bodies are not joint controllers under Article 26 of the General Data Protection Regulation, that project may be notified to the data protection supervisory authorities as the lead data protection supervisory authority.

(2) Where the notification referred to in paragraph 1 has been made jointly by all entities to all competent data protection supervisory authorities, the data protection supervisory authority having jurisdiction over the entity involved in the project referred to in paragraph 1 with the highest annual turnover in the preceding financial year shall be the lead competent authority. In the event that not all entities involved in the operation referred to in paragraph 1 have an annual turnover, the data protection supervisory authority responsible for the entity involved in the operation referred to in paragraph 1, which employs the majority of persons who permanently process personal data by automated means, shall instead become the lead competent authority. The notification referred to in paragraph 1 shall be accompanied by the relevant supporting documents.

(3) The lead competent data protection supervisory authority shall be responsible for coordinating the activities and supervisory measures of the competent data protection supervisory authorities; promote cooperation between the competent data protection supervisory authorities in respect of the operation referred to in paragraph 1 and work towards a joint decision; The supervisory powers of all competent data protection supervisory authorities pursuant to paragraph 1 shall remain unaffected. The competent data protection supervisory authorities shall coordinate with each other when acting in their area of competence.

(4) Where, in a health and care research project involving the processing of health data, one or more non-public bodies are involved as controllers in such a way that more than one data protection supervisory authority of the Länder is competent, and the non-public bodies involved are joint controllers in accordance with Article 26 of the General Data Protection Regulation, they may jointly indicate that they are joint controllers and that, therefore, the data processing for which they are jointly responsible should be the sole responsibility of the data protection supervisory authority within whose jurisdiction the non-public body with the highest annual turnover in the financial year preceding the submission of the application falls. The joint notification shall be addressed to all data protection supervisory authorities responsible for the joint controllers and shall include the documents proving the highest turnover of the non-public sector body. From the date on which the notification referred to in the first and second sentences is received by the competent authority for the largest non-public body, that authority shall become the sole competent data protection supervisory authority. For non-public bodies which are joint controllers in accordance with Article 26 of the General Data Protection Regulation but which do not have an annual turnover, the first to third sentences shall apply mutatis mutandis, with the proviso that the competent authority shall be the sole authority responsible for the controller employing the majority of persons who permanently process personal data in an automated manner.

Abschnitt 2

Chapter IV of Regulation (EU) 2025/327

§ 6

Health data access bodies

(1) The tasks of health data access bodies referred to in Article 55 of Regulation (EU) 2025/327 shall be carried out by a coordinating health data access body and by domain-specific health data access bodies in accordance with this Section.

(2) The coordinating health data access body and the domain-specific access bodies shall provide advice to health data applicants, health data users and health data holders. The coordinating health data access body and the domain-specific health data access bodies shall cooperate in the performance of their tasks to ensure a consistent application of Regulation (EU) 2025/327.

§ 7

K Oordinating health data access body

(1) A coordinating health data access body shall be established within the Federal Institute for Medicinal Products and Medical Devices.

(2) The coordinating health data access body shall be the health data access body pursuant to the first sentence of Article 55(1) of Regulation (EU) 2025/327, unless a domain-specific access body pursuant to § 9 is competent. The coordinating access point shall be the coordinating body referred to in the fourth sentence of Article 55(1) of Regulation (EU) 2025/327 and shall perform the tasks of the national contact point for secondary use referred to in Article 75(1) of Regulation (EU) 2025/327.

(3) D ie coordinating health data access body

1. maintain a management system in accordance with Article 57(1), first sentence, point (e), of Regulation (EU) 2025/327; receive incoming health data access applications and health data requests in that regard and forward them to the health data access body responsible for processing and taking decisions;

2. maintain a public information system in accordance with Article 57(1), first sentence, point (f), of Regulation (EU) 2025/327;

3. K omm complies with the cooperation obligations set out in Article 57(1), first sentence, points (g) and (h), of Regulation (EU) 2025/327;

4. facilitate cross-border access to electronic health data referred to in Article 57(1), first sentence, point (i), of Regulation (EU) 2025/327;

5. v publishes by electronic means on the website of the Federal Institute for Medicinal Products and Medical Devices or another appropriate website the information referred to in Article 57(1), first sentence, point (j), of Regulation (EU) 2025/327 and, in accordance with Article 57(1), second sentence, of Regulation (EU) 2025/327, also makes the national dataset catalogue referred to in Article 57 (1), first sentence, point

(j)(i), of Regulation (EU) 2025/327 available to the single information points referred to in Article 8 of Regulation (EU) 2022/868; and

6. publish and submit the activity report referred to in Article 59 of Regulation (EU) 2025/327.

(4) Where competence pursuant to Section 22(1)(2) does not lie with a domain-specific health data access body competent under federal law pursuant to Section 9, or where non-domain-specific health data access bodies pursuant to Section 9 are established as public bodies of the federal states and the following tasks are incumbent on the domain-specific access bodies competent under federal state law, the coordinating health data access body shall also be responsible for:

1. Decisions on health data access applications and health data requests pursuant to Article 57(1), first sentence, point (a), of Regulation (EU) 2025/327;

2. processing of electronic health data pursuant to Article 57(1), first sentence, point (b), of Regulation (EU) 2025/327;

3. take measures pursuant to Article 57(1), first sentence, point (c), of Regulation (EU) 2025/327 to protect intellectual property rights, trade secrets or data exclusivity;

4. cooperating with and supervising health data holders pursuant to Article 57(1), first sentence, point (d), of Regulation (EU) 2025/327;

5. performing any other tasks related to secondary use referred to in Article 57(1), first sentence, point (l), of Regulation (EU) 2025/327;

6. the fulfilment of obligations towards natural persons referred to in Article 57(1), first sentence, point (k), in conjunction with Article 58 of Regulation (EU) 2025/327;

7. the cooperation referred to in Article 57(2) of Regulation (EU) 2025/327;

8. supporting public sector bodies pursuant to Article 57(3) and (4) of Regulation (EU) 2025/327;

9. the collection of fees pursuant to Article 62 of Regulation (EU) 2025/327 and in accordance with § 14, including the setting of fees pursuant to Article 62(4) of Regulation (EU) 2025/327 and the provision of information on the cost estimate pursuant to Article 62(5) of Regulation (EU) 2025/327;

10. D establishment measures referred to in Article 63(1) to (6) of Regulation (EU) 2025/327;

11. the imposition of administrative fines pursuant to Article 64 of Regulation (EU) 2025/327;

12. informing health data holders of significant findings pursuant to Article 58(3) of Regulation (EU) 2025/327, where there is no declaration of non-knowledge pursuant to Section 16(2), first sentence, point 3;

13. review of download requests pursuant to Article 73(2), second subparagraph, of Regulation (EU) 2025/327;

14. ensuring that audits pursuant to Article 73(3) of Regulation (EU) 2025/327 take place on a regular basis in the secure processing environments; take any necessary remedial action;

15. verifying and revoking data quality and utility labels in accordance with Article 78(4) of Regulation (EU) 2025/327; and

16. Complaints under Article 81 of Regulation (EU) 2025/327; in particular, it shall establish an easily accessible tool for complaints under Article 81(3) of Regulation (EU) 2025/327.

§ 8

Other tasks of the coordinating health data access body; Executive power

(1) In addition to the tasks under § 7, the coordinating health data access body shall:

1. support the Federal Government in projects and bodies to increase the availability of health data and in the development of an interconnected health data infrastructure at federal level and in the European Union, and

2. Create recipes to use secure processing environments as a measure to improve data protection and data security in the context of the further processing of health data for secondary use.

(2) The Federal Ministry of Health shall be authorised to issue a statutory ordinance, without the consent of the Bundesrat, laying down detailed rules on:

1. D organising the coordinating health data access body, in particular to avoid conflicts of interest as referred to in Article 55(3) and (4) of Regulation (EU) 2025/327; and

2. details of the performance of the tasks of the coordinating health data access body pursuant to this provision and the procedures to be followed in that regard.

(3) The coordinating health data access body shall set up a working group on the use of health data in consultation with the Federal Ministry of Health and the Federal Ministry of Research, Technology and Space. The working group shall be composed of representatives of health data holders, representatives of patient organisations referred to in the Patient Participation Regulation or recognised under the Patient Participation Regulation, representatives of healthcare providers under the Social Code, representatives of health research and representatives of other groups and institutions concerned. The working group shall provide advice on the design, further development and evaluation of the tasks of the coordinating health data access body.

§ 9

D Omani-specific health data access bodies

(1) In order to ensure the necessary expertise in the processing of health data access applications and health data requests, additional health data access bodies for specific areas (domain-specific health data access bodies) shall be established in accordance with this Act or national law.

(2) Domain-specific health data access bodies shall decide on health data access applications and health data requests falling under their sole or predominant competence. The sole or predominant competence shall be decided by the coordinating health data access body.

§ 10

V Inform health data access bodies of health data access applications and health data queries

(1) The coordinating health data access body shall forward the incoming health data access applications pursuant to Article 67 of Regulation (EU) 2025/327 and health data requests pursuant to Article 69 of Regulation (EU) 2025/327 to the competent domain-specific health data access body. Where possible, an appropriate automated procedure shall be used for the transfer.

(2) Where a health data access application or health data request does not fall within the exclusive or predominant competence of a domain-specific health data access body, the coordinating health data access body shall decide on the health data application or health data request with the involvement of the domain-specific health data access bodies concerned. The concerned domain-specific health data access bodies shall issue a decision recommendation within the scope of their competence. The coordinating health data access body shall not be bound by the decision-making recommendations.

(3) Health data bodies shall not be entitled to submit health data access applications or health data requests. Where an organisation with a domain-specific health data access body submits a health data access application or a health data request, the coordinating health data access body shall decide. The Federal Ministry of Health decides on applications for access to health data or requests for health data from the Federal Institute for Medicinal Products and Medical Devices.

(4) Where data is provided pursuant to paragraphs 2 and 3 on the basis of a data permit issued or an approved health data request, the domain-specific health data access bodies shall carry out all necessary measures to access data under this Section, in particular the electronic health data request referred to in Article 57(1), first sentence, points (a)(i) and (iii), of Regulation (EU) 2025/327.

§ 11

V Connection, pseudonymisation and making available

(1) For the preparation and making available of electronic health data for access in the context of a health data access application or health data request, the linking of such data shall be allowed to the extent necessary to fulfil the right to access data. The competent health data access body shall link the data of different health data holders using the research metric referred to in Section 3.

(2) Linked data shall be pseudonymised before being made available to the health data user in the secure processing environment, unless they are made available anonymously. The research metric referred to in Section 3 shall not be disclosed to health data users.

(3) B When making the data available, the competent health data access body shall inform the health data user of the extent to which data have not been made available due to an objection to secondary use, where necessary for the purpose pursued by the health data user.

§ 12

Obligations of health data holders

(1) G Health data holders shall provide health data access bodies with the information necessary to carry out their tasks under this Act.

(2) In the context of fulfilling their obligations under Article 60(1) and (2) of Regulation (EU) 2025/327, health data holders shall make the relevant personal electronic health data available to the requesting health data access body to the extent necessary, together with the relevant research metric pursuant to § 3.

(3) G Health data holders should, where possible and appropriate, use the telematics infrastructure pursuant to Section 306 of Volume V of the Social Code when making electronic health data available pursuant to Article 60(1) of Regulation (EU) 2025/327.

(4) Obligations under Article 60 of Regulation (EU) 2025/327 also apply to health data holders that have already concluded data supply contracts with third parties.

§ 13

S my processing environments

(1) The competent health data access body shall specify in the decision on the health data access application or health data request in which secure processing environment health data is made available. Health data applicants may request that the data be made available in a specific secure processing environment.

(2) Health data access bodies may engage third parties to provide and operate a secure processing environment as part of the provision of electronic health data in secure processing environments pursuant to Article 73 of Regulation (EU) 2025/327, to the extent that they ensure compliance with the requirements of Article 73 of Regulation (EU) 2025/327. Under these conditions, the secure processing environment may also be offered or operated by health data holders.

(3) To the extent that they are part of the approved application, health data users may also bring electronic health data of which they are health data holders into the secure processing environment. Section 12(2) shall apply mutatis mutandis.

§ 14

G stirring and display; Executive power

(1) F Fees and expenses shall be charged in respect of individually attributable public benefits under this Law and the statutory ordinances adopted on the basis thereof.

(2) The Federal Ministry of Health, in consultation with the coordinating health data access body and the domain-specific health data access bodies, shall adopt the Special Fees Regulation pursuant to Section 22(4) of the Federal Fees Act.

§ 15

D Information obligations under nuclear safety law

(1) Where health data holders are required to inform in accordance with Article 13 of the General Data Protection Regulation, this shall include information that the data collected may be made available to health data users in accordance with Chapter IV of Regulation (EU) 2025/327. The coordinating health data access body shall make templates available to health data holders for that purpose.

(2) By way of derogation from paragraph 1, the information obligation of health data holders pursuant to Articles 13(3) and 14(4) of the General Data Protection Regulation shall not apply to... [insert: Date of promulgation of this Act] electronic health data already collected. This also applies if the data were processed based on consent under Article 9(2)(a) of the General Data Protection Regulation.

(3) G Health data users have no information obligations to data subjects under Articles 13 and 14 of the General Data Protection Regulation in the context of secondary use under Chapter IV of Regulation (EU) 2025/327.

§ 16

R egister on the enforcement of data subjects' rights; Executive power

(1) D as Federal Ministry of Health entrusts an appropriate body with the establishment and operation of a register for the enforcement of data subjects' rights under Regulation (EU) 2025/327. The financial, organisational, technical and human resources of the body shall be such as to enable it to carry out the tasks assigned to it under the following paragraphs.

(2) P ersons who have reached the age of 15 years may at any time, at the establishment designated in accordance with paragraph 1:

1. D object in its entirety to the processing of personal electronic health data relating to him or her for secondary use pursuant to the first sentence of Article 71(1) of Regulation (EU) 2025/327;

2. limit the opposition referred to in point 1 to specific purposes referred to in Article 53(1) of Regulation (EU) 2025/327; or

3. e In the exercise of the right to non-knowledge of material findings in accordance with the third sentence of Article 58(3) of Regulation (EU) 2025/327.

For persons under the age of 15, the declarations referred to in the first sentence may be made by the legal representative. Declarations may be made directly to the body appointed in accordance with paragraph 1, to the ombudsman body referred to in Section 342a of Volume V of the Social Code or, where possible, via the user interface in the electronic health record referred to in Section 342(2)(1)(b) of Volume V of the Social Code. Where a declaration is made to the Ombudsperson or in the electronic health record, the data controller concerned shall transmit the declaration to the entity entrusted pursuant to paragraph 1. The persons making the declaration may consult the data relating to them in the register and may amend or withdraw their declarations in accordance with the first sentence. The body entrusted pursuant to paragraph 1 shall, in consultation with the Federal Office for Information Security and the Telematics Society, establish secure authentication procedures for the submission, consultation, amendment and revocation of declarations referred to in the first and second sentences.

(3) The entity entrusted pursuant to paragraph 1 may process the following personal data with regard to the person making a declaration pursuant to the first sentence of paragraph 2 or with regard to the person making a declaration pursuant to the second sentence of paragraph 2:

1. the statement itself,

2. D atum and time of submission, amendment or revocation of the declaration;

3. the unchangeable part of the health insurance number in accordance with the second sentence of Section 290(1) of Volume V of the Social Security Code,

4. the research code referred to in § 3, and

5. data necessary for the authentication referred to in the sixth sentence of paragraph 2.

(4) Personal data recorded in the register may be processed only for the purpose of enforcing the data subject's declared wishes and establishing:

1. o b the electronic health data of the person who made the declaration can be made available to health data users pursuant to Article 68(7) of Regulation (EU) 2025/327 or used for health data requests pursuant to Article 69 of Regulation (EU) 2025/327; or

2. o b the person who made the declaration or for whom the declaration was made wishes to be informed of material findings.

Where an objection pursuant to point 2 of the first sentence of paragraph 2 is limited to one or more purposes, it shall be taken into account by health data access bodies in health data access applications or health data requests targeting those purposes; this also applies if the application is also directed towards purposes that are not covered by the opposition. The comparison of the data stored in the register with the competent health data access bodies shall be carried out in an automated retrieval process. The body entrusted pursuant to paragraph 1 shall determine the details of the automated retrieval procedure in consultation with the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information.

(5) The entity entrusted pursuant to paragraph 1 may use the data stored in the register for the purpose of drawing up an annual report without any reference to a person.

(6) The Federal Ministry of Health, in consultation with the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information, may issue a statutory instrument, without the consent of the Bundesrat, specifying:

1. D the authentication procedure referred to in the sixth sentence of paragraph 2,

2. D the data sets referred to in paragraph 3;

3. the declaratory and enforcement procedures referred to in paragraph 4; and

4. requirements for the annual report referred to in paragraph 5.

§ 17

Data protection supervisory authority and cooperation with health data access bodies

The Federal Commissioner for Data Protection and Freedom of Information shall be:

1. the data protection supervisory authority competent under Article 65 of Regulation (EU) 2025/327 to monitor and enforce the application of the right to object referred to in Article 71 of Regulation (EU) 2025/327; and

2. by way of derogation from Section 40(1) of the Federal Data Protection Act, the data protection supervisory authority for non-public bodies responsible for monitoring the application of Chapter IV of Regulation (EU) 2025/327 on the protection of personal data.

§ 18

B Enforcement powers under Articles 63 and 64 of Regulation (EU) 2025/327

(1) Competent health data access bodies shall be empowered to take the measures necessary for the enforcement of Regulation (EU) 2025/327 in accordance with Articles 63 and 64 of Regulation (EU) 2025/327.

(2) The taking of measures pursuant to Article 63 of Regulation (EU) 2025/327, in particular the procedure for excluding health data users and health data holders pursuant to Article 63(3), second subparagraph, and (4), third sentence, of Regulation (EU) 2025/327, shall be governed by the provisions of the Administrative Enforcement Act, in so far as the procedure is not determined by Regulation (EU) 2025/327. The competent health data access bodies may impose a periodic penalty payment of up to EUR 500.000.

§ 19

V Informed for complaints under Article 81 of Regulation (EU) 2025/327

(1) The competent health data access body shall investigate a complaint to the extent appropriate as a contact point within the meaning of Article 81 of Regulation (EU) 2025/327 and inform the complainant of the progress and the outcome of the investigation within a reasonable period, in particular where further coordination with other health data access bodies or other supervisory authorities is necessary.

(2) The coordinating health data access body shall facilitate the submission of a complaint pursuant to Article 81 of Regulation (EU) 2025/327 by providing a complaint form, which may also be completed electronically, without excluding other means of communication.

(3) Where a complaint is submitted to a domain-specific health data access body competent under federal law, that body shall transfer the complaint to the coordinating health data access body.

§ 20

E Electrical communication

Communication, including the transmission of statements, information and documents, between health data access bodies and between health data access bodies and natural or legal persons on the basis of Regulation (EU) 2025/327 or this Act shall, where possible, be carried out electronically, unless a law prescribes a stricter form.

§ 21

B Specific rules for electronic health data referred to in Article 51(1), points (f) and (g), of Regulation (EU) 2025/327

(1) The processing of the following electronic health data for secondary use shall only be allowed if the data subject has consented to the processing of those data for secondary use in accordance with Article 9(2)(a) of the General Data Protection Regulation:

1. e Electrical health data referred to in Article 51(1), point (f), of Regulation (EU) 2025/327;

2. p roteomic and transcriptomic data referred to in Article 51(1), point (g), of Regulation (EU) 2025/327;

3. any of the data referred to in Article 51(1), point (g), of Regulation (EU) 2025/327, to the extent that the risk of re-identification of the data subjects posed by the processing of those data is equivalent to that posed by the data in the cases referred to in points (1) or (2).

(2) The coordinating health data access body shall provide model information and statements to health data holders for the required consent of data subjects.

§ 22

Further power to enact regulations; Loan-to-value

(1) The Federal Government shall be authorised to issue a statutory ordinance, with the consent of the Bundesrat, stipulating:

1. by way of derogation from Section 7(1), designate another federal public body as the coordinating access body for health data;

2. establish Omani-specific health data access bodies pursuant to § 9, and

   a) T confer on associations and legal persons governed by private law, as persons entrusted with legal personality, the performance of some or all of the tasks referred to in Paragraph 7(4), points 1 to 9 and 12 to 16, for a field to be defined, in particular for certain categories of electronic health data to be defined in the statutory ordinance or for data of certain categories of health data holders to be defined in the statutory ordinance, and

   b) provide that a public sector body or individual organisational units of a public sector body perform some or all of the tasks referred to in Section 7(4) for an

area to be specified, in particular for certain categories of electronic health data to be specified in the statutory ordinance or for data of certain categories of health data holders to be specified in the statutory ordinance;

3. provide that, by way of derogation from the third sentence of Section 10(3), the decision on applications for access to health data or health data requests from the Federal Institute for Medicinal Products and Medical Devices is entrusted to a domain-specific health data access body,

4. where another public sector body is designated pursuant to point 1 to carry out the tasks of the coordinating health data access body, to stipulate that the decision pursuant to the third sentence of § 10(3) is to be taken by the coordinating health data access body,

5. I n related to health data holders

   a) D as further specified in case the same dataset is held by more than one health data holder, with the aim that in that case the dataset is requested and made available only by one health data holder;

   b) D to regulate further details on specific requirements for trusted open databases referred to in Article 60(5) of Regulation (EU) 2025/327;

   c) regulate that the obligations of certain health data holders to be specified in the statutory ordinance or advisory duties pursuant to § 6(2) sentence 1 are fulfilled by health data intermediaries pursuant to Article 50(3) of Regulation (EU) 2025/327;

   d) D as procedures for the designation and verification of health data holders as trusted health data holders pursuant to Article 72(2) of Regulation (EU) 2025/327;

6. D to further specify the accelerated procedure for health data access applications for public sector bodies pursuant to Article 68(6) of Regulation (EU) 2025/327;

7. in relation to secure processing environments pursuant to Article 73 of Regulation (EU) 2025/327 and § 13, to regulate further details on:

   a) D selecting secure processing environments;

   b) legal, technical and organisational requirements for providers and operators of secure processing environments to process data under this Act.

(2) The delegation referred to in paragraph 1, point (2)(a), shall be subject to proof that the entrusted entity is equipped to carry out the delegated tasks effectively and to exercise the delegated powers referred to in Article 55(2), first sentence, (3) and (4) of Regulation (EU) 2025/327. The legal and technical supervision of the authorised persons referred to in paragraph 1(2)(a) shall be laid down in the statutory ordinance referred to in paragraph 1(2)(a). If the Federal Government is sued by a third party for damage caused to it by the delegated person in the performance of the duties entrusted to it as a result of a breach of official duties, the Federal Government may, in the event of intent and gross negligence, have recourse to it in the performance of the delegated duties. The Federal Government’s contractual claims against third parties arising from the same damaging event shall remain unaffected and shall be asserted as a matter of priority.

§ 23

E Valuation of the coordinating health data access body

(1) D as Federal Ministry of Health shall evaluate the performance of the tasks of the coordinating health data access bodies pursuant to § 7. The evaluation shall cover the period from 26 March 2029. The evaluation report shall be submitted by 31 December 2031 to be submitted to the Federal Government and published within six months.

(2) The evaluation shall examine in particular:

1. the number of data access applications and health data requests received and the type of decision taken, broken down by:

   a) S ektor of the applicant,

   b) Awakening, as referred to in Article 51 of Regulation (EU) 2025/327;

   c) b open data categories within the meaning of Article 51 of Regulation (EU) 2025/327 and the health data holders concerned by them;

   d) the applicant’s national or cross-border origin;

   e) proper domain-specific health data access body;

2. the processing workload and the staffing requirements derived from it, and

3. cost recovery, in particular the ratio of fee income to budgeted shares.

(3) The coordinating access point shall continuously collect the data required under paragraph 2 from 26 March 2029. The coordinating health data access body shall submit an annual report to the Federal Ministry of Health, starting on 1 March 2030.

(4) On the basis of the evaluation, the Federal Government is examining how staffing needs at the coordinating health data access body are to be secured on a permanent basis.

Abschnitt 3

B Specific data use procedures

§ 24

Processing of care data for quality assurance, patient safety and research purposes

(1) D Atmospheric processing health institutions may further process the data lawfully stored with them in accordance with Article 9(2)(h) and (i) of the General Data Protection Regulation, to the extent necessary

1. quality assurance and patient safety;

2. medical, rehabilitative and nursing research, including the development of AI models and AI systems as defined in Article 3, point (1), of Regulation (EU) 2024/1689 in the field of health; or

3. Z u statistical purposes, including health monitoring.

The personal data further processed in accordance with the first sentence shall be pseudonymised; they shall be anonymised as soon as possible in the context of further processing for the respective purpose referred to in the first sentence. Where several natural persons work in the health institution processing the data, the health institution shall establish a rights and roles policy that ensures that only authorised persons can further process the data referred to in the first sentence, that further processing is logged and that unauthorised processing is punishable. Data which are further processed in accordance with the first sentence shall be deleted at the latest 30 years after the start of further processing. Section 14 of the Transplant Act must be complied with.

(2) The results of the further processing of health data pursuant to paragraph 1 shall be anonymised as soon as possible in accordance with the respective purpose pursuant to the first sentence of paragraph 1.

(3) Disclosure of personal data to third parties in the context of the further processing referred to in paragraph 1 shall be prohibited. By way of derogation from the first sentence, the disclosure of personal data in the context of further processing pursuant to paragraph 1 shall be permitted if the data subject has given his or her consent or if another statutory provision of the Federal Government or the Länder or a directly applicable legal act of the European Union so provides. Health institutions processing data may anonymise the health data lawfully stored pursuant to Article 9(2)(h) of the General Data Protection Regulation in order to transmit the anonymised data to third parties for the purposes referred to in the first sentence of paragraph 1. By way of derogation from the first sentence, the data referred to in the first sentence of paragraph 1 may be shared and processed for the purposes referred to in the first sentence of paragraph 1 by publicly funded associations of data-processing health institutions, including collaborative research projects and research practice networks, provided that:

1. processing is necessary for the purposes referred to in the first sentence of paragraph 1;

2. the requirements set out in paragraphs 1, 2 and 4 with regard to processing are complied with;

3. the data controller’s interests in the processing significantly outweigh the data subject’s interests in excluding the processing; and

4. the competent data protection supervisory authority has given its consent to the sharing and processing of the data.

The data protection supervisory authority shall decide on the consent referred to in point 4 of the fourth sentence within one month.

(4) D Ate processing health institutions processing data pursuant to paragraph 1 shall be obliged to inform publicly and generally in a concise, transparent, easily understandable and accessible form, using clear and plain language, of the purposes for which data are further processed pursuant to paragraph 1. Information shall also be provided on ongoing research projects and published research results that have been registered or published in accordance with § 27. At the request of a data subject for the purposes referred to in points 2 or 3 of the first sentence of paragraph 1, the data processing health institution shall be obliged to provide information in a concise, transparent, intelligible and easily accessible form, using clear and plain language, about the nature, scope and specific purpose of the processing of the data for the purposes referred to in points 2 or 3 of the first sentence of paragraph 1.

§ 25

V Preparation of health data with the authorisation of the data protection supervisory authority

(1) In the case of a health and care research project, data controllers may, with the authorisation of the competent data protection supervisory authority, process the necessary health data in accordance with this provision without the consent of the data subjects.

(2) The competent data protection supervisory authority may, on request, authorise the processing of health data for operations referred to in paragraph 1, provided that the processing is necessary for the operation referred to in paragraph 1 and that the interests of the controller in the processing outweigh the interests of the data subject in being excluded from processing. An authorisation pursuant to the first sentence may be granted only for projects limited in content and time. The authorisation may be withdrawn, revoked or accompanied by ancillary provisions, in whole or in part, at any time.

(3) The application shall contain the following information:

1. D as the objective of the operation referred to in paragraph 1;

2. e a description of the data processed in the context of the operation referred to in paragraph 1;

3. e a clear demonstration that the scope and structure of the data to be processed are appropriate and necessary to achieve the intended purposes;

4. e a description of the envisaged data processing, including the methodological approach;

5. e a description of the technical and organisational measures envisaged for the operation referred to in paragraph 1, in accordance with Article 32 of the General Data Protection Regulation;

6. D the period during which the data are to be processed; and

7. justification demonstrating that the intended purpose cannot be achieved by access to data on the basis of other legal bases.

(4) Authorisation may not be granted if access to the data specified in the application or to a data set comparable to the data described under paragraph 3(2) is possible in an appropriate form and within a reasonable time on the basis of another statutory provision of the Federal Government or the Länder or a directly applicable legal act of the European Union. Access in an appropriate form pursuant to the first sentence shall be deemed to exist if a comparable data set can be used for the operation pursuant to paragraph 1 in such a way that, taking into account the quality of the data and the circumstances in which the data are provided, it appears to be suitable for achieving the objective pursuant to paragraph 3(1). Access within a reasonable time within the meaning of the first sentence shall be deemed to exist where access to data appears possible within the time limits laid down in another statutory provision without the objective of the research project specified in accordance with paragraph 3(1) no longer being achieved because of a time lag. The competent data protection supervisory authority shall decide on the request referred to in paragraph 2 within one month of receipt of the request.

(5) Health data to be processed pursuant to paragraph 1 shall be pseudonymised; they shall be anonymised as soon as possible in the context of processing for the

operation referred to in paragraph 1. The health data to be processed pursuant to paragraph 1 shall be deleted after the completion of the operation. The supervisory authority shall publicly inform about the applications received for operations referred to in paragraph 1.

§ 26

V linking data from the Research Data Centre with data from the clinical cancer registries of the countries; Executive power

(1) The linking of pseudonymised data from the research data centre pursuant to Section 303d of Volume V of the Social Code with pseudonymised data from the clinical cancer registers of the Länder pursuant to Section 65c of Volume V of the Social Code and the processing of these data for research projects shall be permitted in accordance with the following paragraphs.

(2) The linking and processing of the pseudonymised data referred to in paragraph 1 shall be subject to prior authorisation by the coordinating health data access body. Authorisation shall be granted on application, provided that:

1. the linking of the data referred to in paragraph 1 is necessary for the research question under investigation;

2. the necessary requests for access to the data to be linked have been approved in pseudonymised form at the research data centre pursuant to Section 303e(3) of Volume V of the Social Code and at the competent clinical cancer registers of the Länder pursuant to Section 65c of Volume V of the Social Code in accordance with the applicable Land law for access to the data to be linked in pseudonymised form, and

3. the legitimate interests of the data subject are not prejudiced, or the public interest in the research outweighs the data subject’s interest in confidentiality, and the specific risk of re-identification in relation to the data requested has been assessed and minimised by appropriate measures, with due regard to the intended scientific benefit.

(3) In the application, applicants must clearly demonstrate that the scope and structure of the data to be linked are appropriate and necessary to answer the research question to be examined.

(4) D ie coordinating health data access body

1. as part of the procedure for granting authorisation in accordance with the first sentence of paragraph 2, the applicant shall assist in communicating with the research data centre and with the clinical cancer registries of the Länder involved in accordance with Section 65c of Volume V of the Social Code and in submitting the applications referred to in point 2 of the second sentence of paragraph 2,

2. for the application for authorisation referred to in the first sentence of paragraph 2 and for the applications referred to in point 2 of the second sentence of paragraph 2, a uniform application process shall be available in consultation with two representatives appointed by the clinical cancer registers of the Länder pursuant to Section 65c of Volume V of the Social Code and the Centre for Cancer Register Data at the Robert Koch Institute pursuant to Section 1(1) of the Federal Cancer Register Data Act; and

3. shall forward the applications referred to in point 2 of the second sentence of paragraph 2 to the competent authorities.

(5) Where the authorisation referred to in the first sentence of paragraph 2 is granted, the data specified in the application shall be linked to a secure processing environment of a public sector body to be defined by the coordinating health data access body for the respective application and shall be made available to the applicants as pseudonymised individual data sets, without making pseudonyms visible. In a secure processing environment, appropriate technical and organisational measures must be in place to ensure that processing by applicants is limited to what is necessary for the purposes for which they are used and, in particular, that copying of data can be prevented.

(6) If the authorisation referred to in the first sentence of paragraph 2 is granted, the clinical cancer registers of the Länder pursuant to Section 65c of Volume V of the Social Code shall transmit the requested data in pseudonymised form to the secure processing environment established by the coordinating health data access body, together with a pseudonym to be created on an ad hoc basis on the basis of the unalterable part of the health insurance number, with the involvement of the trust authority pursuant to Section 303c of Volume V of the Social Code and in accordance with the provisions of the statutory ordinance pursuant to paragraph 9. In order to ensure quality-assured data fusion, a data cleaning procedure is to be used for the transmission of data from the clinical cancer registers of the Länder in accordance with Section 65c of Volume V of the Social Code.

(7) If the authorisation referred to in the first sentence of paragraph 2 is granted, the research data centre referred to in Section 303d of Volume V of the Social Code shall transmit the requested data in pseudonymised form to the secure processing environment established by the coordinating health data access body, together with a pseudonym to be created on an ad hoc basis, with the involvement of the trust authority referred to in Section 303c of Volume V of the Social Code and in accordance with the provisions of the statutory ordinance referred to in paragraph 9.

(8) Applicants shall not have access to the data made available in accordance with paragraph 5:

1. use it only for the purposes for which it is made available; and

2. do not share with third parties.

During processing, applicants must ensure that they are not related to persons, service providers or service providers. In the case of unintentional creation of a personal link, the coordinating health data access body shall be informed. The coordinating health data access body shall forward the information contained therein to the Research Data Centre and to the competent clinical cancer registries of the Länder in accordance with Section 65c of Volume V of the Social Code.

(9) The Federal Ministry of Health shall be authorised to issue a statutory ordinance, with the consent of the Bundesrat, laying down detailed rules on:

1. the technical procedure for linking the data by means of a pseudonym to be created on an ad hoc basis, including the processing of the data necessary for that purpose by:

    a) D as a research data centre pursuant to Section 303d of Volume V of the Social Code,

    b) clinical cancer registers of the Länder in accordance with Section 65c of Volume V of the Social Code,

c) D as the Centre for Cancer Registry Data at the Robert Koch Institute pursuant to Section 1(1) of the Federal Cancer Registry Data Act,

d) central application and registration body pursuant to Section 10 of the Federal Cancer Register Data Act (Bundeskrebsregisterdatengesetz), and

e) the trusted offices of those bodies involved;

2. requirements for secure processing environments referred to in paragraph 5 and the criteria for the selection of the processing environment by the coordinating health data access body;

3. the single application process and the other supporting actions of the coordinating health data access body referred to in paragraph 4;

4. the data cleaning procedures referred to in paragraph 6.

With regard to point 2 of the first sentence, the statutory ordinance shall be adopted in consultation with the Federal Commissioner for Data Protection and Freedom of Information and with the Federal Office for Information Security.

Abschnitt 4

S Empowerment and Orientation for the Common Good

§ 27

R Mandatory documentation and publication

(1) Where, in a research project, health data are processed for research purposes on the basis of this Act without the consent of the data subjects, the persons responsible for the research project are obliged to register the research project with the coordinating health data access body before the start of the data processing.

(2) E registration under paragraph 1 is not necessary if the research project has already been registered on the basis of another legal provision.

(3) Those responsible for the research project shall be required to publish the results of the research in an anonymised form and in a manner accessible to the general public within 18 months of the completion of the research project and, where the research project has been registered in accordance with paragraph 1, to deposit them with the coordinating health data access body.

(4) By way of derogation from paragraph 1, research projects commissioned by them or carried out under their legal or technical supervision shall not be registered and, by way of derogation from paragraph 3, shall not be published or shall be published only at a later date if this is necessary for the protection of particular public interests in accordance with Section 3 of the Freedom of Information Act.

§ 28

G Confidentiality obligations

(1) Natural persons may not have access to health data made available to them in accordance with this Law;

1. use it only for the purposes for which it was made available to them; and

2. not divulge to third parties unless permitted under paragraphs 3 or 4.

The first sentence shall also apply to the health data of a person who has already died.

(2) B Data generated shall not be processed for the purpose of establishing a link with persons or for the purpose of identifying service providers or providers. This also applies to health data of a person who has already died.

(3) Natural persons who have been entrusted with, or otherwise become aware of, foreign health data for the purpose of research may make those health data available for the purpose of research to their professional associates or to the persons working within them to prepare them for the profession. Natural persons to whom external health data have been entrusted or otherwise become known for the purpose of research may disclose such external health data to other persons involved in their professional or official activity in so far as this is necessary for the use of the activity of the other persons involved. The second sentence shall apply mutatis mutandis to the participating persons referred to therein if they make use of other persons involved in the professional or service activity. Paragraphs 1 and 2 shall apply mutatis mutandis to the persons referred to in the first to third sentences.

(4) In contrast to paragraph 1, natural persons may further process health data made available to them under this Act for other purposes or pass them on to third parties in so far as they are permitted to do so by federal or Länder legislation or by directly applicable legal acts of the European Union.

(5) Where the competent data protection supervisory authority has taken a measure pursuant to Article 58(2)(b) to (j) of the General Data Protection Regulation against a natural or legal person to whom data has been made available pursuant to this Act, it shall inform the institution of the body that made the data available and the coordinating health data access body.

§ 29

S rules of procedure

(1) A custodial sentence of up to one year or a fine shall be imposed on any person who:

1. contrary to point 2 of the first sentence of § 28(1), also in conjunction with the second sentence, in each case also in conjunction with the fourth sentence of § 28(3), passes on data, or

2. contrary to the first sentence of Section 28(2), also in conjunction with the second sentence, in each case also in conjunction with the fourth sentence of Section 28(3), processes the data referred to therein.

(2) Any person who, in the cases referred to in paragraph 1(1), acts for remuneration or with the intention of enriching himself or another person or of causing damage to another person shall be liable to imprisonment not exceeding two years or a fine.

(3) In the cases referred to in point 1 of paragraph 1, proceedings shall be brought only on application. The data subject, the controller within the meaning of Article 4(7) of the General Data Protection Regulation, the Federal Commissioner for Data Protection and Freedom of Information and the competent data protection supervisory authority are entitled to apply.

§ 30

Provisions on fines in Regulation (EU) 2025/327

(1) Anyone who intentionally or negligently infringes an enforceable order pursuant to Article 63(1) of Regulation (EU) 2025/327 in the version of 11 February 2025 acts contrary to the law.

(2) An administrative offence may be punishable by a fine of up to fifty thousand euros.

§ 31

A Application of the provisions on administrative fines and criminal proceedings

(1) F For infringements under Article 64(4) and (5) of Regulation (EU) 2025/327, the provisions of the Administrative Offences Act shall apply mutatis mutandis, unless otherwise provided for in this Act. The following provisions of the Administrative Offences Act shall not apply:

1. Section 17, also in conjunction with Section 30(3), and

2. § 30(1) and (2).

(2) F For proceedings concerning an infringement under Article 64(4) and (5) of Regulation (EU) 2025/327, the provisions of the Administrative Offences Act and the general laws on criminal procedure, namely the Code of Criminal Procedure and the Law on the Judiciary, shall apply mutatis mutandis, unless otherwise provided for in this Law. Sections 35, 36, 87, 99 and 100 of the Administrative Offences Act shall not apply. The second sentence of Section 69(4) of the Administrative Offences Act shall apply with the proviso that the public prosecutor’s office may discontinue proceedings only with the consent of the coordinating health data access body.

§ 32

G fines against public authorities

No administrative fines shall be imposed on public authorities and other public bodies within the meaning of Section 2(1) and (2) of the Federal Data Protection Act in the cases referred to in Section 30(1) and Article 64(4) and (5) of Regulation (EU) 2025/327.

Artikel 8

Amendment of the Health Data Utilisation Act

The Health Data Utilisation Act of... [insert: Date of issue and publication of the law referred to in Article 7] is amended as follows:

1. The table of contents is amended as follows:

   a) The reference to § 26 is deleted.

   b) The entry for Sections 27 to 32 is replaced by the following:

   ‘Paragraph 26 Obligation to register and publish

   § 27 Confidentiality rules

   Paragraph 28 Penal provisions

   Section 29 Provisions on fines under Regulation (EU) 2025/327

   Section 30 Application of the provisions on administrative fines and criminal proceedings

   § 31 Fines on public authorities’.

2. In Section 24(4), second sentence, ‘Section 27’ is replaced by ‘Section 26’.

3. Section 26 is deleted.

4. Sections 27 and 28 shall become Sections 26 and 27.

5. § 29 shall become § 28 and in paragraph 1, points 1 and 2, the words ‘§ 28’ shall be replaced by the words ‘§ 27’.

6. §§ 30 and 31 shall become §§ 29 and 30.

7. § 32 shall become § 31 and the indication ‘§ 30’ shall be replaced by the indication ‘§ 29’.

Artikel 9

Amendment of the Law on medicinal products

The Arzneimittelgesetz [Medicinal Products Act] in the version published on 12 December 2005 (BGBl. I p. 3394), as last amended by Article 6 of the Act of 26 June 2026 (BGBl. 2026 I No 195), is amended as follows:

1. In Section 40(3), fifth sentence, and (5), first sentence, the words ‘, (5) and (6)’ are replaced by the words ‘and (5)’.

2. Section 40b is amended as follows:

   a) (A)(b)(6) is deleted;

   b) The current paragraph 7 becomes paragraph 6.

3. Section 42 is amended as follows:

a) In the first sentence of paragraph 2 and the first sentence of paragraph 4, the words ‘to 6’ are replaced by the words ‘to 5’.

b) In the third sentence of paragraph 5, the words ‘paragraphs 5 and 6’ are replaced by the words ‘and paragraph 5’.

Artikel 10

Amendment of the Genetic Diagnostics Act

The Gendiagnostikgesetz (Genetic Diagnostics Act) of 31 July 2009 (BGBl. I, p. 2529, 3672), as last amended by Article 15(4) of the Act of 4 May 2021 (BGBl. I, p. 882), is amended as follows:

1. Section 9(2) is amended as follows:

a) In point 6 of Section I, the words ‘Section 16(2)’ are replaced by the words ‘Section 16(2)’.

b) In point 6, the following point 7 is inserted:

1. ‘ the possibility to give consent for secondary use in accordance with Chapter IV of Regulation (EU) 2025/327 in accordance with Section 21 of the Health Data Usage Act.’

2. § 11 is replaced by the following § 11:

§ 1‘

Communication of the results of genetic examinations and analyses

(1) Subject to paragraphs 2 to 4, the result of a genetic examination may be communicated only to the data subject and only by the responsible medical person or the doctor who carried out the genetic consultation.

(2) A person or institution entrusted with the genetic analysis pursuant to § 7(2) may communicate the result of the genetic analysis only to the medical person who commissioned it.

(3) The responsible medical person may communicate the result of the genetic examination or analysis to others only with the explicit consent of the data subject in writing or electronically.

(4) The result of the genetic examination or analysis shall be made available for secondary use in accordance with Chapter IV of Regulation (EU) 2025/327 in accordance with Section 2 of the Health Data Usage Act.

(5) The result of the genetic examination may not be communicated to the person concerned if that person has decided pursuant to the first sentence of Paragraph 8(1) in conjunction with the second sentence that the result of the genetic

examination must be destroyed or that that person has withdrawn his or her consent pursuant to Paragraph 8(2).'

3. § 17 is amended as follows:

   a) In paragraph 5, the words 'Section 11(2) to (4)' are replaced by the words 'Section 11(2) to (5)'.

   b) In the fourth sentence of paragraph 8, 'Section 11(4)' is replaced by 'Section 11(5)'.

Artikel 11

Amendment of the BSI Act

The BSI Act of 2 December 2025 (BGBl. 2025 I No 301, p. 2), as amended by Article 4 of the Act of 11 March 2026 (BGBl. 2026 I No 66), is amended as follows:

In Section 28(6), point 2, the words 'Section 311(6)' are replaced by the words 'Section 363a(1), first sentence, point 1'.

Artikel 12

Amendment of the Second Farmers' Health Insurance Act

The Second Farmers' Health Insurance Act of 20. December 1988 (BGBl. I p. 2477, 2557), as last amended by Article 2(8) of the Act of 12 May 2026 (BGBl. 2026 I No 143), is amended as follows:

Section 56 is amended as follows:

1. The heading is replaced by the following:

§ 1'

Medical service, insurance and performance data, data protection, data transparency; Telematics infrastructure, interoperability, IT security, cloud computing services; National Health Portal'.

2. S atz 3 is replaced by the following sentence:

'Chapters 11 and 12 of Book V of the Social Code shall apply mutatis mutandis to telematics infrastructure, interoperability, IT security and the use of cloud computing services, as well as to the national health portal.'

Artikel 13

Amending the Digital Health Applications Regulation

The Digital Health Applications Regulation of 8 April 2020 (BGBl. I, p. 768), as last amended by Article 1 of the Regulation of 27 January 2026 (BGBl. 2026 I, No 22), is amended as follows:

1. In Section 2(1), second sentence, point 21a, the following point 21b is inserted:

   ‘21b. the medication data from the electronic health record processed by the digital health application, where applicable;’;

2. § 20(3)(7) and (8) shall be replaced by the following points (7) to (9):

   1. ‘ the data that can be transferred from assistive devices and implants to the digital health application, where applicable;

   2. the reasons for removing a digital health application from the list of digital health applications; and

   3. reading medication data from the electronic health record, where applicable.’;

Artikel 14

Amendment of the Telematics Charges Regulation

The Telematic Fees Regulation of 4 September 2017 (BGBl. I, p. 3382), as amended by Article 1 of the Regulation of 29 June 2021 (BGBl. I, p. 2246), is amended as follows:

Section 3 is amended as follows:

1. The first sentence of the first subparagraph is amended as follows:

   a) In point 5, ‘EUR 3500.’ is replaced by ‘EUR 3500.’

   b) In point 5, the following point 6 is inserted:

      1. ‘ confirmation of the implementation of the interface in accordance with Section 374a of Volume V of the Social Code;

      EUR 1800 to EUR 2200.’

2. In the first sentence of the second paragraph, ‘points 4 and 5’ is replaced by ‘points 4, 5 and 6’.

Artikel 15

A Excluded

The Health Data Usage Act of 22 March 2024 (BGBl. 2024 I No 102) enters into force on... [insert: Date of the day following the promulgation of this Act].

Artikel 16

I enter into force

(1) Subject to paragraphs 2 to 5, this Law shall enter into force on the day following its promulgation.

(2) Point 1(104)(b)(aa) shall enter into force on 26 March 2024.

(3) Artikel 2 shall enter into force on 26 March 2029.

(4) Artikel 8 shall enter into force on 1 January 2030.

(5) Artikel 3 shall enter into force on 26 March 2031.

EU legal acts:

1. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73; OJ L 23, 29.1.2015, p. 19; OJ L 155, 14.6.2016, p. 44), as last amended by Regulation (EU) 2024/1183 of the European Parliament and of the Council of 11.4.2024 amending Regulation (EU) No 910/2014 as regards establishing the European Digital Identity Framework (OJ L, 2024/1183, 30.4.2024).

2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2026, p. 1; OJ L 314, 22.11.2026, p. 72; OJ L 127, 23.5.2018, p. 2; (General Data Protection Regulation) (OJ L 74, 4.3.2021, p. 35).

3. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (OJ L 152, 3.6.2022, p. 1; L, 2023/90204, 21.12.2023) (Data Governance Act).

4. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (OJ L, 2024/1689, 12.7.2024; L, 2025/90802, 9.10.2025) (Artificial Intelligence Act).

5. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

Justification

A. General part

I. Objective and necessity of the provisions

The consistent and user-focused digitalisation of our health and care systems is key to ensuring modern, efficient and future-proof care in Germany. The rapid, safe and complete provision of medical and nursing information and the expansion of digital technologies and infrastructure can optimise care, increase patient safety and thus improve healthcare in a sustainable way.

In recent years, we have seen great progress in Germany in digitalising our healthcare and care systems. Many legal and practical steps have been taken to make healthcare more efficient and patient-centred, using digital services and applications. The comprehensive introduction of the electronic health record (ePA) in the Digital Act (DigiG) now brings together health data of insured persons in the hands of insured persons. With the introduction of applications such as the electronic prescription (e-prescription) and the electronic reporting of disability data from the medical office to the health insurance fund to the employer, important conditions have been created for digitalisation in care to reach its full potential. The law on the improved use of health data makes health data more extensively usable for care and research than before. And the digitalisation strategy for health and care also highlights the need for digitalisation to be optimally integrated into care processes.

This high pace of digitalisation in healthcare and care needs to be maintained. Building on past experience and achievements, there are many more opportunities to harness the potential of digital applications and data-driven processes, thus contributing to better and more cost-effective healthcare. In order to exploit these potentials and achieve the core objectives of digitalisation in healthcare and care – better care, more patient safety, less red tape for healthcare providers – this law aims to take action in almost all areas of our healthcare system that are relevant to digitalisation.

For example, further development of the telematics infrastructure, the ePA and the Telematics Society is needed. The existing digital utility elements will be further developed in a more user-friendly way, integrated into good processes and linked to new digital opportunities. It is also necessary to promote the interoperability, but also the performance, stability and user-friendliness of service providers' information technology systems in order to ensure seamless and therefore user-friendly healthcare processes. The ePA will be continuously developed to make best use of it for supply-related purposes. The aim is to make existing data from the ePA fully usable, to increase competition for good and useful applications for insured persons and to promote innovation within the ePA. User-friendly usability and accessibility for specific patient groups and ePA users will be taken into account. Further development of access to the ePA by pharmacists is also needed to ensure a comprehensive review of drug therapy safety. The Act also aims to provide technical guidance on the planned primary care concept for the outpatient sector.

Potential in the secondary use of health data will also be better exploited, for example in the area of cross-sectoral research, improved governance of our health system and care or the integration of innovative technologies. By further developing the legal framework, existing hurdles can be reduced and clear, workable rules can be put in place that not only enable the use of health data for medical research, but also serve

the objective of sustainably improving patient care. This law continues the path towards an interconnected and interoperable health data infrastructure.

All these arrangements must take into account the new European law requirements of Regulation (EU) 2025/327 on the European Health Data Space (Regulation (EU) 2025/327). Regulation (EU) 2025/327 aims to establish a common framework for the use and exchange of electronic health data across the EU (European Health Data Space ('EHDS'). Regulation (EU) 2025/327 allows patients to better access and control their personal electronic health data (primary use). In addition, certain data can be re-used for purposes of public interest, support for public health policies and scientific research (secondary use). This Act serves to implement Regulation (EU) 2025/327 in a timely manner, both in the area of primary use and in the area of secondary use.

The purpose of this law is therefore, in particular, to:

– create essential technical conditions for the preparation of a digitally-supported primary care system;

– Harnessing health data for care, research and improving our health system;

– to strengthen the innovative use of data held by health and care insurance funds in a flexible and legally certain manner in the interests of insured persons,

– implement Regulation (EU) 2025/327 in Germany in a non-bureaucratic, timely and innovation-friendly manner;

– build a European-ready and interconnected health data ecosystem in Germany;

– further develop the interoperability process in health and care in a consistent and cross-sectoral manner;

– further develop the ePA for supply-related purposes to ensure the best possible and feasible use of the ePA;

– strengthen competition for applications that are well-managed and beneficial for insured persons with different levels of digital literacy and until old age, and promote innovation within the ePA;

– improve the operational resilience of the telematics infrastructure; and

– further advance the digitalisation of communication between healthcare and care providers.

II. Essential content of the draft

In order to achieve the objectives outlined above, the following main measures will be added to the existing legislation.

Strengthening primary use of health data and care-orientation:

This Act makes the necessary adaptations to national law to implement Regulation (EU) 2025/327. In the area of primary use of health data (for care purposes), the future mandatory cross-border infrastructure MyHealth@EU will gradually transfer different categories of electronic health data between EU Member States from 2029 onwards. The tasks of digital health bodies and market surveillance authorities implementing primary use rules and electronic health record systems (in short: EHR systems) are allocated to

appropriate bodies within the German health system, with a particular focus on assigning tasks to the Society for Telematics (gematics). The role of gematics will also be further developed in the area of interoperability. The tasks of the Competence Centre on Health Interoperability shall be extended, in particular as part of the conformity assessment procedure. Reassigned tasks, including by defining qualitative and quantitative functions of information technology systems in healthcare, will ensure that they can not only communicate with each other at the technical, semantic and syntactic level, but can also be used in practice by users as intended. At the same time, this reduces the administrative burden on healthcare providers and further increases the quality and patient-centricity of healthcare. Both service providers and manufacturers of information technology systems will be required to further strengthen and implement the right to interoperability of patients. The former will have to keep health-related data of their patients in interoperable format. This corresponds to the obligation for manufacturers of information technology systems to make this interoperable data retention in the service providers' systems possible in the future. The Associations of Statutory Health Insurance Physicians will also provide service providers with digital advice on the digitalisation of practices and the expansion of competences, including on cybersecurity.

In order to provide advice and support to specific patient groups and users of the ePA more specific to the target group (e.g. (older) people with low digital skills, people with disabilities, children and young people, and taking into account gender-specific needs), further rights will be granted to the Ombudsperson bodies of the health insurance funds. First of all, it will be possible to set up, manage and delete representative arrangements via the Ombudsman's Office.

Strengthening secondary use of health data for care, research and innovation:

The requirements of Regulation (EU) 2025/327 are also being implemented in the area of secondary use of health data. This will create the legal framework for building an interconnected, European-ready health data ecosystem. First, the envisaged roles and tasks in the data access process are distributed in accordance with Chapter IV of Regulation (EU) 2025/327. A decentralised system with a coordinating access point and additional dome-specific access points are envisaged. In addition, the necessary arrangements will be made for the organisation of opposition proceedings and a register of the rights of interested parties will be set up. In order to enable the linking of data and the implementation of opposition rights in the EHDS secondary use process, a *unique research identifier* shall be established.

In addition to the EHDS secondary use process, the use of health data will also be further improved. In particular, the further use of data from health insurance funds will be strengthened. A legal basis for the establishment of regulatory sandboxes will allow health insurance funds to test innovative data use with legal certainty in the future. The existing rule on data-based identification of individual health risks by health insurance funds and long-term care funds will also be revised.

The Health Research Data Centre (FDZ) at the Federal Institute for Drugs and Medical Devices will also be further developed. In future, in certain cases, an application for access to data will also be made to the FDZ, in which individual health care providers will be identified. Such a request would be admissible, for example, if it serves to establish contact between health care providers with similar cases, for example in order to allow for technical exchanges between health care providers.

Making health data of all genders available without discrimination reduces *the gender data gap*. The data thus available allow for more gender-sensitive assessments that can help identify gender differences in care, diagnostics and therapy. Research and development will also take better account of women's health needs and circumstances.

Adding value through digital applications and supply processes

Various rules create tangible added value for insured persons and relief for health care providers. The aim is to provide insured persons with user-friendly, digital pathways to outpatient care, which will also prepare for the introduction of the planned primary care system. An important tool is the e-transfer, which we intend to establish during this legislative term. We also want to create a digital start: Insured persons can be redirected nationwide via the ePA user interface (ePA app) to the nationwide standardised initial assessment by the appointment service points of the health insurance fund associations and then, if necessary, to a digital appointment booking, thus using a simple, digital route to outpatient care. In further steps, the standardised initial assessment is to be replaced by a more comprehensive digital needs assessment to assess the need for and urgency of treatment and to allocate treatment needs to the appropriate level of care. The Federal Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) and the Central Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen) are instructed to agree on the requirements and requirements necessary for the digital assessment of needs; the Federal Association of Statutory Health Insurance Physicians is also tasked with implementing and providing an electronic system for a uniform national digital needs assessment. In addition, we are making the necessary regulations to ensure that also digital appointment intermediation via private providers is carried out in a non-discriminatory manner and that the requirements of data protection and data security are complied with.

In addition, the legislative framework for digital health applications (Diga) is to be developed in a targeted manner, thereby reducing red tape.

In addition, the legal framework for the introduction of value-added applications by the health insurance funds in the ePA will also be made more accessible. In addition, existing data from the ePA will continue to be used. As a concrete added value application, digital vaccination documentation will be introduced as a preliminary step in the digitalised vaccination process, based on billing data. By expanding access for pharmacists, drug therapy safety is taken into account in other supply-related scenarios. The existing rules on e-prescription will be adapted to the new requirements in practice, including the implementation of new types of prescriptions. The scope of the e-invoice is extended to include direct billing for service providers and to allow its use by accident insurance. Secure methods of transmission in the health and care sectors will be further developed by consolidating and specifying the requirements. This will facilitate the use of secure transfer procedures.

The rules on the medical communication applications (KIM) and the instant messaging service of the telematics infrastructure (TI-Messenger – TI-M) will be bundled, clarified and supplemented. The aim is to ensure ubiquitous, interoperable and secure communication. Therefore, all service providers affiliated to TI will in future be obliged to use KIM for medical, nursing and administrative communication.

In the future, the gematics will play a more steering role in order to improve the operational resilience of the telematics infrastructure. To this end, it should be able to centrally tender, bundle, operate or have operated components, services and applications and, in future, directly enforce operational obligations vis-à-vis the operators actually responsible. In addition, comprehensive security and troubleshooting powers are granted.

III. Executive footprint

Interest representatives and mandated third parties did not directly contribute to the content of the draft law.

An important foundation of the digital transformation of health and care is the Digitalisation Strategy ‘Digital Together’. Representatives of relevant stakeholder groups have been and will be involved in their development, implementation and further development.

In preparation for the implementation of Regulation (EU) 2025/327, representatives of health data infrastructures, in particular the Health Research Data Infrastructure Coordination Group, were involved in a series of workshops on the design of the health data ecosystem in Germany.

IV. Alternatives

Absent. The objectives can only be achieved through legislative adaptation. Other alternatives are neither useful nor effective. The draft is intended, inter alia, to implement the directly applicable Regulation (EU) 2025/327.

V. Legislative power

Due to the wide range of issues covered by the provisions, the legislative competence for the draft law stems from several competence titles. It is not always necessary to base a provision solely on a single title of competence. Rather, for certain rules or sets of rules, reference must be made to an overall view of different competence titles of the competing legislation (‘mosaic theory’). This applies in particular to the rules implementing Regulation (EU) 2025/327.

The legislative competence of the Federal Government derives from Article 74(1)(1) of the Basic Law (civil law and criminal law), Article 74(1)(11) of the Basic Law (economic law), Article 74(1)(12) of the Basic Law (social security law), Article 74(1)(13)(2) of the Basic Law (research funding) and Article 74(1)(19) of the Basic Law (measures against diseases which are dangerous or communicable to the public), possibly in conjunction with Article 72(2) of the Basic Law.

The Federal Government’s legislative competence for the digitalisation of healthcare in the area of statutory health insurance derives from Article 74(1)(12) of the Basic Law (social security law).

This draft also serves to implement Regulation (EU) 2025/327, the rules of which interfere in an orderly and guiding manner in the area of digital health. The regulatory content of Regulation (EU) 2025/327 is linked to the sensitive item of electronic health data.

Regulation (EU) 2025/327 mainly requires healthcare professionals in the area of so-called primary use. The regulatory focus is on access, provision and transmission rights or obligations with regard to electronic health data. In this respect, legislative competence derives from Article 74(1)(11) (economic law) and Article 74(1)(12) (social security law) of the Basic Law. In the area of secondary use, legislative competence follows electronic health data and their ownership: Data from electronic health records and billing data are data from health insurers. Competence for statutory health and long-term care funds and other social security funds derives from Article 74(1)(12) of the Basic Law (social security law) and for private health and long-term care insurance and technical service providers of insurers from Article 74(1)(11) of the Basic Law (economic law). Data held by health care providers are covered, for example, by Article 74(1)(12) of the Basic Law (social security law) in the case of contracted doctors, by Article 74(1)(11) of the Basic Law (business law) in the case of private health care professionals, and by Article 74(1)(19) of the Basic Law (pharmacies). With regard to other health data holders, Article 74(1)(11) of the Basic Law (Economic Law) applies to the industrial health sector, Article 74(1)(19) of the Basic Law (Measures against communicable or dangerous diseases) applies to registries, and Article

74(1)(13)(2) of the Basic Law (Research funding) applies to universities, universities and research-related registries. The inclusion of these latter entities in the EHDS secondary use process will greatly facilitate research with the data available there, thus significantly reducing the financial burden on researchers. The implementation of Regulation (EU) 2025/327, as well as the further actions in DGNG, thus contribute to removing structural barriers to research.

The European provisions of Regulation (EU) 2025/327 require implementation within the Member State by means of a single infrastructure. Other actors involved also need to be co-regulated nationwide on the basis of related facts in order to be able to build a single, interconnected, interoperable and low-bureaucratic health data ecosystem and research data infrastructure and to prevent fragmentation into parallel infrastructures.

Provisions of federal law based on the titles of competence pursuant to Article 74(1)(11) and Article 74(1)(13), second alternative, of the Basic Law are also necessary in order to preserve legal and economic unity in the interests of the State (Article 72(2) of the Basic Law). Only a uniform national rule can prevent the legal situation in the Federal Government and the Länder from diverging. Given the macroeconomic importance of health data, the application of different standards in the supervision and enforcement of the Data Act within the Federal Republic of Germany would entail significant disadvantages for the digital health economy and research. Regulation (EU) 2025/327 has created an area of law in which many questions of substantive interpretation will have to be resolved. Inconsistent interpretation in the area of requesting access to, making available and using health data poses a real risk of distortion of competition and inconsistent respect for data subjects' rights within the German economic area, in particular for companies and institutions operating nationwide and across borders. Uniform rules at federal level in the area of research funding are necessary in the interest of the state as, in particular, cross-border research projects are best facilitated by uniform requirements. Inconsistent regulation leads to a severe stifling of research and innovation. Lack of research will have a negative impact on society as a whole and its quality of supply.

In the context of its legislative competence under Article 74(1)(1) of the Basic Law (Civil Law) and Article 74(1)(11) of the Basic Law (Economic Law), the Federal Government establishes in DGNG a special competence of the Federal Commissioner(s) for Data Protection and Freedom of Information under the first sentence of Article 87(3) of the Basic Law in relation to Regulation (EU) 2025/327 (non-public sector). A coherent answer to the questions of interpretation for the purposes of legal certainty will require intensive coordination between the competent bodies under Regulation (EU) 2025/327 and the Federal Commissioner for Data Protection and Freedom of Information within their respective competences. If the responsibility for data protection supervision within the scope of Regulation (EU) 2025/327 remained with the data protection supervisory authorities of the Länder, the multiplicity of legal issues to be resolved would multiply with the multiplicity of legal opinions represented within the circle of data protection supervisory authorities. Such a state of affairs would create and not remove obstacles to the smooth functioning of the internal market for data, hinder and not promote digital innovation and prevent the optimal use of data for the benefit of patients, and is therefore not acceptable in the general interest (cf. Article 72(2) of the Basic Law).

VI. Compatibility with European Union law and international treaties

The draft law is compatible with European Union law and international agreements concluded by the Federal Republic of Germany.

VII. Legislative consequences

1. Legal and administrative simplification

By creating clear responsibilities for the digitalisation of healthcare, processes will be managed more efficiently, thus significantly reducing red tape. The draft law also simplifies existing rules in order to cut red tape and save time and costs. For example, Section 25b of Volume V of the Social Security Code (SGB V) simplifies the procedure by removing the requirement for health insurance funds to inform their management board in advance. In addition, the requirement for information under § 25b SGB V to be in writing has been relaxed. We are also cutting red tape in the area of digital health applications (Diga): The Central Federal Association of Health Insurance Funds (GKV-SV) is released from its obligation to draw up a report on Diga coverage (§ 33a(6) SGB V).

The medical communication applications (KIM) and the instant messaging service of the telematics infrastructure (TI-Messenger – TI-M) contribute significantly to cutting red tape in the telematics infrastructure by avoiding media breaks and enabling end-to-end digital communication. Paper-based processes, printouts, faxes and manual transfers are eliminated, which significantly reduces the administrative burden. At the same time, standardised and binding communication channels speed up the exchange of information and reduce the coordination and coordination burden. Through transparent and traceable communication processes, multiple recordings and queries are minimised. Overall, KIM and TI-M lead to more efficient administrative processes and significantly reduce the bureaucratic burden on service providers.

2. Sustainability

The draft law has been assessed in the light of the principles of sustainable development with regard to sustainability and follows the Federal Government’s guiding principle for sustainable development. Several measures in the draft law aim at accelerating and improving the achievement of the Sustainable Development Goals (SDGs). In particular, it promotes SDG 3 ‘Good health and well-being’, SDG 5 ‘Gender equality’ and SDG 9 ‘Industry, innovation and infrastructure’.

The draft law continues the necessary measures to digitalise the healthcare system. The aim is, in particular, to further improve the provision of medical care to people and to ensure that insured persons continue to receive medical care that meets their needs, is of high quality and is as diverse as possible and accessible as possible. Improving the availability and usability of health data in a connected health data ecosystem will continue to lay the groundwork for secure, efficient and data-driven care. At the same time, it will enable data-driven innovation, for example in the development of new technologies. This will improve the conditions for an internationally competitive research, business and health base in Germany. Making health data of all genders available without discrimination also reduces *the gender data gap*. In doing so, it helps to ensure that research and development take better account of women’s health needs and circumstances.

3. Budgetary expenditure without compliance costs

(a) Federal Government

The establishment of a coordinating data access body, in particular the implementation of the Regulation on the European Health Data Space at the Federal Institute for Medicinal Products and Medical Devices, gives rise to one-off budgetary expenditure of approximately EUR 11.3 million, which is to be used in particular for the construction of the technical infrastructure, and up to EUR 2.3 million per year, which is needed in particular for the staff of the coordinating data access body and ongoing material costs.

There are also one-off costs of EUR 0.65 million for the expansion of the Research Data Centre for Health at the BfArM. Increasing effort in setting semantic interoperability results in an additional annual effort of EUR 0.9 million for the BfArM.

The Federal Government also incurs one-off costs of around EUR 10 million for setting up and operating a register for the implementation of data subjects' rights, as provided for in Regulation (EU) 2025/327, and one-off costs of around EUR 10 million from the start of operations (vsl. 2029) annual costs of approximately EUR 5 million. These one-off costs for the deployment of the interconnected health data infrastructure will be funded by the Special Fund for Infrastructure and Climate Neutrality (SVIK).

The annual staff costs for setting up a complaint-handling body in the field of gematics amount to approximately 0.2 million. Euro. The cost of financing BSI expenditure as a market surveillance authority is approximately EUR 0.1 million.

The resulting additional annual needs of the Federal Government in terms of material and staff expenditure must be compensated for financially and in terms of (planned) posts in the relevant section of the budget. An agreement must be reached by 31 March 2034 on the financing of any additional annual needs of the Federal Government for material and personnel expenditure arising from the implementation of Chapter IV of Regulation (EU) 2025/327 on the basis of the evaluation pursuant to § 23 GDNG.

Affected	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***
BfArM	Article 7, § 7 GDNG	Staff coordinating data access point	Staff to carry out tasks related to the implementation of Regulation (EU) 2025/327 in the following areas: Public information and advice (1hD), EU cooperation (1hD), coordination of legal issues (1hD), operation of metadata catalogue and application portal (1 gD, 1hD), coordination of technical issues regarding secure processing environments (1hD) Total 5* 170.123 (hD)+ 1*154.122 (gD) = EUR 1004740	1.004.740	yearly
BfArM	Article 7, § 7 GDNG	Material costs including temporary staff/external service providers	Material costs and costs for external service providers: 2027: Parallel backend extensions, extensions and adaptations of the application management system and metadata catalogue, support for SPE design including interfaces, design of application register and frontend, user management, piloting frontend adaptations, also temporary staff (3 years) to prepare for the implementation of Regulation (EU) 2025/327 in the following areas: conceptual development/scaling of	EUR 11333100	One-off 2027-2029

			the application portal (1hD), conceptual development/scaling of metadata catalogue (1 gD, 1hD), conception/scaling of secure processing environments (2hD), conception of data quality and linking (1hD) and process design of application registers and fee notices (1gD, 1mD) Material costs EUR 2638000 Staff costs 3*(5* 97.221 (hD) + 2*84.855 (gD) + 1*61.947) = 2. EUR 153.286 2028: Stabilisation and expansion of the overall system, scaling, bugfixing, as well as temporary staff (2 years) to prepare for the implementation of Regulation (EU) 2025/327 in the following areas: Piloting application portal (1hD), piloting metadata catalogue (1hD), piloting data provision in secure processing environments (2hD), process design including legal issues (1hD) and piloting application registers and fee notices (1gD, 1mD) Material costs EUR 2638000 Staff costs 2*(5*97.221 (hD) + 1*84.855 (gD) + 1*61.947 (mD) = EUR 1265814 2029: Final work, Documentation & Support, Further development as required Material costs EUR 2638000		
BfArM	Article 7, § 7 GDNG	Material costs including external service providers	Material costs for operation and maintenance of the system as a whole	1.250.000	As of 2030
BfArM	Article 1, § 303e	Extension of FDZ Health services	Investment costs in order to be able to process increased application volumes: EUR 155.000 Investment costs associated with increased number of interfaces	655.000	unique

			related to extended uses (data products and RD identification): EUR 250.000 Investment costs related to the provision of new data products and quality assurance: EUR 250.000		
BMG	Article 7, § 16 GDNG	Structure of the register for the implementation of the rights of the persons concerned	Estimate based on the set-up costs of similar registers	500.000	2026
BMG	Article 7, § 16 GDNG	Structure of the register for the implementation of the rights of the persons concerned	Estimate based on the set-up costs of similar registers	Approx. 3 million	2027
BMG	Article 7, § 18 GDNG	Structure of the register for the implementation of the rights of the persons concerned	Estimate based on the set-up costs of similar registers	Approx. 7 million	2028
BMG	Article 7, § 16 GDNG	Operation of registers for the implementation of data subjects' rights	Estimate based on operating costs of similar registers	Approx. 5 million	Annually from 2029
BfArM	Article 1, § 219d(6) in conjunction with (8)	Future increase in the number of use cases in the definition of semantic interoperability	For the NCPeH, 6 FTE (4xE14(108.160*4 = EUR 432.640), 2xE11(64.640*2 = EUR 129.280)) and a further EUR 350.000 of material resources (annually) will be required until 2032.	912.000	yearly
genetics	Article 1, § 383a(	Establishment of a complaint-	HR costs: About 45 % of Germans	223.000	Yearly

	3)	handling body within the coordinating body of the GM sector	(GKV+PKV insured persons) travel abroad every year= 80 million + 0.45 = 36 million insured persons Of which an estimated 80 % to other European countries= 36 million*0.8=28.8 million Of these, an estimated 25 % actively lead to an ePA = 28.8 million*0.25 = 7.2 million insured persons Of which fall ill abroad in Europe and are looking for a healthcare provider estimated at 5 %= 7.2 million*0.05= 360000 insured persons Of which an estimated 1 % = 360.000*0.01= 3.600 complaints Time taken to deal with a complaint is estimated at 1 h because most of the time is standard= 3.600*1= 3.600 hrs/8 hrs= 450 man-days 450PT/200=2.25 persons Expenses: 3600h*62 (wage costs health) = EUR 223.200		
genetics	Article 1, § 383b	Market surveillance authority	Financing of BSI expenditure as market surveillance authority: 1 MAK hD= EUR 112.800	112.800	yearly

(b) Länder and municipalities

None

(C) Social security

Additional expenditure of around EUR 2.2 million per year is incurred on statutory health insurance as a result of the extension of the services of the Research Data Centre for Health. On the other hand, there is an annual reduction of around EUR 4 million as a result of the removal of the lump sum for the e-doctor’s certificate.

‘,	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***
GKV-SV	Article 1; Sectio	Service provider re-	Additional expenditure of 1 gD for the implementation of the service provider re-	154.122	yearly

	n 303e	identification	identification is incurred in the trusted office at the KKI and is covered by the statutory health insurance scheme. Staff costs 1gD= EUR 154.122		
GKV-SV	Article 1; Section 303e	Extension of FDZ Health services	The increase in demand due to improved use possibilities (possibility of service provider re-identification) leads to approximately 75 extra requests per year, requiring 1 FTE hD and 0.5 gD. The provision of new data products and quality assurance (paragraph 4b) requires 0.25 FTE hD. Cost savings of 0.5 hD result from the reduction of red tape and the streamlining of previous legal requirements (in particular the obligation on users). In total, there are additional requirements of 0.75 hD and 0.5 gD in the Health FDP, which are financed by the SHI-SV: Annual staff costs: EUR 0.75*170.123 (hD) + EUR 0.5*154.122 (gD) = EUR 205.653	205.653	yearly
GKV-SV	Article 1; Section 303e	Extension of FDZ Health services	Material costs in order to be able to process an increased volume of applications: EUR 1500000 Material costs associated with increased number of interfaces related to extended uses (data products and LE identification): EUR 250.000 Material costs related to the provision of new data products and quality assurance: EUR 50.000	1.800.000	yearly
Health insuran	Article 1,	Deletion of Pau-	According to the GKV-SV, the cost of the e-doctor’s letter	—4 million	yearly

ce funds	Section 383(1)-(6) of Volume V of the Social Code	schale e-doctor's certificate	and the transmission of a fax in 2023 is around EUR 4 million.		

4. Compliance costs

The regulatory scope of Regulation (EU) 2025/327, for which no national legislation has been introduced, means that, in addition to the load changes listed below, other changes may result directly from Regulation (EU) 2025/327.

4.1. Compliance costs for citizens

Citizens incur an annual implementing cost of approximately 0.2 million hours and a one-off implementation cost of approximately 1.3 million hours.

Seq. number	***Affected***	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***	***Discharge***	***Transposition of EU legislation***
1.1	Insured	Article 1; Paragraph 345b of SGB V	Read and process information, seek further information if needed	Assumptions: 2 million new active ePA users per year; one in ten of them is actively looking for the information. Effort per person: 2 minutes (knowledge of the new possibility in the ePA app/browser), 1 in 50 gives their consent (burden: 30 seconds) = Total annual minor expenditure (approx. 7 000 hours)		Yearly		No

1.2	Insured	Article 1; Paragraph 345b of SGB V	Read and process information, seek further information if needed	Assumptions: 20 million active ePA users in 2026 (number of logins); one in ten of them is actively looking for the information. Effort per person: 2 minutes (knowledge of the new possibility in the ePA app/browser) One in fiftieth of them gives their consent (expenditure: 30 seconds) = one-off approx. 70.000 hours		unique		No
1.3	Insured	Article 1; §383 a(3)	Submit a complaint	Estimated time needed to lodge a complaint 20 min 3600 complaints*20min= 72 000 min/60 = 1 200 hours		yearly		yes
1.4	Citizens	Article 7; § 3 GDNG	Collection of KVNR by health data holders	9.000.000 (comprehensive estimate of the number of personal data records in the population for which no KVNR is currently collected) *		yearly		yes

				Time spent 1 minute = 150.000 hours				
1.5	Citizens.	Article 7, § 7 in conjunction with § 16;	Filing objections/declarations of non-knowledge	80.000 (Ca. 800.000 young people reach the age of 15 per year, 10 % exercise their right to object) * Time taken 10 minutes = 13.333 hours		yearly		yes
1.6	Citizens.	Article 7; Section 7 in conjunction with Section 16;	Filing objections/declarations of non-knowledge	7.230.000 (72.300.000 citizens over the age of 15, of whom 1 in 10 exercise His right to object) * Time taken 10 minutes = 1 205 000 hours		unique		yes
	Total annual (Hours)			**171.533**				
	Total one-off (Hours)			**1.275.000**				

Details:

Re 1.1 and 1.2

Insured persons should be able to view, via the user interface of a suitable device (app/browser), information on clinical studies for which they, as participants, might be individually suitable on the basis of the data available in the electronic health record (ePA). To do so, they must consent to the processing of their ePA data. At the time of the introduction of this possibility, it is estimated that 20 million. People actively use the ePA. It is assumed that one in ten of them will actively consult the notice and take about two minutes to read the information, and one in fiftieth of them will give their consent (expenditure of about 30 seconds). Again, a fraction of this will be proposed for appropriate studies. This results in a one-off implementing cost of approximately 70.000 hours. Assuming that 2 million new active ePA users are added each year, an additional annual implementation cost of around 7 000 hours will arise. The burden of any subsequent information on studies and participation in the studies is unquantifiable.

Re 1.3

Due to the expected number of 3600 complaints per year under Regulation (EU) 2025/327 from German insured persons abroad in Europe and an estimated duration of 20 minutes per complaint submission, a total implementation cost of 1 200 hours per year is expected on the part of the corresponding insured persons.

Ad 1.4

As a result of the introduction of the research code, the KVNR of the citizens concerned will in future also be collected as an additional date when health data are collected (albeit in the process of being collected). This will only lead to additional costs if the KVNR has not already been collected in the process. Assuming that this generates a maximum of one additional minute of work and affects approximately 9 million citizens per year, citizens incur implementing costs of approximately 150.000 hours per year.

Re 1.5 and 1.6

Citizens may object to the so-called secondary use of their data or make a declaration that they do not wish to be informed of material findings from secondary use concerning them. To this end, they must be given access to information and the opportunity to make declarations. This creates implementing costs for citizens, in particular through the exercise of rights to information and to object. The implementation of the opt-out and the declaration of non-knowledge provided for in Regulation (EU) 2025/327 is for those citizens who wish to be informed about and exercise those rights. It is assumed that, at the time of application of the provision in 2029, 72.300.000 citizens are 15 years of age and over, of whom 10 % exercise their right to object, i.e. submit their declaration to the register of data subject rights. Assuming that this process takes 10 minutes, a one-off implementation cost of approximately 1.2 million hours will arise in 2029. Assuming that a further 800.000 young people reach the age of 14 each year and also make use of 10 % of their rights, an annual implementing cost of approximately 13.000 hours will arise in the following years.

4.2. Compliance costs for industry

Overall, this results in an annual relief for the economy of approximately EUR 445 million and a one-off burden of approximately EUR 0.6 million. At the same time, the relief concerns administrative costs arising from information requirements.

Seq. numb	***Affected***	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***	***Discharge***	***Transposition of***

er								***EU legislation***
2.1	Service Provider	Article 1; § 86a SGB V in conjunction with § 75(1a), § 87 SGB V and § 13(4) Bundesmantelvertrag	electronic credit transfer	Estimate: Approx. 70 million referrals to medical specialists/year Cost of transfer: EUR 1.5 = EUR 105 million	105 million	yearly	105 million	No
2.2	Service Provider	Article 1; § 295(1c) and § 363 c(5) in conjunction with § 73(1b)	Saving on legal obligation to send via KIM	Cost Fax: 0,05+ 0,05+ 1,5*X Cost of postage: 0.85+ 2.50*X average costs Fax 1.60/Porto 3.35 = 2.48 150 million medical letters by post/fax TI refusal 10 % = 135 million medical letters Cost:135	335 million	yearly	335 million	No

				million * EUR 2.48 = EUR 334.8 million				
2.4	PVS Manufacturer	Article 1; § 295(2b)	Interface for EBM data	60 PT (EUR 8*63.70) x 150 PVS manufacturers = EUR 4.5864 million	EUR 4.5864 million	yearly	EUR 4.5864 million	No
2.5	Service Provider	Article 1; Section 339(1b)	Implementation costs of the pharmacy information system	14 AIS x (50PT gD + 10 PT hD) = 14 x EUR 21.500 = EUR 301.000	301.000	unique		No
2.6	PHI	Article 1; Section 362(1)	Applicability of the governance arrangements implementing Regulation (EU) 2025/327 to PHI	No cost	0			yes
2.7	Platform provider for the transfer of vital data from patients to providers	Article 1 §, 374 a(7)	Implementation of an interface	Case number 10 (providers of data aggregation platforms and telemedicine clouds), cost EUR 30.000 per case (220h*135)	300.000	unique		No
2.8	Health data holders Business community	Article 7; § 3	KVNR survey for	Number of cases approx. 150	29.000	unique		yes

		GD NG	research indicator	(private health insurers, data processing companies in the German health sector), cost per case EUR 193 (adjustment of standard procedures, effort 300 minutes) = (300/60 * EUR 36.90/h (WZ: (Q)				
2.9	Health care providers	Article 7; § 15 GD NG	Information requirements under data protection law (Obligation to provide information)	No new obligation to provide information, but clarification	Slightly	unique		yes
2.10	Health data holders Business community	Article 7; § 21 GD NG	Obtaining consent (Obligation to provide information)	Soda costs, consent for the secondary use of certain categories of data is already required today	Slightly	unique		yes
2.11	Researcher business audience	Article 7; § 26 GD	Obligation to register and	Most of the soda-ash costs due to existing	Slightly	yearly		No

		NG	publish (Obligation to provide information)	publication obligations and self-interest				
	Total one-off (Euro) (Burden)					**609.999,8**		
	Total annual (Euro) (Discharge)						**444,586 million**	

Details:

Generally:

Study managers conducting a clinical study may voluntarily carry out their study for the comparison procedure pursuant to § 345b SGB V. Participation shall be voluntary. It can be assumed that this offer will be taken up if this simplifies recruitment. This results in a non-quantifiable reduction of workload for those responsible for the studies.

There is not yet available information on the pro rata costs incurred by the Federal Association of Statutory Health Insurance Physicians on the basis of the requirements of Section 360c in connection with the tendering, development, implementation and provision of an electronic system for a digital assessment of needs. On the basis of partly comparable market products from other European countries, one-off pro rata costs in the medium one-digit to low tens of millions and an annual average six-digit amount for updating, maintenance and further development can be expected.

For manufacturers and providers of information technology systems in the health sector and manufacturers and providers of digital health and care applications, the preparation and implementation of the extended conformity assessment procedure within the meaning of the amended Section 387 of Volume V of the Social Code generates a minor, but unquantifiable, additional burden. Since manufacturers and suppliers of information technology systems are already required to undergo certification or confirmation procedures under the existing scheme, the adjustments are therefore marginal. In addition, there may be an unquantifiable burden for industry in adapting products to the required requirements, which have been extended in the course of this legislative procedure within the meaning of § 387 SGB V, but which are offset by savings due to standardisation potential.

The costs of TI connection as a result of the obligation in the first sentence of § 32a(1) SGB VI cannot be quantified in more detail. The proportion of persons and institutions under the first sentence of § 32a(1) SGB VI who do not yet have a TI connection via SGB V or SGB VII has not yet been determined, in particular for 2029, the year from which the obligation applies. However, the part is likely to be very small because most persons and

institutions provide statutory health and/or accident insurance services at the same time and therefore have an TI connection at least from 2017.

Re 2.1

The introduction of electronic remittances in the outpatient sector as a digitally efficient supply process helps to automate bureaucratic tasks and avoid redundancies, and leads to savings in time and material costs, including by eliminating the manual issuance of paper remittances. In addition, electronic referrals will, in future, create the conditions for efficient and responsive care that avoids duplication of examinations and the associated costs for the health system. By facilitating coordination between general practitioners and specialists and making medical information available safely and quickly, electronic referrals promote more efficient treatment processes and save costs.

In the absence of available figures, the estimated cost of treatment and discharge is estimated at around 70 million referrals per year from contracted doctors. This figure is based on an estimated number of 350 million specialist contacts in the outpatient sector and an estimate of one in five. Specialist contact is established by referral. In the event that, depending on the specific design of the planned primary care project, in the majority of cases of outpatient specialist treatment a transfer reservation should apply in future, up to 350 million transfers under contract would have to be issued, even depending on the design of the primary care system.

For the removal of special printer forms, toners and maintenance costs and the time-relief of doctors and other practitioners, reductions of EUR 1.50 are assumed per transfer case, leading to an estimated annual saving of around EUR 105 million.

On the other hand, the costs associated with the introduction of electronic credit transfers are primarily limited to one-off time-limited development and conversion costs based on the existing telematics infrastructure and its components, services and applications, and are marginal in relation to the long-term, regular savings.

Re 2.2

In order to determine the implementing costs, the average costs of sending a doctor’s letter are first calculated by comparing and averaged the costs of sending by fax and the costs of sending by post. This average cost of delivery is then multiplied by the approximately 150 million medical letters sent annually. As it is assumed that around 10 % of TI refusals still do not use electronic communications, these cases are deducted from the calculation. The calculation is therefore based on 90 % of the total number of medical letters sent. On this basis, the annual cost volume or potential savings from the mandatory use of the secure transmission procedure KIM can be determined. The result is a saving of EUR 335 million.

Re 2.4

The EBM data for the settlement of medical services previously provided via the KBV website will in future be made available to primary system manufacturers via an interface specified by the KBV. This removes the need for PVS manufacturers to manually compile EBM data on a quarterly basis. In future, the primary systems will be able to download the data directly from the KBV-EBM interface to the primary system and integrate it there. This leads to a saving of 15 PT in the higher service per quarter for each primary system manufacturer.

Re 2.5

The 14 pharmacy information systems (AIS) on the market need to be technically updated based on the e-prescription mesh specification adaptation to support the new e-prescription token functionality to access the ePA. The cost of this is 0.3 million euro.

Re 2.7

The number of providers of data aggregation platforms and telemedicine clouds operating on the market in Germany transferring data from patients' assistive devices and implants to healthcare providers is estimated at ten. If the cost of implementing an interface is EUR 30.000 per case (EUR 220h*135), the total cost is EUR 300.000.

Re 2.8

The amendment to the Health Data Usage Act will create implementing costs for industry as a result of the introduction of the research metric, which obliges industry actors to collect both the health insurance number and the research metric when collecting personal health data. For the survey of the KVNR, one-off implementing costs of approximately EUR 0.7 million are estimated for the adaptation of specialist procedures. Further implementing costs arising in connection with the generation of the research indicator will be determined in the course of the adoption of the statutory ordinance on §3 GDNG.

4.3. Implementation costs for the administration

Bund

In total, the Federal Government will be burdened with a one-off additional charge of approximately EUR 0.2 million.

Seq. number	***Affected***	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***	***Discharge***	***Transposition of EU legislation***
3.1		Articles 1 and 312(5) of Volume V of the Social Code	Task allocation	There are no additional costs arising from the implementation of the existing mandate to the Telematics Company pursuant to § 312(5) SGB V.				No
3.2	Bund	Article 1, § 370c	Agreement on digital	72*67.60 (100 % hD)	5.000	unique		No

		SGB V	appointment booking platform	= EUR 5000				
3.3	BfArM	Article 1, § 374a(2)	Interfaces and testing system	740*67.60 (100 %hd) = EUR 50.000 120*67.60 (100 %hd) = EUR 8000	58.000	unique		No
3.4	genetics	Article 1; Section 354(8)	Terms of reference of the Telematics Society for the ePA		minor (feasible in the context of ongoing tasks and activities)			No
3.5	Accident and pension insurance, federal research institutions, districts/district-free cities, state aid agencies	Article 7; § 3 GDNG	KVNR survey for research indicator	Approx. 440 (accident and pension insurance, federal research institutions, districts/district-free cities, state aid agencies) EUR 193 = (300/60 * EUR 48.10/h EUR 106.000	106.000	Unique		yes
3.6	BfDI	Article 7; § 17 GDNG	Competent data protection supervisory authority	Minor (low number of cases expected)				yes

3.7	Data holder Addressee group Administration	Article 7; § 21 GDNG	Specific rules for electronic health data	Minor, consent for the secondary use of certain categories of data is already required today and needs to be regularly adapted.				yes
3.8	Federal Government/Länder	Article 7; § 24 GDNG	Processing of health data with authorisation from the data protection supervisory authority	Approx. 5 cases/year	Minor (low number of cases)			No
3.9	Administrative users of data	Article 7; § 26 GDNG	Obligation to register and publish	Most of the soda-ash costs due to existing publication obligations and self-interest	Slightly			No
	Total annual (Euro)							
	Total one-off (Euro)					**170.400**		

Details:

Generally:

The extension of the tasks of the Competence Centre for Interoperability in Health Care, and in particular with regard to the further adaptations of Sections 385 to 388 of Volume V of the Social Code, does not entail any additional implementing costs for the Federal Government. The publication of the binding provisions may be carried out by the competence centre in the same way as the process already set out in the Act on

Accelerating the Digitalisation of Health Care (Digital Act). Again, this will streamline and significantly speed up the process, which will also have an impact on small, non-quantifiable discharges. The extension of the market-centric approach to enforcement under the liability mechanism pursuant to Section 388 of Volume V of the Social Code also further reduces red tape costs to a small, unquantifiable extent.

Additional implementing costs for the administration arise in particular as a result of an extension of the responsibilities of the coordinating data access body, data provision obligations for data holders under Regulation (EU) 2025/327 and in connection with the establishment and operation of the register to implement data subjects' rights. The additional expenditure results directly from the implementation of Regulation (EU) 2025/327 and is therefore not calculated separately here. Implementing costs arising from the establishment of domain-specific data access bodies, the designation of health data intermediaries and trusted data holders will be determined in the course of the adoption of the respective statutory ordinance.

Re 3.3

Section 374a(2): The Federal Institute for Medicinal Products and Medical Devices incurs a one-off cost of EUR 50.000 (two interfaces) plus EUR 8000 (testing system) equal to EUR 58.000 as a result of providing two interfaces and a testing system.

Re 3.5

As a result of the obligation to collect the research indicator, the estimated 440 data holders from the public administration (federal government, Länder, municipalities and social security institutions) will incur one-off implementing costs of an estimated EUR 0.16 million for adapting existing technical methods of data collection.

Social security funds,

In total, compulsory health insurance is relieved by approximately EUR 3.1 million a year. A one-off charge of EUR 12.9 million is incurred.

Seq. number	***Affected***	***Norm***	***Keyword***	***Calculation process***	***Amounts in EUR***	***Frequency***	***Discharge***	***Transposition of EU legislation***
4.1	Health insurance funds	Article 1; Section 33a(6) of Volume V of the Social Code	Removal of the annual reporting obligation for the GKV-SV	8 958 hours* EUR 67.60 (100 % hD) EUR 200.000	200.000	yearly	200.000	No

4.2	KBV	Article 1 § 73(9a) SGB V	Authorisation e Programs	10 authorisations /year (Based on assumptions) 480 min*67,6/ hour (hD) = EUR 5400 Once only: 1 200 min* 67.6/hour (hD) = EUR 1400	5.400 1.400	yearly Unique		No
4.3	KBV	Article 1 § 73(9a) +b SGB V	Certification IT systems/ Interface 116117	10 authorisations /year (Based on assumptions) 480 min*67,6/ hour (hD) = EUR 5400 Once only: 1 200 min* 67.6/hour (hD) = EUR 1400	5.400 1.400	yearly Unique		No
4.4	Health insurance funds	Article 1, § 217f(4e)	Establishment of a Directive on procedures for handling the electronic health	Alignment with the cost structure of previous obligations to establish existing directives Costs below the de minimis level of < EUR	slightly	unique		No

			record	100.000				
4.5	Health insurance funds	Article 1, § 291a(2) SGB V	Costs for the implementation of the MXID	10 hours of work on implementation EUR 48.10 (average qualification) 94 health insurance funds * EUR 48.10 * 10 = 45.214	50.000	unique		No
4.6	KBV	Article 1; § 295(2b)	Interface for EBM data	Interface specification EUR 25.000 Operation of the web service interface EUR 5000 per year	25.000 5.000	unique yearly		No No
4.7	genetics	Article 1, Section 307(5) SGB V	coordinating Body Extension e-prescription and KIM and TIM	3 full-time equivalents 200 days*8h* EUR 52.80 = EUR 84.480* 3 = EUR 253.440	253.440	yearly		No
4.8	genetics	Article 1, Section 329(1-3a) SGB V	organisational measures Disruptions TI	one person hD gemamatically per year; EUR 108.160	108.160	yearly		No
4.9	genetics	Article 1; Section 339(1b) of Volum	E-recipe token specification and devel	500 PT gD + 150 PT hD = EUR 242.720	242.720	unique		No

		e V of the Social Code	opment					
4.10	Health insurance funds	Article 1, § 339(1b) SGB V	Implementation of the e-recipe token in the file system	400PT gD + 125PT hD = EUR 197.000 x 2 file systems = EUR 394.000	394.000	unique		No
4.11	Health insurance funds	Article 1, Section 341(2) of Volume V of the Social Code	Setting up of the health insurance fund and nursing staff in the ePA	One-off adaptation of ePA file systems 4hD 16 PT gD x 2 file systems = EUR 11.000	11.000	unique		No
4.12	genetics	Article 1; Section 341(2) of Volume V of the Social Code	Creation of nursing care and health insurance specialist	8h gD = EUR 323,20	323,20	unique		No
4.1 13	genetics	Article 1; Section 342(2) of Volume V of the Social Code	More rights Ombudsperson	2PT hD + 18PT gD = EUR 6900	6.900	unique		No
4.14	Health insurance funds	Article 1,	Manageme	93 sickness funds x 15 PT	450.0	uniqu		No

		Section 342(2) of Volume V of the Social Code	nt of representatives through the Ombudsperson	gD = 93 sickness funds x EUR 4848 = EUR 450.000	00	e		
4.15	GKV-SV	Article 1, § 343(1a) SGB V	Update info material	One-off adaptation of the information material provided by the funds on the ePA for insured persons: 10 PT gD = EUR 3.232	3.232	unique		Point 25: yes; Points 10 and 18: No
4.16	Health insurance funds	Article 1; Paragraph 345a of SGB V	Health insurance funds must offer insured persons digital access to care in the ePA app	5 EUR 800*67.60 (100 % equivalent to hD) x 5 apps = EUR 270.000	270.000	unique		No
4.17	Health insurance funds	Article 1, Section 345a(1)(2) of Volume V of the Social Code	Health insurance funds must offer digital initial assessment applications to insure		minor (many health insurance funds already offer their insured persons initial			No

			d persons		assessment applications; Costs continue to be incurred to the same extent as before)			
4.18	Health insurance funds	Article 1, Section 350(2) SGB V	digital vaccination overview	50 PT (10PT hD + 40PT gD) x 93 KK = EUR 1.7 million	EUR 1.7 million	unique		No
4.19	KBV/GKV-SV	Article 1, Section 360b(1) SGB V	Agreement on digital assessment of findings	Estimated effort: 2 persons per organisation (wage high EUR 62), 50 % of working time, total duration 160 hours Invoice: 62x2x2x0.5x160= EUR 19.840 + 60h Coordination effort with external organisations and BMG (20+ 40) X 62= EUR 3720 = EUR 23.560	23.560	unique		No

4.20	KBV/GKV-SV	Article 1, Section 360b(5) SGB V	Update of agreement on digital assessment of findings	Estimated effort: 2 persons per organisation (wage high EUR 62), 50 % of working time, total duration 60h Invoice: 62x2x2x0.5x60 = EUR 7.440 + 30h Coordination effort with external organisations and BMG (10+ 20) X 62= EUR 1860 = EUR 9,300	9.300	yearly		No
4.21	KBV/GKV-SV	Article 1, § 360c	proportional funding of an electronic system of digital needs assessment	The initial implementation and deployment of an electronic system of digital needs assessment incurs one-off costs estimated at a small tens of millions of euros.	10 million	Unique		No
4.22	KBV/GKV-SV	Article 1, § 360c	proportional funding of an electronic system of digital needs assessment	The technical maintenance, content and technical update and further development of the electronic system of a digital needs assessment will require an average six-	700.000	yearly		No

				digit amount per year.				
4.23	GKV-SV	Article 1, Section 374a(6) SGB V	Adoption of the Directive	72*67.60 (100 %hd) = EUR 5000	5.000	unique		No
4.24	Health insurance funds	Article 1, Section 383(1)-(6) of Volume V of the Social Code	Deletion of Pau-schale e-doctor's certificate	According to the GKV-SV, the cost of the e-doctor's letter and the transmission of a fax in 2023 is around EUR 4 million.	4 million	yearly	4 million	
4.25	genetics	Article 1, Section 383a(2) SGB V	Activity report every 2 years	Estimated reporting time 8 weeks/1 person: 8*40h=320h EUR 320*62 (high-health wage costs) = EUR 19.840/2	10.000	yearly		yes
	Total annual (euro)						**3.1033 million**	
	Total one-off (euro)				**12.941.535,2**			

Details:

Generally:

The costs of setting up the competence centre for interoperability in healthcare pursuant to Section 311(1), first sentence, point 8, of Volume V of the Social Code and the costs of fulfilling the corresponding tasks pursuant to Section 385 of Volume V of the Social Code have already been recorded and quantified in the context of the Digital Act. The extension of tasks as a result of the current changes to the Twelfth Chapter of Volume V of the

Social Code generates unquantifiable small expenditure on social security. The performance of the extended tasks is reflected in the existing structures and processes.

The costs of pension insurance for connection to the telematics infrastructure as a result of the obligation in the first sentence of § 32a(1) SGB VI cannot be quantified in more detail. The proportion of persons and facilities referred to in the first sentence of Section 32a(1) of Volume VI of the Social Code that do not yet have a connection via Volume V of the Social Code or Volume VII of the Social Code has not yet been determined, in particular for 2029, the year from which the obligation applies. However, the number is likely to be very small because most persons and institutions provide statutory health and/or accident insurance services at the same time and therefore have an TI connection at least from 2017.

Re 4.5

For the introduction of the Matrix ID, a one-off workload of around 10 hours is estimated for each health insurance fund. At an average cost rate of EUR 48.10 per hour, the implementing costs result from multiplying the hourly rate by the time spent and the total of 94 statutory health insurance funds. The implementing costs for this are approximately EUR 50.000 on a one-off basis.

Re 4.7

The existing coordinating body at gematik GmbH is given the additional task of receiving concerns relating to the electronic prescription and the secure communication procedures ‘Communicating in the medical sector’ and the TI Messenger. This will require three additional full-time equivalents from the information and communication sector, at a total cost of EUR 253.440 per year.

Re 48

Due to the increasing complexity of the telematics infrastructure and the increasing number and variety of incidents, additional human resources are needed to efficiently ensure organisational measures for the coordination, analysis and follow-up of incidents. In particular, the additional person is needed to coordinate with the suppliers and manufacturers involved, to provide organisational support for remedial measures and to ensure the TI’s operational resilience in a timely manner. The annual effort corresponds to one FTE with a higher level of complexity.

Re 4.9

The extension of the e-recipe token requires a one-off adaptation of the specification by the mesh. In addition, one-off costs are incurred for the technical adaptations of the e-prescription specialist service in the field of mathematicals. The total cost is 0.24 million euro.

Re 4.10

The support of the e-recipe token as access to the ePA needs to be implemented in the two ePA asset systems on the market. This has to be implemented by the two file system manufacturers in their systems, for which the compliance costs amount to EUR 394.000.

Re 4.14

The health insurance funds must adapt their processes in the already existing ombudsman institutions and train staff with regard to the newly created § 342a(4a) and (4b), according to which insured persons may request the ombudsman institution to set up

one or more representatives or to delete registered representations. This represents a total cost of 0.45 million euro.

Re 4.16

The implementation of the digital service start-up needs to be implemented in the five ePA apps on the market. Manufacturers must implement this in their systems. This will require the social security institutions responsible for the ePA to pay a total of EUR 270.000.

Re 4.18

All 93 health insurance funds have to provide their insured persons with a digital vaccination overview. In order to do so, the billing data held by the health insurance funds must be searched electronically for vaccination data, processed and stored in the ePA. The cost of adapting health insurance systems is EUR 1.7 million.

Ad 4.19

The contractual partners of the Bundesmantelvertrag-Ärzte (BMV-Ä), GKV-Spitzenverband (GKV-Spitzenverband) and Kassenärztliche Bundesvereinigung (Federal Association of Statutory Health Insurance Physicians) incur a one-off cost of EUR 23.500 for the preparation of the contractual content for a digital needs assessment, including the conclusion of a corresponding agreement.

Re 4.10

An annual cost of EUR 9,300 is incurred for updating the agreement on digital needs assessment between the contracting parties of the Bundesmantelvertrag-Ärzte (BMV-Ä), GKV-Spitzenverband (GKV-Spitzenverband) and the Kassenärztliche Bundesvereinigung (Federal Association of Statutory Health Insurance Physicians).

Re 4.21 and 4.22

For the first time, a nationwide uniform electronic system for digital needs assessment is estimated to cost around EUR 10 million in implementing costs. Comparable, complex systems used abroad have generated costs of around EUR 6 to 14 million up to their market maturity. On this basis, the average of around EUR 10 million (~ 161 thousand person-hours/wage costs high) is used for the initial development, implementation and provision of an appropriate electronic system. The costs include, in particular, the technical and medical design, the carrying out of a procurement procedure, project management, the development of the software, including the definition and examination of the medical decision-making logics, safety tests, testing and the initial technical implementation in the statutory health insurance system. The cost is one-half for both parties to the contract.

For the ongoing technical operation, maintenance and updating of the electronic system for digital needs assessment, an annual implementing cost of approximately EUR 700.000 (~ 11.300 man-hours/high wage costs) is estimated on the basis of experience with comparably complex electronic systems. The efforts include, in particular, technical and medical updating and quality assurance, technical maintenance and troubleshooting, the carrying out of security and data protection updates and the continuous development of the electronic system. Each year, half of the costs are incurred by both contractors.

Re 4.23

Section 374a(6): The GKV-Spitzenverband incurs a one-off cost of around EUR 5000 as a result of drawing up a directive.

Re 4.24

The removal of the lump sum for the e-doctor’s certificate will result in a reduction of around EUR 4 million per year.

Re 4.25

The preparation of the activity report pursuant to Section 383a(2) generates an estimated annual expenditure of around EUR 10.000 on the part of the legally mandated gematik GmbH. This was calculated on the basis of eight weeks’ time spent by a person working full-time.

5. Further costs

The draft law does not entail any costs in excess of the listed expenses and the aforementioned implementing costs. No impact on unit prices and price levels, in particular on consumer price levels, is expected.

6. Further legislative consequences

The measures in the draft law will advance the digitalisation of our healthcare system to ensure even safer, better and quality-assured care in the future. This ensures that the population in Germany continues to benefit from high-quality care. People insured under the statutory health insurance scheme in particular benefit from a more data-driven healthcare system. Other sections of the population also benefit from better use of health data, among other things. Better data availability for research and innovation will provide a basis for generating new scientific knowledge.

VIII. Time-limit; Evaluation

This draft law does not provide for a separate evaluation of the EHDS secondary use procedure, as an evaluation and review as well as a progress report are already directly provided for in Regulation (EU) 2025/327. Various rules on evaluation are already foreseen for existing data access mechanisms under GDNG, which will be adapted in this draft law.

B. Specific part

Re Artikel 1 (Amendment of Volume V of the Social Code)

Too Nummer 1

Too Buchstabe a

The purposes in paragraph 1 shall be adapted. A new point 3 is inserted and the existing point 4 (now point 5) is adapted.

Cardiovascular diseases are the leading cause of death in Germany, accounting for about one third of all deaths and contributing significantly to the individual and social burden of disease. The insertion of the new point 3 is therefore intended, in addition to the current point 5, specifically to enable data-based detection and subsequent warnings in the event of an increased risk or in the event of pre-existing early stages of serious cardiovascular disease. In order to promote secondary prevention, account should be taken in particular of family risks, behavioural risk factors (such as physical inactivity, unhealthy diets,

tobacco and alcohol consumption) and pre-existing risk diseases (such as high blood pressure, fat metabolism disorder, diabetes and obesity).

Examples of serious cardiovascular diseases include heart attacks, strokes, heart failure, peripheral arterial closure disease and vascular (co-)dementia.

The aim of the current point 4 is to preserve health resources through preventive benefits, to promote self-employment and thereby to delay or avoid reliance on care. This objective is pursued above all in the case of reliance on care. Since existing reliance on care can be stabilised or delayed by appropriate preventive measures, the threat of reliance on care also addresses an increase in the severity of reliance on care where there is already reliance on care. This is particularly true for people with dementia. For them, preventive interventions are usually not only aimed at preventing the onset of dependency, but also at slowing down the course of the disease and maintaining cognitive skills.

Too Buchstabe b

Too Doppelbuchstabe aa

Under § 25b, health insurance funds and long-term nursing care funds may use the data held by them even without the consent of the insured persons concerned. In principle, this includes all data accessible to the respective health insurance funds or care funds. As a rule, however, health insurance funds do not have access to data in the electronic health records.

The adaptation in point (b) allows health insurance funds and care insurance funds to use data in the electronic health records of their insured persons, provided that the conditions laid down in § 345 are met and that the data from the electronic health record are suitable and necessary for the relevant evaluation programme pursuant to § 25b. § 345 provides for the prior consent of insured persons as a condition. In order to be able to use data from the electronic health records in an evaluation programme, the health insurance fund or nursing care fund must therefore obtain the prior consent of the insured persons concerned. Such consent may be obtained for an individual evaluation programme for a specific purpose pursuant to Section 25b(1). Alternatively, insured persons may also give their general consent to the use of their data in the electronic health record for further future evaluation programmes pursuant to § 25b.

In addition to ePA data, it is also possible to process additional data collected from insured persons or from wellness applications (e.g. wearables, such as smart watches) under § 25b. This also requires informed consent from the insured persons concerned. In so far as this corresponds to the declared will of the insured persons, an extended database can therefore be processed for the evaluations under § 25b in order to obtain even more accurate evaluation results.

The required consents and the analysis of the data are subject to the requirements of the GDPR. In particular, they must be given voluntarily and in an informed manner. Data-driven evaluations shall take into account possible gender biases in the data base and evaluation procedures.

Too Doppelbuchstabe bb

This is a consequential amendment.

Too Doppelbuchstabe cc

This is a consequential amendment resulting from the addition of several additional sentences.

Too Buchstabe c

The amendment is a clarification of an obligation on health insurance funds to provide information to insured persons whose data are processed as part of an evaluation programme pursuant to § 25b. As clearly stated in the explanatory memorandum to the Federal Government's draft law on the improved use of health data, this initial information to insured persons should be provided to the public only and should be of a low-threshold nature. In order to resolve legal interpretation difficulties, the amendment now makes it clear once again that individual, non-public information does not have to be provided in any case. A single public information measure, e.g. on the health insurance fund's website, is sufficient to fulfil the obligation to provide information.

Too Buchstabe d

The amendment to the fourth sentence adapts the formal requirement for statements under the first sentence of paragraph 4. It is true that, in principle, the information must continue to be provided in writing. However, this written form can now be derogated from with the consent of the insured persons.

The new fifth sentence clarifies the relationship between information pursuant to § 25b and information on individually suitable pension innovations and other individually suitable pension benefits pursuant to the first sentence of § 68b(2). This information may also be sent with the notices. For example, attention can be drawn to pension schemes run by the funds. However, specific treatment recommendations or proposals concerning specific providers may still not be submitted with instructions pursuant to the first sentence of § 25b(4).

The adaptation of the previous fifth sentence clarifies the obligation to include the information in the EHR.

Too Buchstabe e

The amendment concerns the deletion of a duty to provide information on the part of the health insurance fund or long-term care fund. Under this provision, the board of directors of a health insurance fund or long-term nursing care fund had to be informed without delay of a programme for an evaluation as referred to in paragraph 1. The deletion is intended to reduce red tape and the burden on health insurance funds and long-term care funds. In view of the many other transparency measures and information obligations provided for under § 25b, the deletion is appropriate. In particular, in view of the continued obligation to notify under the first sentence and the continuing three-tier system of information measures in favour of insured persons, the procedure should be streamlined. Whether a health insurance fund or long-term nursing care fund informs its management board of a programme for an evaluation referred to in paragraph 1 and the timing of such information is thus again placed under the responsibility of the health insurance fund or long-term nursing care fund.

Too Nummer 2

Insured persons who use at least three prescribed medicinal products at the same time are entitled to have a medication plan drawn up by a doctor participating in the statutory health insurance scheme. The doctor is obliged to draw up the medication plan and hand it over in printed form at the request of the insured person. Details are agreed between the Federal Association of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds.

In future, there should be a uniform electronic medication plan in the care sector. If the insured person has an electronic health record (ePA) and has not objected to the digitally-

supported medication process pursuant to Section 342(2a)(1) or to access to the ePA as a whole, the medication plan must be stored in the ePA. Otherwise, the doctor must store it in the information technology system which he uses.

Each doctor must update the medication plan as soon as a change in the medication occurs or the insured person informs him/her accordingly. When a medicinal product is dispensed, the pharmacy must update the medication plan to the extent necessary, for example because a medicinal product other than that prescribed by a doctor is dispensed or in the case of the dispensing of non-prescription medicinal products.

The organisations referred to in paragraph 4 shall be responsible for the content and technical requirements to be laid down for drawing up and updating the medication plan and its updating. In order to ensure uniform technical design of the medication plan and uniform requirements for storage in the ePA, agreement must be reached with the Telematics Society. In view of the objective of establishing a uniform medication plan in care, it is necessary to ensure that the electronic medication plan is drawn up in a uniform format.

Too Nummer 3

This is an editorial adjustment as a result of the restructuring of Section 31a.

Too Nummer 4

Too Buchstabe a

This is a declaratory clarification without extending the entitlement to benefits. For example, the extension of the risk classes in the Digital Act also made it possible to implement technical procedures for the data-driven, timely management of diseases via physical distance (telemedicine monitoring). Due to the continuous collection and analysis of data, Diga can form the core of care processes in the context of telemedicine monitoring. The possibility of including accompanying medical services in the assessment of the positive care effect, as well as the downstream possibility of reimbursing accompanying medical services, ensures that comprehensive monitoring plans can be assessed and reimbursed. At the same time, there is a reliable and tested framework of requirements for the digital medical devices used. In this respect, there is no need to build up complex parallel processes for telemedicine monitoring, so that corresponding care approaches can quickly become part of care after comprehensive examination. The joint assessment of digital mobile applications and applications with the purpose of telemedicine monitoring follows processes currently being introduced in France.

Too Buchstabe b

The purpose of the provision is to regularise the law. Since the legal framework for medical devices has been adapted in the meantime, it needs to be adapted. The change does not alter the entitlement to benefits. On the basis of the provisions of the legislation on medical devices – including transitional provisions – marketability remains fully in place. As a result of the general reference to medical device law, the reference also covers devices which must also comply with the requirements of European law on artificial intelligence (‘the AI Act’).

Too Buchstabe c

Too Absatz 6

The aim of the scheme is to cut red tape. The Central Federal Association of Health Insurance Funds (GKV-SV) is released from its obligation to draw up a report on the

supply of Diga. Instead, the GKV-SV will in future report the anonymised and aggregated raw data collected as part of the reporting to the Federal Ministry of Health. The BMG publishes the data directly. This can also be done, for example, through the Federal Government's health monitoring system, in order to ensure comprehensive access to data and the usability of the data.

Too Absatz 7

The scheme allows for the publication of transmitted data for transparency purposes.

Too Nummer 5

Too Buchstabe a

The amendment to paragraph 3 makes it clear that the GKV-Spitzenverband lays down binding requirements for the participation of service providers in the genome sequencing pilot project in accordance with the sixth sentence. The GKV-Spitzenverband has the 'Criteria for determining eligibility for participation of hospitals or oncological centres (hospitals) organised in networks in the model project of genome sequencing pursuant to § 64e(3) SGB V' as at 1 Published on its website and applied during the current period of validity of the contract pursuant to the first sentence of Paragraph 64e(1) of the SGB V. This procedure corresponds to the procedure provided for in the explanatory memorandum to the Healthcare Development Act of 11 July 2021 (BGBl. I, p. 2754) (BT-Drucksache 19/30560, p. 31). This clarification is necessary for reasons of legal certainty, according to the initial experience with the participant procedure. The mandatory participation criteria laid down by the statutory health insurance association (GKV-Spitzenverband) are a key aspect of the quality assurance of the implementation of the pilot project and essential for its continuation.

Too Buchstabe b

The addition clarifies that the GKV-Spitzenverband determines the details of the application procedure. This applies, for example, to the setting of time-limits and formal requirements.

Too Buchstabe c

Alignment of the citation of EU Regulation with the new requirements of the Manual of Legal Formality, according to which a short quotation is sufficient.

Too Buchstabe d

This is an editorial amendment to change the name of the former Federal Ministry of Education and Research by the organisational decree of the Federal Chancellor of 6 May 2025 (BGBl. 2025 I No 131).

Too Buchstabe e

These are consequential changes due to the change in the data flow in the third sentence of paragraph 10.

Too Doppelbuchstabe aa

Too Dreifachbuchstabe aaa

Too Buchstabe f

Too Doppelbuchstabe aa

The amendment to the third sentence of paragraph 10 optimises the flow of data in the interests of data minimisation and, in particular, to secure pseudonyms. The requesting service provider shall transmit to a data service its request criteria for case identification in accordance with point 1 of the seventh sentence of paragraph 9c and the data service concerned shall query the clinical data nodes or genomic data centres with a project number and the request criteria. The clinical data nodes or genome data centres concerned shall provide the operation number and a list of identified pseudonyms to the trusted entity. The data service shall request the request criteria from the clinical data nodes or genomic data centres, which shall establish a list of identified pseudonyms and send this list with the pseudonyms to the trusted entity. From this, it generates a new, temporary transaction number for each pseudonym, and, in the case of several pseudonyms, a list with transaction numbers, the operation number and the associated contact details of the service provider, and sends it to the platform carrier or data service. Thus, the pseudonyms are known only to the clinical data node concerned, genomic data centres and the trusted entity.

Too Doppelbuchstabe bb

The amendment to the fourth sentence of paragraph 10 is a consequential amendment to the eleventh sentence of paragraph 9c as a result of the amendment to the data flow in the third sentence of paragraph 10.

Too Buchstabe g

The amendment to paragraph 11a bundles the responsibility for the obligation of confidentiality under Section 1(2) and (3) of the Obligations Act with the platform operator. Under the current legal situation, it is true that the platform owner can make the individual data sets available to persons. This presupposes, however, that the provider was obliged to maintain secrecy before accessing the data in accordance with the provisions of the Obligations Act. Pursuant to Section 1(4)(2) of the Obligations Act, the competence of the authority that is required to carry out the obligation under the Obligations Act is determined by the law of the respective federal state. The amendment makes access to data faster and more practicable in order to reduce red tape (‘everything out of one hand’ principle).

Too Buchstabe h

This is an editorial amendment to change the name of the former Federal Ministry of Education and Research by the organisational decree of the Federal Chancellor of 6 May 2025 (BGBl. 2025 I No 131).

Too Nummer 6

The new paragraph 9a provides, in preparation for the introduction of electronic referral processes, that, as of 1 September 2029, contracted doctors may only use electronic programs for the issuance of electronic referrals that contain the functions and information necessary to create, transmit and retrieve electronic referrals and that are authorised by the Federal Association of Statutory Health Insurance Physicians to provide treatment

under the statutory health insurance scheme. The details are to be agreed in the federal coat agreements.

The newly introduced paragraph 9b ensures that contracted doctors use only software approved by the Federal Association of Statutory Health Insurance Physicians to report appointments to the 116117-termination service pursuant to § 75(1a), sentences 20 and 21.

The already existing interface for reporting appointments for the 116117 appointment service – including the specifications for appointment synchronisation and the push notification service – allows appointments to be provided and managed directly from the practice's appointment management system in the 116117 appointment service. It is now to become mandatory for the further development of the 16117-term service as an important building block of the supply system. Therefore, as of January 2028, all software systems used in the practices of panel doctors to report appointments pursuant to § 75(1a) must have mandatory integration of this interface.

The new paragraph 9b gives the Federal Association of Statutory Health Insurance Physicians the responsibility for verifying the integration of the interface for appointments as part of an authorisation procedure for information technology systems. The term IT systems covers both practice management systems and other appointment management systems. It is therefore made mandatory for all manufacturers of IT systems used by contracted doctors to manage their treatment appointments, to implement the appointment service interface and to undergo a corresponding approval procedure at the Federal Association of Statutory Health Insurance Physicians. The Federal Association of Statutory Health Insurance Physicians shall determine the course, form and content of the procedure, such as checking compliance with the technical requirements for the interface pursuant to Section 370a(5), validity and withdrawal of the authorisation, and provisions on any re-approval that may be required, in consultation with the federal associations in the field of information technology in the health sector that are relevant for the defence of the interests of industry. As of 1 March 2027, the Federal Association of Statutory Health Insurance Physicians is to start the approval procedure and report to the Federal Ministry of Health on the status of the procedures carried out by 30 June 2027. The Federal Association of Statutory Health Insurance Physicians is also required to publish a list of approved software systems on an ongoing basis.

Too Nummer 7

The Federal Associations of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds will in future have to conclude their agreements with the Telematics Association on the part of the Federal Sickness Insurance Contracts regulated here. This will enable them collectively to protect the interests of service providers who supply the services covered by this Regulation.

The deletion of time limits in the past is part of the process of legal regularisation.

Too Nummer 8

The new version is due to a specific adjustment of the previous deadline as a result of the newly introduced Section 360a and is intended to ensure that the Federal Associations of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds lay down rules on the accessible use of electronic credit transfers in preparation for the planned primary care system. The wording 'as soon as they become available' in the second sentence is linked to the Telematics Company's mandate under § 312(5) to carry out the necessary measures by 1 September 2028 and takes into account the fact that the exact time of making available depends on technical implementation.

The addition of the characteristics ‘structured’ and ‘interoperable’ is of a clarifying nature; it makes it clear that the intention underlying the draft bill is that the requirements to be laid down in the Federal Master Agreement must ensure that the data set for electronic transfer to the applications and services of the telematics infrastructure can be connected. The necessary rules also include provisions to ensure that the receiving doctor can access the contact details of the transferring healthcare provider through the secure transmission procedures of the telematics infrastructure as part of the electronic referral process.

The additional consultation with the Competence Centre on Health Interoperability follows the system established by the Digital Act and extended by this Act, and ensures that the specifications relevant to the electronic referral data set are designed early and coherently with the requirements for which the Competence Centre is responsible.

Too Nummer 9

This is a consequential adjustment due to the deletion of § 311(6). In addition, a consequential amendment is being made to adapt the legal definition in Section 341(2)(1)(d), which now also includes the electronic discharge letter in addition to the electronic doctor’s letter, by rewording point 3, which refers to it.

Too Nummer 10

Too Buchstabe a

Until now, the health insurance funds have been obliged, within two weeks of being requested to do so by the Institute of the Evaluation Committee (InBA), to submit to the InBA, via the GKV-Spitzenverband, certain data needed for the calculation of the hybrid DRG (case numbers and remunerations, including material costs under the AOP contract and material costs under the overall contract for remunerated cases). As these data are in any case to be transmitted by the health insurance funds to the GKV-Spitzenverband in its capacity as data collection body pursuant to § 303b(1), the use of the data from the data transparency procedure can save the additional data transmission by the health insurance funds. To this end, the GKV-Spitzenverband is authorised to transmit the relevant data to the InBA on request. This avoids duplication of effort – not only for the transmission of data as such, but also for the quality checks required in this context. Contributions will be made to cutting red tape and data minimisation.

Too Buchstabe b

The legislator has provided for a regular evaluation of the hybrid DRG, for which the contracting parties referred to in the first sentence of paragraph 1 must entrust the InBA and the Institute for the Hospital Pay System. In line with the amendment to point (a), provision is made for the GKV-Spitzenverband to transmit the billing data already available to it from the data transparency procedure pursuant to point 3 of the first sentence of Section 303b(1) to the InBA in a uniform pseudonymised form, on a practical, medical and case-by-case basis, by contracted health care providers in accordance with paragraph 3. A deadline of four weeks after the InBA’s request is set for this purpose. The data should make it possible to refer to the practice, doctor and case in pseudonymised form in order to ensure sufficient evaluation and evaluation.

Too Nummer 11

Too Buchstabe a

The extension of the deadline for challenging the agreement will give the Federal Ministry of Health more time for regulatory scrutiny. It is difficult to assess the complex agreement

over a period of one month. An audit within a short period of time is particularly challenging if the audit periods conflict with holidays or holidays.

Too Buchstabe b

Under point 4 of the second sentence of Section 129(5h), assisted telemedicine measures that pharmacies may offer include, in particular, advice on the exercise of the rights of the person concerned under Sections 336 and 337, allowing access to the electronic health record and carrying out the deletion of data at the request of the insured person. The access rights of pharmacists and persons belonging to the pharmacy's pharmaceutical staff (cf. § 352(1), first sentence, point 6), which are necessary for these measures to be available, are now added to § 352(1), first sentence, point 5(b). The current content of sentence 17 has been deleted as it has become redundant with the provision of the opposition-based ePA pursuant to the second sentence of Section 342(1). Instead, sentence 17 now makes it clear that access under sentence 16 is permitted only for the purposes referred to in sentence 2, point 4.

Too Nummer 12

This is a consequential adjustment due to the deletion of § 311(6).

Too Nummer 13

The Central Federal Association of Health Insurance Funds is tasked with laying down uniform procedural requirements for electronic health records for all health insurance funds. In the operational operation of the electronic health record, health insurance funds have in the past implemented requirements in various ways, which have led to individual procedures for both insured persons and manufacturers, in particular with regard to objections to the installation of the ePA and data transfers as part of the change of health insurance fund for insured persons. This Directive should therefore provide the health insurance funds with binding requirements as to how the electronic health record is to be created and migrated, as well as the deletion and correction of data stored therein. This shall be without prejudice to Section 344(6). In order to comply with data protection, data security and information technology requirements, the Central Federal Association of Health Insurance Funds must involve the Federal Commissioner for Data Protection and Freedom of Information and the Federal Office for Information Security.

Too Nummer 14

MyHealth@EU is an infrastructure for the cross-border transfer of personal electronic health data already established on the basis of Directive 2011/24/EU of the European Parliament and of the Council. Until now, the connection to MyHealth@EU has been voluntary for Member States; Regulation (EU) 2025/327 now requires Member States to connect to MyHealth@EU and comply with the technical specifications for MyHealth@EU by 26 March 2029.

Pursuant to Article 23(2), first sentence, of Regulation (EU) 2025/327, each Member State is to designate a national contact point for digital health as the organisational and technical access point for the provision of services related to the cross-border exchange of personal electronic health data related to primary use.

Under current national law, the Central Federal Association of Health Insurance Funds, Deutsche Verbindungsstelle Krankenversicherung – Ausland (DVKA) is already responsible for setting up and operating a national eHealth contact point (see Section 219d(6), first sentence, of Volume V of the Social Code). As Regulation (EU) 2025/327 refers to national contact points for digital health, the national contact point for eHealth will

be renamed as of 26 March 2029 and further developed into a national contact point for digital health that meets the requirements of Regulation (EU) 2025/327.

The setting up and operation of the national contact point also involves the DVKA producing information material on possibilities for cross-border exchange of health data and making it available to insured persons in the form of the Personal Information Notice.

To date, national law contains provisions on the cross-border exchange of data from the electronic patient summary (cf. Sections 352a, 358(1a), 358(7) and 358(9), second sentence, point 5, of Volume V of the Social Code) and regulatory data from electronic regulations pursuant to Section 360 pursuant to Section 341(2)(11)(1). Alternative SGB V (cf. § 360(12)(2) and § 361(3) SGB V; these are the ePrescriptions referred to in Article 14(1), point (b), of Regulation (EU) 2025/327) via the eHealth National Contact Point. Successively from 26 March 2029 and 26 March 2031, in addition to the above-mentioned further categories of data, it must be possible to transmit them via MyHealth@EU (see the further amendments to § 219d SGB V provided for in Articles 2 and 3).

In accordance with Section 219d(6), fifth sentence, of Volume V of the Social Code, the provisions on semantic interoperability necessary for the cross-border exchange of data, including the coordination of these provisions at European level, shall be determined by the Federal Institute for Medicinal Products and Medical Devices in consultation with the Federal Association of Statutory Health Insurance Physicians and the Telematics Society (in this case, in particular with the involvement of the Competence Centre for Interoperability in Healthcare (first sentence of Section 385(1) of Volume V of the Social Code), taking into account the European semantic interoperability provisions. As the number of ‘use cases’ increases in the future, the tasks and expenses of the Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) in connection with meeting the specifications for semantic interoperability and coordinating these specifications at European level, which are necessary in preparation for and in order to carry out these more extensive data exchanges in the future (e.g. participating in the drafting of implementing acts or taking operational decisions with a view to the development and operation of MyHealth@EU by the MyHealth@EU Steering Group pursuant to Article 95 of Regulation (EU) 2025/327), are also increasing considerably. Fulfilling the task to be carried out in the future on the basis of Regulation (EU) 2025/327 pursuant to the fifth sentence of Section 219d(6) of Volume V of the Social Code requires increased human, technical and financial resources at the Federal Institute for Medicinal Products and Medical Devices.

Too Buchstabe b

Too Nummer 15

As a result of the new version of Section 342(5), the provision is obsolete and is deleted.

Too Nummer 16

The amendment adds to the competence of the Federal Medical Service to issue guidelines, in consultation with the Central Federal Association of Health Insurance Funds, on digital data exchange procedures between medical services and, in particular, health insurance funds and service providers. The current governance mechanisms for the timely establishment of mandatory digital standards in medical services have proven insufficient. Different IT systems, inconsistent transmission channels and a lack of process specifications lead to significant efficiency losses.

The Directive shall specify technical transmission methods, formats, interfaces, transmission frequencies or qualitative requirements. Taking into account the state of the art, the secure transmission procedure of the telematics infrastructure pursuant to point 2

of the first sentence of Section 363a(1) shall be used, in particular for communication with the healthcare providers participating in the statutory health insurance scheme. The Federal Medical Service shall, as a first step, within one year of the entry into force of the Act, issue a guideline for communication between the medical services and the providers participating in the statutory health insurance scheme. In this connection, provision shall be made for the use of the secure transmission procedure of the telematics infrastructure pursuant to § 363a(1), first sentence, point 2. Existing inpatient systems, if any, can be continued and further developed as long as they are efficient and cost-effective. The provisions on the database referred to in the first sentence of paragraph 5 and the Directive adopted pursuant to point 3 of the first sentence of paragraph 2 shall remain unaffected.

Standardisation of data transfers contributes to the homogeneity of digital structures, speeding up processes and thus contributing to the digital transformation of healthcare. In doing so, it also strengthens the cost-effectiveness and quality of care for insured persons.

Too Nummer 17

Too Buchstabe a

Point 22 is deleted due to the deletion of Section 350a. In addition, the existing Sections 25a and 25b are added to the list in Section 284(1).

Too Buchstabe b

The newly inserted paragraph 5 provides that health insurance funds may collect personal data from their insured persons, in addition to the social data already held by them, and also from their wellness applications (in particular wearables), provided that the insured persons have expressly consented to this data processing. The processing is based on consent under Article 9(2)(a) in conjunction with Article 6(1)(a) GDPR. Health insurance funds already hold extensive data on the state of health of their insured persons. Nevertheless, it may be useful in many places to collect additional data, e.g. on the consumption of herbal active substances and non-reimbursed medicines, or on dietary habits and alcohol consumption. These data can be used to help insured persons pursuant to § 1 sentence 4 by providing information, advice and services and to promote healthy living conditions, taking into account specific gender, age and disability characteristics.

The provision is intended to supplement the general rule on the collection of social data in Paragraph 67a of the SBG X. This gives insured persons the opportunity to decide themselves, with their consent, whether other data they wish to provide are suitable for the best possible performance of tasks by the health insurance funds.

An example may also be the status of smokers or the weight of insured persons. These data may be suitable for a large number of data processing operations at the health insurance funds. For example, in the context of data evaluations under § 25b SGB V, the risks of illness could be better assessed, for example by identifying risk factors for cardiovascular disease or dementia.

For which tasks of the health insurance funds the data collected in this way may actually be used, insured persons should decide themselves within the framework of defined purposes. The specific purposes under § 284(1) SGB V must be specified in the explicit consent. This prevents the data from being used for unspecified purposes and processing operations without the insured being aware of it.

At the same time, the regulation provides for the data thus collected to be entered in the EHR. In this way, the same data can be made visible to healthcare providers and usable for the benefit of insured persons.

Too Nummer 18

Health insurance funds have a central role to play in our healthcare system. They maintain direct contact with insured persons and collect and store important health data. However, the potential of data use in the statutory health insurance funds has not yet been exploited. One reason for this is the often existing legal uncertainty as to whether and to what extent existing rules allow data processing. This is because, according to Article 9(2) GDPR, the processing of special categories of personal data, like health data, normally requires a basis in Union or Member State law.

As a solution, a new § 284a creates an experimental clause for the use of data in health insurance funds. This new approach is intended to allow scope for extended data processing by health insurance funds in the interest of insured persons. For this purpose, the health insurance funds may, with the authorisation of the supervisory authority, set up regulatory sandboxes in which data processing is permitted even in the absence of an explicit legal provision. The requirement of the opening clauses under European law in Article 9(2) is met by means of a statutory provision in § 284a.

The regulatory sandboxes pursuant to § 284a follow the definition of regulatory sandboxes in § 2(3) of the wording aid of the Federal Testing Act. This is still under parliamentary negotiation. In the regulatory sandboxes referred to in Section 284a, health insurance funds may, within the limits previously set by the supervisory authority's authorisation, test certain data processing on a temporary basis. Thanks to the innovative approaches to data processing made possible by the regulatory sandboxes, health insurance funds can process large amounts of data in order to carry out the tasks assigned to you, including using new technologies for which there is not yet sufficient legislation. For example, it will allow novel data analytics techniques and also explorative data use. This experimentation is intended to serve the public interest. This may, in particular, also be in the form of a cheaper or quicker performance of the health insurance funds' tasks. However, possible public health benefits should also be taken into account when approving the regulatory sandboxes.

The involvement of the supervisory authority always ensures the interest of insured persons. This is because, from the approval required for the establishment of the regulatory sandbox, through clear rules on monitoring to the possibility of withdrawal and participation in the results report, the supervisory authority remains closely involved. For example, the supervisory authority must be informed of the intended method of data processing at the time of the request. The result reports should be designed in a non-bureaucratic way, while enabling regulatory learning. The supervisory authorities may provide forms for the results reports in order to give guidance to the health insurance funds on the scope and form of the results reports.

The interests of the insured persons whose data are processed in the context of a regulatory sandbox are safeguarded by different measures. The obligation to inform the health insurance fund publicly about regulatory sandboxes ensures their transparency. This public information can be provided, for example, through publications in the Members' Magazine or on the Health Insurance Fund's website. It should be accessible. There is no provision for individual information to be provided to insured persons. The supervisory authority may also make the granting of authorisation subject to further conditions and obligations. For example, depending on the needs of a regulatory sandbox, further measures to protect the interests of insured persons may be imposed. Other possible measures are, for example, the restriction to a part of the insured population or a specific set of data. It is also possible for health insurance funds to have more extensive

ongoing information obligations vis-à-vis the supervisory authority. In particular, it may also be laid down as a condition that insured persons must be granted a right of objection vis-à-vis the sickness insurance fund. Such an inconsistency shall only have effect for the future and shall be designed in such a way that the objectives of the respective regulatory sandbox are not compromised. In addition, the supervisory authority may also require data to be pseudonymised or anonymised in the regulatory sandbox from a certain procedural step onwards.

Regulatory sandboxes shall be established for a limited period of time. It is therefore appropriate to set a time limit in the approval. If the purpose of the experiment cannot be achieved within the specified period, the period referred to in the fourth sentence of paragraph 4 may be extended. This will address the need for sufficient long-term testing while ensuring that there is a sufficient basis for the assessment of the results report. Following the termination of the sandbox, pursuant to the principles of data minimisation and storage limitation laid down in Article 4(1), points (c) and (e), of Regulation (EU) 2026/679, § 284a SGB V shall no longer be considered as a basis for the continued storage of personal data. To the extent that personal data processed in the context of a regulatory sandbox are to be retained as well as after the sandbox, a different legal basis is required. In the absence of a regulatory sandbox, the personal data stored in the sandbox shall be deleted, cf. Article 17(1), point (a), of Regulation (EU) 2026/679.

Requirements of higher-ranking law or obligations under international treaties must be taken into account. In particular, the requirements of Regulation 679/2016 must be complied with. For example, it must be ensured that the further processing of data by the health insurance funds allowed in the sandbox is not carried out in a manner incompatible with the original purposes of data collection, cf. Article 5(1)(b) GDPR. The experimentation clause constitutes a basis for the law of a Member State under Article 9(2)(h) and (i) GDPR, the conditions of which must be met.

Too Nummer 19

In connection with the introduction of telematics infrastructure services which link data records to the health insurance number (KVNR), it has been shown that the register of health insurance numbers plays the decisive role in ensuring the uniqueness of the health insurance number in the telematics infrastructure. This makes it possible, inter alia, to prevent multiple awards.

In addition, we also see the need to establish the legal basis for conducting a procedure for the comparison of the KVNR inventory on a date-by-date basis between the KVNR system as a whole and the payers involved in the KVNR procedure.

This is because the introduction of the conflict-based ePA has shown that, in addition to the processes established by law, further measures are needed to ensure the consistency of KVNR stocks between the register of health insurance numbers and those of the payers. This requirement increases with the number of participants in the proceedings, as the risk of inconsistent data sets also increases.

There is also a need to adapt the fifth sentence of Section 290(3) of Volume V of the Social Code, as this currently only provides for data to be transferred from health insurance funds to other payers for the purpose of cross-checking data, but this is done between all payers involved in the KVNR procedure.

Too Nummer 20

Too Buchstabe a

In order to take into account the transitional period provided for in the fourth sentence of Section 291b(2) until 31 March 2026 for the verification of the health insurance fund’s

obligation to provide benefits by comparing the data stored on the electronic health card (eGK) with the current data and updates available at the health insurance fund on the electronic health card, electronic health cards which now only contain the reduced insured person's data pursuant to Section 291(2)(3) are to be issued only from 1 June 2027, after the end of the transitional period. This ensures that the temporarily possible cross-checking of the insured person's master data stored on the electronic health card can be carried out on the basis of corresponding electronic health cards in accordance with the fourth sentence of Section 291b(2).

Too Buchstabe b

In future, insured persons should also be able to obtain an electronic proof of identity from their health insurance fund by means of a European Digital Identity Wallet within the meaning of Article 3(42) of Regulation (EU) No 910/2014 for the purpose of subsequent, secure identification. This also applies to the secure identification for a digital identity.

Too Buchstabe c

Too Doppelbuchstabe aa

In future, insured persons should be able to use the European Digital Identity Wallet as defined in Article 3(42) of Regulation (EU) No 910/2014 in conjunction with corresponding electronic evidence in the wallet in the same way as the electronic health card for the authentication of the insured person in the health care sector and as proof of insurance.

Too Doppelbuchstabe bb

Consequential editorial amendment resulting from point (aa).

Too Doppelbuchstabe cc

Consequential editorial amendment resulting from point (aa).

Too Doppelbuchstabe dd

Consequential editorial amendment due to § 306(1).

Too Buchstabe d

This is a consequential editorial amendment.

Too Nummer 21

In accordance with Section 291a(2)(1), in addition to the name of the issuing health insurance fund, the eGK should also contain the distinguishing sign for the association of health insurance funds in whose district the insured person resides. This mark ('WOP mark') is subject to frequent changes, so the eGK must be replaced whenever the insured person moves to another district of a health insurance fund. Due to the future online comparison of the insured person's master data in conjunction with the provision in Section 291(2)(3) (limiting the data to be stored to points 1 to 3 and 6 of Section 291a(2) from 1 January 2026), the WOP identifier is also to be retrieved exclusively online in order to avoid an exchange of the electronic health card. The WOP flag is therefore included in point 11 as a date to be saved.

With the implementation of the second-stage inventory management of insured persons (VSDM 2.0), the matrix ID (identifier of the TI-Messenger – MXID) will be incorporated into the inventory of insured persons for all insured persons using the instant messaging

service of the telematics infrastructure (TI-Messenger pursuant to Section 363a(1)(1)). The use of the TI messenger for insured persons remains voluntary. The educational rule of the MXID is @[KVNR of an insured person]:[Kassen-Domain]. It is to be automatically transferred to the primary systems of healthcare providers when the electronic health card is inserted into the card terminal. A comparable process already exists for all other insured person master data, such as name and address. This technical measure avoids a multitude of different implementations of the MXID education rule in all different primary systems. This would potentially increase the susceptibility to errors. Thus, the MXID becomes part of the insured person's master data. The components of the MXID are in any case already part of the insured person's master data.

Practices participating in disease management programmes (DMP) must be enabled to obtain reliable, up-to-date information on the DMP status of insured persons in order to be able to provide DMP services with legal certainty. All DMPs in which an insured person participates must be shown on the eGK. Currently, the participation status of an insured person for doctors cannot be reliably determined, which leads to massive problems in care provision and can be accompanied by a lack of care. The mandatory storage of the DMP status on the eGK can solve these problems.

Until now, the insured person's co-payment status has been regulated by law as a date to be stored on the electronic health card. However, this has not yet been implemented. As knowledge of the co-payment status is mandatory for both pharmacies and providers of medicinal products, storage should take place no later than six months after the entry into force of the law.

Too Nummer 22

In order for health care providers to communicate with insured persons via the instant messaging service of the telematics infrastructure pursuant to Section 363a(1)(1), it is necessary for the health care provider to know the respective unique identifier (identifier of the TI messenger – MXID). This becomes part of the insured person's master data by supplementing Section 291a(2). These shall be provided by the health insurance funds with the service of the health insurance funds referred to in paragraph 1 (Insured Master Data Service). The same applies to the co-payment status, which is already part of the insured person's master data. Healthcare providers must collect the co-payment from patients and therefore know the co-payment status. Knowledge of co-payment status is also required for pharmacists and persons belonging to the pharmacy's pharmaceutical staff. It is therefore reasonable that, in future, in addition to the service providers participating in the statutory health insurance scheme, the providers of medicinal products and medical aids, pharmacists and persons belonging to the pharmaceutical staff of the pharmacy will also be able to voluntarily use the insured person's master data service and access the data.

Too Nummer 23

Too Buchstabe a

This is a consequential adjustment due to the deletion of § 311(6).

Too Buchstabe b

This rule obliges all service providers connected to the telematics infrastructure not only to receive electronic letters but also to send them via the secure e-mail service 'Medical Communication' (KIM) via the telematics infrastructure.

Too Buchstabe c

In future, the Federal Association of Statutory Health Insurance Physicians should provide a central uniform interface that can be used for direct data retrieval. This interface provides the data needed to draw up the bill for medical and specialised care services and can thus be accessed automatically by the doctors and institutions participating in the statutory health insurance scheme. The Federal Association of Statutory Health Insurance Physicians shall take into account in its provisions that future changes to the data are to be indicated.

The data shall be made available either quarterly or, if necessary, directly by the Federal Association of Statutory Health Insurance Physicians. The advantage of making the data available via the interface lies in the fact that the data in the information technology systems of the health care providers are more up-to-date. In the current procedure, these data are made available via a web-based platform by the Federal Association of Statutory Health Insurance Physicians and separately by each association of Statutory Health Insurance Physicians. To date, the data required for the billing of medical and specialised care services have to be manually retrieved and processed in a burdensome manner. This leads to high implementation costs and time losses. The new central interface will address these difficulties and save costs.

The data provided via the interface can be used by the associations of health insurance physicians and health insurance funds as part of their task of verifying the legality and plausibility of the bills in the statutory health insurance system.

Details of the interface shall be determined by the Federal Association of Statutory Health Insurance Physicians no later than 9 months after the promulgation of the Act and the interface shall be made available no later than 18 months after the promulgation of the Act.

This rule does not apply to the dental sector.

Too Buchstabe d

This is a consequential adjustment due to the deletion of § 311(6).

Too Nummer 24

The amendment aims at enabling the use of cloud computing services by settlement offices contracted by service providers to process billing data.

Section 393 has already standardised IT security requirements for the use of cloud computing services by service providers within the meaning of Chapter 4 and health and care insurance funds. These requirements ensure a high level of security for the processing of social and health data in the cloud.

It is neither appropriate nor systematically convincing to effectively prevent the use of modern cloud infrastructure, particularly in the area of billing, while the processing of data in the context of the actual provision of services is permissible under the conditions laid down in § 393. The addition therefore makes it clear that billing agencies may also use cloud computing services, provided that the requirements of Section 393 are complied with.

The amendment aims to standardise regulation, reduce unnecessary bureaucracy and strengthen IT security.

Re sentence 2 (new):

The new first half-sentence of the second sentence also provides for the application of Paragraph 80 of Book Ten, without continuing the previous general prohibition on subcontracting relationships. This means that the general regime of contract processing under § 80 SGB X in conjunction with Article 28 of Regulation (EU) 2016/679 applies, which allows subcontractors under the conditions laid down therein (in particular prior authorisation from the controller).

Re sentence 3 (new):

The new third sentence provides that the requirements of Section 393 apply mutatis mutandis to the use of cloud computing services by the delegated body (billing agency). The wording ‘appropriately’ takes account of the fact that, according to its wording, Paragraph 393(1) addresses service providers within the meaning of Chapter 4 and their processors. The application by analogy extends the substantive requirements of Paragraph 393(2) to (4) (place of processing, establishment in Germany, C5 certification, technical and organisational arrangements) to the situation in which a settlements office, as processor of the service provider, itself uses a cloud computing service.

Too Nummer 25

This is a consequential adjustment due to the deletion of § 311(6).

Too Nummer 26

As part of its tasks as the data collection point for the data transparency procedure for the research data centre for health, comprehensive data are transmitted by the health insurance funds to the Central Federal Association of Health Insurance Funds. The newly inserted paragraph 5 allows the Central Federal Association of Health Insurance Funds to extract certain parts of the data pursuant to Section 303b(1) and to continue to use them for certain data procedures laid down by law. The aim of the provision is to save existing data transmissions by the health insurance funds to the Spitzenverband for these data procedures by the Spitzenverband independently removing the same data. The aim is to cut red tape and avoid duplication of data.

Too Nummer 27

Too Buchstabe a

The amendment clarifies who is entitled to use it. While reference was previously made to the scope of the GDPR, it is now made clear that only natural and legal persons established in Germany or in another Member State of the European Union or in a State party to the Agreement on the European Economic Area can access data from the FDZ Health.

Too Buchstabe b

Too Doppelbuchstabe aa

The wording in point 9 is aligned with the terminology of Regulation (EU) 2024/1689 and 3 67 SGB X. There is also a consequential amendment due to the new point 11.

Too Doppelbuchstabe bb

This is a legal adaptation.

Too Doppelbuchstabe cc

The new point 11 introduces a further purpose for which access to the data in the FDZ Health can be granted. According to this, the purpose of an application is to establish contact with certain health care providers for applicants. For the first time, the identification of health care providers from the FDZ data is not only permissible, but the very purpose of data access. However, the re-identification of insured persons remains prohibited and also punishable under criminal law. Instead, it allows the re-identification of health care providers for three specific use cases. The three use cases are very limited and each have a very limited group of potential applicants.

Too Buchstabe c

The provision on the obligation of certain applicants to use the FDP Health has been adapted. First of all, it is clarified that the FDZ itself is responsible for obligations under the Obligations Act. It had previously been unclear who was responsible for the obligation as a result of an incorrect reference. This is because the reference to the Obligations Act could be understood as meaning that Land authorities are competent.

Moreover, to date, only a personal obligation has been possible. This required applicants to travel to the FDZ Health, although the rest of the application process, including data access, could be fully digital. This has now been adapted so that an obligation can also be imposed by means of simultaneous transmission of images and sound, e.g. via videoconferencing. This will maintain the necessary safeguards, but make them low-threshold and modern.

Too Buchstabe d

The Joint Federal Committee pursuant to § 91 and the Institute for Quality Assurance and Transparency in Health Care pursuant to § 137a are allowed to submit, within narrow limits, additional data themselves for data use in the FDZ. This is limited to requests for re-identification of service providers for the performance of their statutory tasks in the field of quality assurance. This input may be linked to the data available in the FDP.

Too Buchstabe e

The provision makes it possible for the Research Data Centre for Health, at the request of the Federal Ministry of Health, to produce and submit to the Federal Ministry of Health recurring aggregated data analyses without reference to insured persons and doctors for the purpose of more detailed analysis and forecasting of the development of benefits and expenditure in the statutory health and long-term nursing care insurance.

In the interests of transparency regarding the use of this scheme by the Federal Ministry of Health, relevant information on the evaluations will be published in the application register of the Research Data Centre for Health.

Too Buchstabe f

The insertion of the new sentences pursuant to the fourth sentence of paragraph 5 is linked to the new purpose pursuant to § 303e(2)(11). In the case of authorised service provider identification, the trust office shall enable the personal reference to be dissolved on an ad hoc basis for the purposes of point 11. The detailed procedure for the identification of service providers may be laid down by order of the BMG.

Too Buchstabe g

The adaptation of the rule in the second sentence of paragraph 6 simplifies the procedure for excluding beneficial owners who have processed data unlawfully. Previously, it was necessary that the competent data protection supervisory authority had first taken a measure pursuant to Article 58(2)(b) to (j) GDPR vis-à-vis the beneficial owner. Following the amendment, this is no longer necessary, so that the FDZ Health can act more quickly against abusive beneficial owners.

Too Nummer 28

The amendment exempts the Joint Federal Committee and the Institute for Quality Assurance and Transparency in Health Care from paying fees for applications to the Health FDZ.

Too Nummer 29

The telematics infrastructure is constantly subject to technical changes resulting, inter alia, from technological innovations and the modernisation of the security architecture.

The central security infrastructure referred to in point 1 shall also include the secure network and in the future its successor in the form of the zero-trust architecture.

In addition, the secure transmission processes and services dedicated to the cross-border exchange of health data between the European Health Data Space under Regulation (EU) 2025/327 and the telematics infrastructure are explicitly included in the regime.

Too Nummer 30

Too Buchstabe a

On the one hand, the adjustments are consequential adjustments due to the adaptation of § 306. Section 307 is also intended to reflect the role of the parties in the various work-sharing data processing processes of the telematics infrastructure and to make a specific allocation of responsibility under data protection law in the sense of a specific provision pursuant to the second half-sentence of Article 4(7) GDPR.

The allocation of responsibilities for providers under Section 307(4) shall be made to the provider who makes an application available on the basis of a direct legal relationship with the final customer. ‘End-user’ means the user of a telematics infrastructure application or a secure means of transmission who does not offer or operate such an application or a secure means of transmission;

Too Buchstabe b

The existing coordinating body within the Telematics Society is given the additional task of receiving requests relating to the electronic prescription and the secure communication procedures ‘Medical Communication’ (KIM) and the TI Messenger (TIM). On the one hand, this should provide users with a central point for their concerns. On the other hand, because of the importance of these applications and processes, the Telematics Society must also be informed at an early stage if, for example, disturbances occur. In addition, the coordinating body is to provide information on log data in the electronic regulation. This is of particular interest to those who do not manage the applications through their own user interface. In order to be able to provide the insured persons with the information requested, the coordinating body must have access to the log data of the electronic regulations. This provision does not affect the data subjects’ right of access under Article 15 GDPR against the service provider pursuant to Section 311(1), second sentence, point

6. The provision also serves to clarify the liability of the Telematics Company under data protection law in the performance of its activities as a coordinating body and to ensure that the coordinating body performs the tasks of the central appeal body in the event of complaints in relation to the provisions of Chapter II of Regulation (EU) 2025/327 (Regulation (EU) 2025/327) pursuant to Section 383a(3) of Volume V of the Social Code.

Too Nummer 31

Too Buchstabe a

Too Doppelbuchstabe aa

Too Dreifachbuchstabe aaa

In future, in addition to Section 323(2), the Telematics Society should be able to tender for not only the operation of the central infrastructure, but also the development or operation of components and services of the telematics infrastructure and of selected applications (see Section 334) and make them available to users of the telematics infrastructure. Past experience has shown that the current structure in the pure market model has generated a high degree of complexity due to a variety of different components, services and applications, which has had a negative impact on operational stability and service quality. Therefore, the required high availability and security requirements for a critical infrastructure cannot be sufficiently met.

With the new provision in point 4, the Telematics Company is to gradually assume a steering role as a so-called provider. In particular, for components, services and applications that are the backbone of digital healthcare, governance of selected service providers and a high level of enforcement skills of the Telematics Society are essential. The combination of offers via centralised procurement procedures and the associated contractual control possibilities of the Telematics Society are intended, on the one hand, to improve the quality and timeliness of the products. On the other hand, the main aim of this reorganisation is to make it easier for service providers to connect to telematics infrastructure and to increase the stability of the system as a whole by reducing complexity, thus enabling digitally-assisted coverage throughout. In addition, costs can also be saved, as the Telematics Company can obtain economic pricing from the suppliers by means of a call for tenders.

The provision gives the Telematics Society discretion to decide which components, services and applications should be procured through procurement procedures in order to best ensure the availability, integrity, authenticity and confidentiality of those components, services and applications. When deciding on centralised procurement and provision of individual selected components, services and applications through procurement procedures, due consideration shall be given to the criticality of the respective components, services and applications by the Telematics Society. For example, components and services that can be centralised and unique should be the responsibility of and procured by society for telematics. Components, services and applications, which are the backbone of digital healthcare, may in future also be procured and provided by the Telematics Society as an alternative to the pure market model via tender procedures. This decision on whether and how components, services and applications will be procured and operated in the future is taken by the Telematics Society in close consultation with the Federal Ministry of Health. Where the decision particularly affects the area of activity of other authorities and other stakeholders, the parties concerned must be heard in the decision.

The contract may not only be awarded to one supplier, but may also be awarded to several suppliers, depending on the circumstances of the case.

Under the new Section 325(1), second sentence, in the case of centralised procurement, instead of approval, the security of components and services must be demonstrated by means of an external security opinion, in particular proof that the availability, integrity, authenticity and confidentiality of components and services are ensured (cf. Section 323(2), fifth and sixth sentences). Functionality and interoperability (see the first sentence of Section 325(2) and the first sentence of Section 325(3)) are checked by the Telematics Company as part of the tendering procedure.

Point 5 is a necessary consequential amendment to point 4. The essential components and services of the telematics infrastructure, for which the possibility of central procurement and provision by the Telematics Society is also to be created in the future, include in particular the secure services for procedures for the transmission of medical and care data via the telematics infrastructure. Here too, the Telematics Society has a corresponding discretion as to whether it wishes to maintain the previous procedure with regard to the secure services for procedures for the transmission of medical and care data via the telematics infrastructure or whether it wishes (in the future) to make use of the possibility of a centralised award. The decision to issue a call for tenders is taken by the Telematics Company in close consultation with the Federal Ministry of Health. Where the decision particularly affects the area of activity of other authorities and other stakeholders, the parties concerned must be heard in the decision. Under the new Section 325(1), second sentence, in the case of a centralised award, the security of the components and services must be demonstrated by means of an external safety assessment instead of an approval (see above).

Too Dreifachbuchstabe bbb

The adaptation in point 10 makes it clear that, in future, the telematics infrastructure components which enable insured persons to access the electronic medical prescription will no longer be developed by themselves, but will instead award a contract for this and make the developed component available.

Too Dreifachbuchstabe ccc

In order for the Telematics Society to be able to take over tasks relating to the use of the telematics infrastructure by the statutory pension insurance scheme in the field of medical rehabilitation and aftercare services, tasks are allocated accordingly. On this basis, the Telematics Society can plan and implement individual concrete measures to ensure that the use is technically successful on the part of the statutory pension insurance scheme. This concerns both the sector of providers of benefits and the sector of pension insurance institutions. The active cooperation between the Telematics Society and the DRV Bund with its fundamental and cross-cutting tasks (see § 138 SGB VI) is necessary for this purpose.

Too Dreifachbuchstabe ddd

Re point 18

Digital health authorities are responsible for the implementation and enforcement of Chapter II of Regulation (EU) 2025/327 at national level, in accordance with the first sentence of Article 19(1) of Regulation (EU) 2025/327 (Regulation (EU) 2025/327). The Telematics Society, as a modern agency in the field of digitalisation, is assigned substantial parts of the tasks and powers of the digital health authorities (see Section 383a(1)(2) of Volume V of the Social Code), as well as the tasks of the coordination body between several digital health authorities and the digital health authority responsible for the activity report (see Section 383a(2) of Volume V of the Social Code). In addition, under Section 307(5) of Volume V of the Social Code, the coordinating body set up within

the Telematics Society becomes the central appeal body (see Section 383a(3) of Volume V of the Social Code).

Re point 19

In future, the Telematics Society will be tasked with providing users of the telematics infrastructure with clear information on the compliance of suppliers of authorised components and services with the applicable operational requirements. With the increasing relevance of the telematics infrastructure and its applications for healthcare in Germany, there is a growing interest from service providers and insured persons, as well as from the general public, in information on the availability and reliability of telematics infrastructure applications, components and services. It is important for users of telematics infrastructure to hire providers that meet their needs. To this end, the performance of the various components and services offered must be transparent to the user. Demand and interest in more and detailed information is also growing. Information on the availability and stability of services and their respective providers is essential for service providers who rely on the stability of TI services to carry out their activity and ensure healthcare in Germany.

Re point 20

The Telematics Society will be able to pilot regulatory sandbox environments to improve digital healthcare. These pilots are intended to enable the Telematics Society to develop the telematics infrastructure in an innovative and at the same time conveniently process-oriented way. By way of derogation from the current step-by-step approach with specification, testing and approval tests, it should in future be possible to pilot privacy-compliant and safety-tested solutions, thereby testing the utility of supply and optimising technical implementation at an early stage in the development process, without first generating major expenditure as part of nationwide implementation. The results of the piloting will feed into the definition of the Telematics Society. The aim is to make the best and most cost-effective use of the optimisation potential of digital solutions in healthcare and care in the future.

Too Doppelbuchstabe bb

Costs incurred by the Telematics Society in connection with the use of the telematics infrastructure by the statutory pension insurance scheme shall be reimbursed to the Telematics Society by the statutory pension insurance institutions.

Too Buchstabe b

The delegation clause in Section 311(1a) of Volume V of the Social Code supplements the tasks and powers of the Telematics Sales Community as a digital health authority pursuant to Section 383a(1)(2), (2) and (3) of Volume V of the Social Code.

Too Buchstabe c

This is a consequential editorial amendment resulting from the re-systematisation of the rules on secure procedures for the transfer of medical data pursuant to Sections 363a to 363f.

Too Buchstabe d

The Act on the acceleration of public procurement enters into force on 1 July 2026. It provides, inter alia, for an increase of the value limit for direct contracts to EUR 50.000. In the interests of simplification and cutting red tape, the increase in the direct contract value limit applicable to the federal budget (Paragraph 55(2) of the BHO) and the social security

budget (Paragraph 22(2) of the SVHV) is to be transferred to the procurement procedure of the Gesellschaft für Telematictik (Society for Telematics) by applying Paragraph 55 of the BHO mutatis mutandis.

Too Nummer 32

Too Buchstabe a

Too Doppelbuchstabe aa

This is a consequential adjustment due to the deletion of § 311(6).

Too Doppelbuchstabe bb

This is a consequential adjustment due to the deletion of § 311(6).

Too Doppelbuchstabe cc

This is a consequential editorial amendment.

Too Doppelbuchstabe dd

This is a consequential editorial amendment.

Too Doppelbuchstabe ee

Point 19

By including number 19, the Telematics Society is tasked with carrying out the necessary measures to ensure that service providers with access rights can access electronic credit transfers by means of the electronic health card and in accordance with the conditions for access laid down in Section 361d. In this way, the technical basis is created for insured persons to be able to choose, in accordance with Section 360a(3), whether the access data necessary to access their electronic transfer should be made available to them in an accessible manner, either by means of a paper printout or by electronic means.

Point 20

The Telematics Association shall, by 1 January 2030, carry out the necessary measures to ensure that providers involved in emergency care have emergency access to the data in the electronic health record referred to in Section 341(2)(1)(c), irrespective of the temporal link with the treatment under Section 339(1).

Too Buchstabe b

A deadline is included in the first sentence for the timely, comprehensive, practical and legally certain implementation of the electronic transfer in order to fulfil the already regulated mandate to the Telematics Society. The specific deadline is based on the normal implementation time of comparable projects and is intended to ensure that electronic credit transfers are available in a timely manner as an application of the telematics infrastructure. In the light of the objectives set out in the coalition agreement for the 21st The planned transformation of outpatient care during the parliamentary term through the introduction of a primary care system requires early technical decisions, as electronic credit transfers are expected to play a major steering role. The newly added second and third sentences lay down, not exhaustively, important requirements to be taken into account by the Telematics Society when implementing the measures. They are clarifying and appealing. In the future, electronic credit transfers should not be an isolated

application, but an integral part of a digitally interconnected supply process involving telematics infrastructure and other existing and planned digital solutions and other service providers, such as care. For this reason, existing telematics infrastructure services and applications, such as the electronic health record (ePA) and ePrescription, and existing data transfers and links to appointment booking solutions, such as the 116117 switching code and electronic programs for standardised initial assessments, need to be considered from the outset and, where possible, reused. The applications, solutions and groups of service providers mentioned in this connection are expressly listed only by way of example. In a first stage of development, the scheme focuses on statutory health insurance and is intended to be the starting point for gradual development. The intention is to gradually extend electronic credit transfers to other care areas and groups of care providers, while continuously improving the care process for insured persons. Further stages of fitting-out shall be reserved for the following provisions.

Too Nummer 33

Too Buchstabe a

The current version of Section 313(1), fourth sentence, provides for the inclusion of a single unique identification number in the directory service (VZD). In practice, however, this is not sufficient to clearly and reliably identify service provider institutions. Operational experience shows that searching in the CVD on the basis of name, address and field of expertise alone often leads to imprecise or ambiguous results. This increases the risk of misaddressing and unlawful data transfers and creates additional burden for searchers.

However, in day-to-day care, different unique identification numbers are used, which are established on documents, in specialised applications or in billing processes, depending on the context. These identifiers cannot be clearly assigned to any of the existing data categories, but they play a key role in uniquely identifying persons and organisational units. The extension to ‘identification numbers’ creates the necessary legal basis to keep several such identifiers in parallel in the BTI and to use them for search and addressing processes depending on the situation.

In addition, cross-checking with external registers and registers and thus linking providers and institutions without the exchange of additional identifiers is only possible with disproportionate effort.

The focus here is in particular on the following numbers/flags pursuant to § 75 and § 293 SGB V: I

- Identification of the institution (§ 293)
- BSNR/NBSNR (secondary) establishment number) (§ 75(7))
- Hospital location numbers (§ 293(6))
- Hospital doctor number (§ 293(7))
- LANR/LZNR (doctor/dental practitioner) (§ 293(4))
- LBNR (Lifelong employee number) (care) (§ 293(8))

Too Buchstabe b

This is a consequential editorial amendment resulting from the re-systematisation of the rules on secure procedures for the transfer of medical data pursuant to Sections 363a to 363f. The second sentence of Section 313(3) is deleted because the prohibition on the

use of directory service data in the context of the use of secure means of transmission for advertising purposes is now regulated in Section 363d(2).

Too Buchstabe c

The directory service (VZD) lacks inter alia links between SMC-B and eHBA. This does not make it possible to identify affiliations between service providers and service providers' institutions. This complicates the correct identification of communication partners and leads to increased effort and potential misaddressing. A purely manual link between SMC-B and eHBA is time-consuming and will result in only a few relationships. This requires an automated solution that establishes and keeps up-to-date these ratios for all entries in a sector. This requires the use of external registers that can provide the necessary linking information to the CAD. In this respect, the processing power should be extended to data in directories and registers set up with the persons referred to in the first and third sentences in accordance with the provisions of SGB V. The focus here is in particular on the lists pursuant to Section 293 of Volume V of the Social Code.

Too Nummer 34

Clarification that the availability, integrity, authenticity and confidentiality of components and services shall be demonstrated upon approval.

In addition, the selection of the safety assessor as part of the examination procedure is carried out by the Gesellschaft für Telematictik in consultation with the Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security).

Too Nummer 35

The intention is to give the possibility in the future to allow a service provider to operate in the context of addressing operational obligations. This role is to be reinstated in the law and coexist with the role of provider in the context of operational control (comparable to the role of manufacturer in the context of product authorisation). In contrast to the provider, the operator's licence should be able to address those who implement certain operational cooperation obligations (including ITSM processes, operation of a data centre in the telematics infrastructure). The gematics therefore have direct access, in their governance role, to the person who actually provides the operational services. Requirements can be enforced effectively and on a mandatory basis directly against service and component operators. The operator is therefore the person who operates the service on behalf of a provider or as a provider himself. Provider is the person who offers the service to end-users and operates it himself or has it provided by a third party (operator). Operational cooperation obligations are addressed to the operator as part of the operator's authorisation. The amendment creates a lack of clarity so far and clearly distinguishes the role and obligations of a provider from the role of operator.

In addition, provision is made for the possibility of imposing additional requirements in connection with authorisations (second sentence of paragraph 1). The components and services in the telematics infrastructure are constantly being developed in order to implement the state of the art and, in particular, new security requirements. To this end, new versions of components and services are being rolled out continuously and new components and services are being introduced into the telematics infrastructure. Due to the complexity of the overall system and the close interaction of a variety of telematics infrastructure components and services to keep individual applications or services available to the end-user, the roll-out of new versions or new components and services may pose a risk to operational resilience. In particular, when services and components are modified (e.g. through new software versions or hardware modifications), there is a significant risk to the availability of the platform. This risk increases in particular if several providers change their services or roll out components in the space at the same time. In

order to address this risk, it may therefore be necessary for the Telematics Society to impose regulatory requirements on the roll-out of new versions or components and services.

Too Nummer 36

Re paragraph 1

This is a necessary consequential amendment to § 311(4) and (5). In so far as the Telematics Society makes use, with regard to the components and services in question, of the possibility afforded to it by Paragraph 311(4) and (5) of central procurement and provision by means of procurement procedures, the authorisation referred to in the first sentence shall not apply. In this case, the security of the components and services shall be demonstrated by means of an external security opinion, demonstrating in particular that the availability, integrity, authenticity and confidentiality of the components and services is ensured (cf. § 323(2), fifth and sixth sentences).

Furthermore, in so far as the Telematics Company does not make use of the possibility of awarding contracts, the requirement for approval of components and services of the telematics infrastructure is maintained.

Re paragraph 2

The Telematics Society shall approve the components and services of the telematics infrastructure at the request of the suppliers if the components and services are functional, interoperable and secure. During the accreditation process, appropriate evidence from accredited European independent audit bodies may be included, with the aim of reducing the burden on the companies concerned.

The components and services in the telematics infrastructure are constantly being developed in order to implement the state of the art and, in particular, new security requirements. To this end, new versions of components and services are being rolled out continuously and new components and services are being introduced into the telematics infrastructure. Due to the complexity of the overall system and the close interaction of a variety of telematics infrastructure components and services to keep individual applications or services available to the end-user, the roll-out of new versions or new components and services may pose a risk to operational resilience. In particular, when services and components are modified (e.g. through new software versions or hardware modifications), there is a significant risk to the availability of the platform. This risk increases in particular if several providers change their services or roll out components in the space at the same time. In order to address this risk, it may therefore be necessary for the Telematics Society to impose regulatory requirements on the roll-out of new versions or components and services.

Too Nummer 37

These are adjustments with regard to the introduction of the concept of operator.

Too Nummer 38

The amendment allows the Telematics Society to charge the polluter also for the costs, fees and expenses incurred under Section 329(3a) and Section 374a(5). In addition, this is a consequential editorial amendment resulting from the re-systematisation of the rules on secure procedures for the transfer of medical data pursuant to Sections 363a and 363b.

Too Nummer 39

Ensuring the uninterrupted and safe operation of the telematics infrastructure is one of the key tasks of the Telematics Society as part of the security mandate. In order to be able to perform this task, the Telematics Society has a central role to play in security and the repair of disruptions. In so far as risks and malfunctions of the telematics infrastructure result from a breach of the conditions for authorisation, the Telematics Society can already counteract risks and malfunctions of the telematics infrastructure in the context of the granting of the authorisation, including the monitoring of compliance with the conditions for authorisation. However, problems often occur in the telematics infrastructure that cannot be solved by the authorisation conditions, such as in case of incorrect implementation in the practical management systems. These can lead to significant disruptions to telematics infrastructure and to outages of applications, such as the electronic prescription (e-prescription), thus endangering supply. The complexity of telematics infrastructure will increase steadily in the future, making it even more difficult for the Telematics Society to act. The ongoing digitalisation of healthcare requires the stability and performance of telematics infrastructure that keeps pace with the ongoing digitalisation. In order to enable the Telematics Society to fulfil its security mandate efficiently, the Telematics Society's powers in the field of security and troubleshooting need to be extended accordingly to all relevant suppliers and manufacturers. This includes, in particular, manufacturers of primary systems, which, due to technical interfaces, can cause significant disruption to the telematics infrastructure or its essential parts. The provision enables the Telematics Association, in the interests of the prompt removal of disruption and stability of care for insured persons, to clarify the causes of disruption as soon as possible by means of a corresponding request for information (paragraph 2a), to oblige the parties to take specific measures suitable for the removal of disruption (paragraph 3) and, where a disruption is not remedied immediately or within the deadline, to take the necessary measures themselves (paragraph 3a). As the Telematics Society has full access to the entire telematics infrastructure and the interaction of all its stakeholders, it is in a position to identify in particular what measures are necessary and appropriate to remedy disruptions promptly and successfully. The authorisation of the Telematics Society to issue binding orders to suppliers and manufacturers to eliminate or avoid interference with the telematics infrastructure pursuant to Section 329(3) is given concrete expression by means of standard examples: In order to prevent disruptions and to resolve incidents as quickly as possible, the Telematics Society may issue binding instructions to the suppliers and manufacturers referred to in paragraph 2 to take the necessary technical and organisational measures and, in the event of intended changes in the performance of operational services, to set a deadline for them to do so. In order to be able to issue such orders, it is essential that the Telematics Society be able to instruct providers and manufacturers to report incidents, security incidents, identified vulnerabilities of a service and intended changes in the performance of operational services to the Telematics Society, especially as telematics infrastructure service providers are obliged to regularly monitor the IT technologies they use for technical vulnerabilities in terms of data protection and data security. Only such a notification enables a joint assessment to be made and the necessary measures to be taken. Failure to notify, or failure to notify promptly, may result in significant and serious damage to the entire telematics infrastructure in terms of confidentiality, integrity or availability. Furthermore, the amendment to the first sentence of paragraph 3 allows the Telematics Society to (temporarily) exclude individual suppliers or manufacturers from the use of the telematics infrastructure in order to prevent damage to the central infrastructure or damage to other users. Under Paragraph 328(1), the Telematics Company may charge fees and expenses for the costs incurred under Paragraph 329(3a).

In addition, pursuant to Section 324 of Volume V of the Social Code, providers and operators providing critical services and components in the telematics infrastructure should, in addition to the actors listed so far, be required to notify the Telematics Society

without delay of significant disruptions that lead to the loss or impairment of availability, and should be able to be involved in measures to prevent threats to functionality and security. Service and component operators are technically in the first place able to detect a fault and also those who are technically able to effectively perform the troubleshooting.

Too Nummer 40

In line with Section 329(2), primary system manufacturers who, due to technical interfaces, can cause significant disruption to the telematics infrastructure or its essential parts, and service and component operators, as well as the providers already referred to in Section 330(1), are required to establish and continuously update appropriate organisational and technical arrangements to avoid disruptions to the availability, integrity, authenticity and confidentiality of the information technology systems, components or processes of the telematics infrastructure. Moreover, this is a consequential editorial amendment.

Too Nummer 41

Too Buchstabe a

Additions relating to the fact that measures to monitor operations by the Telematics Society must also include services and components provided by operators in order to ensure the safety, availability and usability of the telematics infrastructure. Operators shall provide critical services and components in the telematics infrastructure and shall be highly relevant for the overall security, availability and usability of the telematics infrastructure. In addition, an already expired deadline is deleted.

Too Buchstabe b

The Telematics Society may already use test user identities under the applicable law pursuant to Section 331(5) in so far as this is necessary for measures to monitor the operation of the telematics infrastructure in order to ensure its security, availability and usability. This should also cover audit user identities for insured persons. For this purpose, the Gesellschaft für Telematik requires numbers of persons with health insurance cover who can be clearly assigned to fictitious insured persons. Pension insurance numbers, which can be uniquely assigned to a fictitious insured person, are also required to form the test-health insurance number. The rules create the necessary conditions for this.

In addition, this is a consequential adjustment due to the deletion of § 311(6).

As a result of changes in the Telematics Society requiring 24/7 availability, more people will be required in future to be able to use an audit user identity. It is therefore necessary to increase the number of staff to twenty. In addition, this is a consequential editorial amendment.

Too Nummer 42

Firstly, information technology systems for providers of medicinal products and assistive devices and their suppliers and manufacturers are included in the scheme. In addition, in order to remove any ambiguity in the interpretation of the question of which interfaces are covered by the regulation, it is made clear, on the one hand, that these are interfaces defined by the Telematics Society. It has also been specified that these are interfaces with the information technology systems. In addition, it is stipulated that the integration of components and services must be independent of the efforts of the manufacturer or provider.

Too Nummer 43

Too Buchstabe a

These are editorial amendments resulting from other amendments.

Too Buchstabe b

These are consequential editorial amendments, in particular to Section 329(2) extending the powers of the Telematics Association in the field of security and the removal of disruptions to all relevant suppliers and manufacturers within the framework of the telematics infrastructure. This includes, in particular, manufacturers of primary systems which, due to technical interfaces, can cause significant disruption to the telematics infrastructure or its essential parts.

Too Nummer 44

Too Buchstabe a

Too Doppelbuchstabe aa

This is a consequential editorial amendment following the introduction of electronic credit transfers in Section 360a.

Too Doppelbuchstabe bb

This is a consequential editorial amendment following the renaming of the electronic invoice as a digital patient invoice in § 359a.

Too Doppelbuchstabe cc

This is a consequential editorial amendment following the introduction of electronic credit transfers in Section 360a.

Too Buchstabe b

Too Doppelbuchstabe aa

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Doppelbuchstabe bb

This is a consequential adjustment due to the adaptations in Section 342(2b).

Too Doppelbuchstabe cc

This is a consequential adjustment due to the adaptations in Section 342(2b).

Too Nummer 45

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Nummer 46

In order for the insured person to have access to data in an application pursuant to Section 334(1), second sentence, points 1 to 4, 6 and 7, by means of his electronic health

card or digital identity, authentication by means of an appropriate technical procedure shall be required. To date, the necessary identification can also be carried out in a pharmacy. Now that new identification procedures have become widely available, the possibility of identification in a pharmacy is no longer necessary.

Too Nummer 47

The data sets and information objects referred to in Section 342(2a)(1) and (2)(a) are the digitally-supported medication process and the electronic patient summary. These data can only be fully and completely useful in terms of care, so that insured persons can exercise their rights in relation to the datasets or information objects in their entirety, but not in relation to individual components thereof.

Too Nummer 48

The current paragraph 1 has been deleted because the client is no longer needed in the context of insured persons' applications (AdV client). With the introduction of the coordinating body in Section 307(5), insured persons can sufficiently exercise their rights through this new institution.

Too Nummer 49

Too Buchstabe a

This is a consequential adjustment due to the transfer of Section 359(4) to the newly created Section 352a.

Too Buchstabe b

Access to the data necessary for the safety of medicinal products and to the electronic medication plan in the insured person's ePA is currently provided either by opening the treatment context by means of an electronic health card in the pharmacy or by granting access via the ePA app. Therefore, in cases where only an e-recipe token is available upon redemption, the ePA cannot be accessed. The newly introduced rule also allows limited access to the ePA in these cases by means of the e-recipe token.

A lack of access to the ePA would mean that the electronic medication plan could not be updated and that the prescribed medication could not be checked for possible interactions with medicinal products already listed.

This rule addresses in particular the use of the e-prescription functionality via the relevant user interfaces or when only an e-prescription printout is available. Pharmacies should therefore now also have limited access, via the e-prescription token, to the electronic medication plan, prescription and dispensing information, the electronic medication list and additional information relevant to medicinal products, which is necessary for the performance of their tasks.

The access data pursuant to the first sentence of Section 360(9) does not constitute proof of identity. The redemption of the e-recipe token is therefore not proof by the redeemer of further claims in relation to the ePA. It serves only the dispensing pharmacy to fulfil the statutory filling obligation and to ensure the safety of medicinal products.

Too Nummer 50

Too Buchstabe a

Practice/institution cards (SMC-Bs) are to be issued by the Chambers of Skilled Trades for hairdressers (secondary hairdressers), as for other health-care craftsmen.

Too Buchstabe b

The first sentence of Section 340(5) provides that the issue of a component for the authentication of service providers' institutions may be issued not only to service providers who hold an electronic health professional or professional card but also to service providers who hold a digital identity for service providers. From 1 January 2028 at the latest, a digital health identity may be made available to the healthcare provider upon request.

Too Buchstabe c

Digital identities for health care providers not linked to a smart card pursuant to paragraph 6 are to be implemented in a technologically convergent manner with the 2024 recast of the eIDAS Regulation. The deadline set for the provision of such digital identities will be adapted to the current state of the overall implementation of the eIDAS Regulation at European and national level.

Too Buchstabe d

Digital identities for healthcare institutions pursuant to paragraph 7 are to be implemented in a technologically convergent manner with the 2024 recast of the eIDAS Regulation. The deadline set for the provision of such digital identities will be adapted to the current state of the overall implementation of the eIDAS Regulation at European and national level.

Too Nummer 51

Too Buchstabe a

Clarification that discharge letters also fall under the data category of electronic letters between doctors and institutions involved in providing care to insured persons.

Too Buchstabe b

This is a drafting clarification. This does not entail any substantive change. As under the current legal situation, this amendment allows only the certificate of incapacity for work to be entered in the electronic health record (ePA) in the copy intended to remain with the insured person (insured copy); the copy of the medical certificate of incapacity for work as proof to the employer (employer's copy) within the meaning of Section 73(2), first sentence, point 9, of Volume V of the Social Code in conjunction with Section 5(1a), second sentence, of the Remuneration Continuation Act (EFZG) cannot be included in the ePA.

Too Buchstabe c

It is provided that data on preventive medical services pursuant to Sections 23 and 24 and on medical rehabilitation and follow-up care provided by statutory health and pension insurance pursuant to Sections 40 and 41 and Sections 15, 15a, 17 and 31(1)(2) of Book Six may also be entered in the electronic health record.

Too Buchstabe d

This is a formal follow-up adjustment due to the newly added numbers in § 341(2).

Too Buchstabe e

This is a formal follow-up adjustment due to the newly added numbers in § 341(2).

Too Buchstabe f

Ad inserted point 20:

Health data processed at the health and care insurance funds for the insured person may in future be stored directly in the ePA. This may, for example, be data processed by the health insurance fund pursuant to § 345(1), § 350(5) or (6) or § 25b. It must be clear to the insured person that the data are processed by the health insurance fund. In this way, the data can be found directly for the insured person in the electronic health record. Storage in the EHR also allows for better, immediate and cross-sectoral availability of medical information in care. In addition, the data remain available, in particular in the event of a change of health insurance fund.

With regard to inserted points 21 and 22:

This is a consequential amendment to Section 345a(1) and Section 360a.

As part of the functional area for digital access to care under Section 345a, which is to be set up on the ePA app, it is planned that data from applications for the nationwide standardised initial assessment procedure for appointment mediation in acute cases will be entered into the electronic health record by the appointment service points of the associations of social security doctors under Section 75(1a), third sentence, point 4, if the insured person so wishes. Section 360a also provides for the automated transmission and storage of data on electronic credit transfers and, as far as technically possible, of information on the activation of the electronic credit transfer in the electronic health record.

Too Nummer 52

Too Buchstabe a

The obligation of health insurance funds to provide a consent-based (opt-in)ePA, previously laid down in the first sentence of Section 342(1), applied until 14 January 2025 and has therefore become devoid of purpose as a result of the passage of time, with the result that it must be deleted by means of a legal settlement. In the former second sentence, which is now the first sentence, the reference to the requirements has been adapted. This is a consequential adjustment as a result of the introduction of the functional area for digital access to care to be used for insured persons via the ePA app, the new rule whereby insured persons may object to persons with access rights to the ePA being filled in with the insured person’s data on electronic credit transfers and information on the redemption of electronic credit transfers, and the rule that insured persons may access the same data on electronic credit transfers and information on the redemption of electronic credit transfers in an accessible manner via the user interface of an appropriate terminal equipment and may request the correction of their personal data pursuant to Article 16 of Regulation (EU) 2016/679 vis-à-vis the controllers pursuant to Section 341(4) (see new points 4 to 8).

Too Buchstabe b

Too Doppelbuchstabe aa

Too Dreifachbuchstabe aaa

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Dreifachbuchstabe bbb

Section 342(2)(1)(c) to (f) applied only to the consent-based ePA pursuant to the first sentence of Section 342(1) (cf. the previous Section 342(1), second sentence, on the opposition-based ePA, which did not refer to these points) and must therefore be deleted by way of a legal settlement, in the same way as Section 342(1), first sentence. In order to avoid errors of reference to the different letters within § 342(2)(1) SGB V, the deletion here is made without renumbering, i.e. the letters to be deleted are later reproduced with the indication '(deleted)'.

To Dreifachbuchstabe ccc and Dreifachbuchstabe ddd

The legal definition of 'use case' has been deleted, as practice has shown that each of these use cases of the EHR is considered on its own merits and that uniform handling is not possible. At all relevant points, the data sets and information objects that are processed comprehensively and in a coherent manner in the ePA are now specifically named with reference to the standard.

Furthermore, this is a consequential amendment as a result of the adaptation of § 353(1) and (3). It provides that the insured person's separate possibility of objecting to access pursuant to § 353(1) (majority of those entitled to access pursuant to § 352; (H) or in accordance with Section 353(4) (occupational doctors and public health service; Point (j), which now only applies to the datasets and information objects pursuant to Section 342(2a)(1) and (2)(a), i.e. in future there will be the possibility of a total objection to processing or access only with regard to the digitally-supported medication process (dgMP) and the electronic patient summary (EPKA).

Too Dreifachbuchstabe eee

The duration of access is adapted to the reality of supply in pharmacies. Supply shortages and associated complicated procurement processes, follow-up consultations, checks on the safety of medicinal products or other circumstances require an extension of the standard duration of access to the electronic health record by providers with access rights pursuant to § 352 sentence 1 points 5 and 6 from three to seven days in the future. Insured persons will still have the possibility to customise the default setting via the user interface of a suitable terminal device according to their own needs.

Too Dreifachbuchstabe fff

Re point (o):

This is a consequential amendment to the introduction of points 20 to 22 in § 341(2). In order to ensure the completeness of the electronic health record (ePA), reference is made in full to Section 341(2) and thus to all categories of possible content of the ePA.

Re point (p):

This is a follow-up to the deletion of points (c) and (f).

Too Dreifachbuchstabe ggg

This is a consequential amendment resulting from the adaptation of point (h).

Too Dreifachbuchstabe hhh

This is a consequential adjustment in view of the newly created Section 342a(4a), according to which insured persons may request the Ombudsperson's Office to set up one or more representatives or to delete registered representatives.

Too Doppelbuchstabe bb

This is a consequential adjustment due to the deletion of § 311(6).

Too Doppelbuchstabe cc

The new point 5 is a consequential amendment to Section 345a(1).

The newly inserted point 6 is a consequential amendment in relation to the newly introduced electronic credit transfer in Section 360a of the Social Code, which provides that, unless the insured person has objected, the credit transfer data and information on the redemption of the electronic credit transfer are automatically transferred to the electronic health record and provided in accordance with Section 341. The rules on the user interface pursuant to Section 342 are supplemented by a requirement relating to access by insured persons.

The new point 7 introduces a consequential amendment in relation to the newly introduced electronic credit transfer in Section 360a of the Social Code, which provides that, unless the insured person has objected, the credit transfer data and information on the redemption of the electronic credit transfer are automatically transferred to the electronic health record and provided in accordance with Section 341. The rules on the user interface pursuant to Section 342 are supplemented by a rule on the exercise of the right of objection by insured persons.

The new rule set out in point 8 is intended to enable insured persons, in implementation of Article 6 of Regulation (EU) 2025/327, to assert their rights under Article 16 GDPR vis-à-vis the health insurance funds as controllers of the processing of data for the purpose of using the electronic health record via their ePA app. Health insurance funds should ensure that corresponding requests for rectification from insured persons are sent via the electronic health record to the health care providers or other data-processing bodies responsible for the data in each case. The Central Federal Association of Health Insurance Funds shall lay down appropriate procedural requirements for handling corresponding requests for corrections in accordance with Section 217f(4e). The health insurance fund does not change the content of the data as a result of the correction.

Too Buchstabe c

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Buchstabe d

In future, it will no longer be necessary to lay down separate rules on the scope and use of the datasets and information objects that can be processed comprehensively and in a coherent manner in the electronic health record, and on additional time limits pursuant to points 1 and 2. Deadlines for the implementation of the requirements in paragraph 2(6), paragraph 2a(2)(a) to (c) and (e) and Section 351(2), on the one hand, and the

identification of further information objects and other data pursuant to Section 341(2)(1)(a) and (d), (9), (10) to (14a) and (16), on the other hand, shall be determined by a binding decision of the Telematics Society pursuant to Section 315(1), first sentence, with the consent of the Federal Ministry of Health. As part of its determinations, the Telematics Society shall take into account the deadlines set by Regulation (EU) 2025/327: It must therefore take account of the fact that, by 26 March 2029 at the latest, the EHR must technically ensure that data in the EHR can be made available as an information object in a semantic and syntactically interoperable form (see Section 342(2a)(2)(a)) and by 26 March 2031 at the latest, it must technically ensure that data on laboratory findings can be made available as an information object in a semantic and syntactically interoperable form (see Section 342(2a)(2)(b)). This is because, in accordance with Article 105(3), points (a) and (b), of Regulation (EU) 2025/327, natural persons are to be able to exercise their rights in relation to their personal electronic health data covered by the patient summaries data referred to in Article 14(1), point (a), of Regulation (EU) 2025/327 and the laboratory results data referred to in Article 14(1), point (e), of Regulation (EU) 2025/327 from those dates.

In the case of data pursuant to Section 341(2), points 14 or 14a, which fall within the competence of the Federal Ministry of Labour and Social Affairs, the Federal Ministry of Labour and Social Affairs shall be involved at an early stage in the procedures for setting the requirements in accordance with the second sentence. This is because the pension and rehabilitation processes in the statutory accident and pension insurance are based on specific technical requirements. These should be reflected in the EHR in the sense of an overall picture by integrating specific document types and data structures accordingly. Early involvement of the Federal Ministry of Labour and Social Affairs ensures that the specific requirements of accident and pension insurance are systematically taken into account and allows for a binding definition of information objects based on in-depth knowledge of Books 6 and 7.

Decisions on § 341(2)(12) can only relate to the insured person’s copy referred to therein, not to the copy of the medical certificate attesting to the existence of the incapacity for work as evidence to the employer (employer’s copy) within the meaning of § 73(2), first sentence, point 9 SGB V in conjunction with § 5(1a), second sentence, of the Act on the Continued Payment of Pay (Employer’s Payments Act).

The decisions of the Telematics Agency shall be published in the Federal Gazette.

Too Buchstabe e

As in the case of Section 342(2b), the determinations pursuant to paragraph 2c should in future be made by binding decision of the Telematics Society pursuant to the first sentence of Section 315(1) with the consent of the Federal Ministry of Health, instead of by statutory instrument of the Federal Ministry of Health.

According to point 1 of the second sentence of paragraph 2c, the binding decision shall contain the time limit with regard to the obligation of the health insurance funds to process data pursuant to points 2 to 5 of Section 341(2) as specific medical information objects, provided that they are available in a semantic and syntactically interoperable form. The provision of medical information objects is comprehensively regulated by § 355 in conjunction with § 372 and § 373. In addition, the decision referred to in point 2 of the second sentence of paragraph 2c shall specify the deadline by which insured persons or their representatives must be able to explain any contradictions with regard to the information objects referred to in point 1 in an accessible manner via the user interface of a suitable terminal equipment.

The decisions of the Telematics Agency shall be published in the Federal Gazette.

Too Buchstabe f

The penalties imposed on the health insurance funds are now linked to the future requirements of the ePA in accordance with paragraphs 2b and 2c and are intended to ensure the timely introduction of relevant applications and the provision of essential data in the ePA. The penalty is no longer imposed by reducing the allocations for administrative expenditure referred to in Section 270(1), first sentence, point 3, but in the form of a fixed amount based on the number of members. The amount shall be paid to the Central Federal Association of Health Insurance Funds and shall be used by the latter in the context of the financing of the Telematics Society in accordance with Paragraph 316.

Too Buchstabe g

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Nummer 53

Too Buchstabe a

The Ombudspersons' Offices will also be given the task of advising insured persons on all questions and problems relating to the registration procedure and the use of the electronic health record; in addition, the provision is adapted to the new version of Section 342(1).

Too Buchstabe b

This is an adjustment for the purpose of legal regularisation. The reference to § 353(1), which governs only the type of opposition referred to here, is sufficient. Furthermore, this is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Buchstabe c

These are consequential adjustments due to the deletion of the first sentence of Section 342(1).

Too Buchstabe d

The newly inserted paragraph 4a is intended in particular to support and strengthen the rights management of insured persons who do not use and manage their electronic health record in accordance with Section 336 via the user interface of a suitable terminal equipment. You will now be able to appoint, with the assistance of the Ombudsman, one or more representatives in accordance with Section 342(2)(1)(p). As a mirror image, insured persons are given the possibility to have registered representations deleted with the assistance of the Ombudsperson.

The newly inserted paragraph 4b obliges the ombudsman bodies, in order to strengthen the rights of insured persons, to set up, at the request of the insured persons, a representative office for the entry into digital care in accordance with Section 345a of Volume V of the Social Code. For example, insured persons who do not themselves use digital devices can easily appoint other insured persons as their representative and benefit from assistance in coordinating their care and receiving healthcare.

Too Buchstabe e

These are consequential adjustments due to the deletion of the first sentence of Section 342(1).

Too Buchstabe f

This is a consequential adjustment due to the newly inserted paragraphs 4a and 4b.

Too Nummer 54

Too Buchstabe a

Too Doppelbuchstabe aa

These are consequential adjustments due to the deletion of the first sentence of Section 342(1).

Too Doppelbuchstabe bb

Too Dreifachbuchstabe aaa

This is a consequential adjustment due to the newly created paragraphs 5 and 6 in § 350.

Too Dreifachbuchstabe bbb

This is a consequential amendment due to the adaptation of Section 342(2)(1)(j).

Too Dreifachbuchstabe ccc

This is a consequential adjustment due to the restructuring of § 350.

Too Dreifachbuchstabe ddd

This is a consequential adjustment due to the newly created Section 342a(4a). As part of the information material provided by the health insurance funds, insured persons should also be informed of the newly created possibility in Section 342a(4a) of registering with the Ombudsman’s Office one or more representatives or having registered representatives deleted.

Too Dreifachbuchstabe eee

Editorial change due to new point 25.

Too Dreifachbuchstabe fff

In point 24, a follow-up adjustment is made as a result of the adaptations in Section 342(2b).

By inserting a new point 25, insured persons are to be informed about the newly created possibility to assert their rights under Article 16 GDPR vis-à-vis the health insurance funds as controllers of the processing of the data for the purpose of using the electronic health record via their ePA app.

Too Buchstabe b

The deadline has been deleted as it has become obsolete due to the passage of time.

Too Buchstabe c

These are consequential amendments due to the adaptation of § 342(2)(1)(h) and § 353(1) and (3), according to which the legal definition of ‘use case’ is deleted and the

possibility of a total objection to processing or access now exists only with regard to the digitally-supported medication process and the electronic patient summary.

Too Buchstabe d

This is a consequential amendment due to the amendment of § 342(2b) and (2c).

Too Nummer 55

The purpose of the provision is to remove legal uncertainty with regard to the taking into account of contradictions in the context of changes of insurance. If insured parties object to the ePA, the objection is forwarded between the health insurance funds. This also applies in cases where the insured person, for example in the context of the application for membership, objected to the ePA in the event of a change of health insurance fund with the newly elected health insurance fund, without any objection having been made to the former health insurance fund, with the result that the former health insurance fund would otherwise continue the ePA for the insured person. In these cases, the receiving health insurance fund takes over the file from the previous health insurance fund at the start of the insurance, and then immediately deletes it on the basis of the objection submitted to it.

To this end, the health insurance funds are granted the right to store the objection in the ePA.

Too Nummer 56

Too Buchstabe a

The recast clarifies that health insurance funds not only have the right to process insured persons' data from the EHR in the EHR itself or in the health insurance funds' IT systems in order to make additional applications available, but also have the explicit power to store the data thus generated in the EHR. The processing and storage of data in the EHR by the health insurance fund can only take place on the basis of the prior consent of the insured person. In addition, health insurance funds do not have further access to data in the electronic health record. Storing the data generated in the electronic health record makes the applications made available by the health insurance funds usable in care. At the same time, insured persons themselves can directly benefit from the added value of the applications and, in particular, also in the event of a change of health insurance fund. Last but not least, the explicit power to store the data generated in the electronic health record is intended to strengthen competition among health insurance funds by expanding the scope for developing and introducing beneficial innovations and value-added applications. The data stored in the electronic health record shall be identified there as data generated by the health insurance fund. These are data pursuant to § 341(2) No 20. Insured persons may withdraw their consent to the processing of their data at any time. Withdrawal may be declared to the health insurance fund or via a user interface of a suitable terminal equipment. The health insurance fund must provide comprehensive and easy-to-understand information in this regard.

Too Buchstabe b

This is a follow-up adaptation that is necessary because the provision on information material on consent-based ePA in § 343(1) has been deleted and the information material on the ePA made available on a contradictory basis since 15 January 2025 is regulated in § 343(1a).

Too Nummer 57

On § 345a (Digital Entrance to Care)

With the functional area for digital access to care in the ePA front ends of insured persons, health insurance funds provide insured persons with an easy-to-use digital route in addition to the established routes to care. To this end, the necessary conditions should be created for user-centric, integrated interaction between the services and applications of the telematics infrastructure and the services offered by the Federal Association of Statutory Health Insurance Physicians. The take-up of digital care does not require the use of the EHR, but it is the interaction with the EHR that can bring particular added value to insured persons. In the ePA front end, insured persons are securely identified and authenticated with the health ID, they are sovereign in the use and sharing of their data, and the functionalities of the EHR can be fully exploited. This opens up the opportunity to provide targeted support to insured persons in their care management in a safe environment with integrated processes, to provide tailored and needs-based care and to establish more efficient care organisation processes between insured persons, service providers and health insurance funds.

Re paragraph 1

Insured persons should be given the possibility to book and manage their appointments via the ePA front. In situations where they need acute care, they should be able to use the initial assessment procedure offered by the Federal Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) at the start of digital care and use it to carry out a digital self-assessment. As a result, they receive an assessment of their care needs and can use them on the 116117 appointment service to request a corresponding care offer for acute care or regular care. Similarly, as soon as the electronic credit transfer becomes available, they can be routed seamlessly to the acute care or to a suitable appointment in the normal care via the activation of an electronic credit transfer.

Re paragraph 2

The design of the digital service start should focus on ease of use in order to enable insured persons to organise their care in a convenient manner, while at the same time making the processes in the practices as efficient as possible. This requires the integration of the various technical functions and applications into intuitively detectable operating patterns. To this end, it will also be possible to use simplistic default settings at the request of insured persons. For example, the insured person may choose to set the default setting that, after booking an appointment with a doctor’s office, he or she would each wish to have access to the EHR, which will be withdrawn if an appointment is cancelled. Information as part of the booking process always reminds the insured person of the selected default setting and allows him or her to modify it and not to grant access to the ePA in individual cases. Similarly, the insured person can choose the default option that proof of insurance status should always be sent before the start of a telemedicine appointment, so that the doctor can document, issue and invoice prescriptions. In addition, the insured person may arrange for the relevant practice to be notified when an appointment is booked that the insured person uses the TI messenger and would like to use this means of communication for further communication on the appointment. Alternatively, the insured person should also be able to adjust each time in such a way that it is asked, on an ad hoc basis, whether the relevant function is to be used and active confirmation is then required in each case. The use of the functionalities described in paragraph 2 shall be subject to the prior informed consent of the insured person.

Re paragraph 3

In addition, in future, once the relevant technical possibilities have been created, it will also be possible to personalise the initial assessment or appointment search by using patient data. This makes it possible to simplify procedures and address individual care needs in a tailored manner. For this purpose, status information, such as participation in a structured treatment programme, used inter alia for appointments with the coordinating doctor or for check-ups in the specialist field, or health information, such as taking blood-diluent medicines, which can be given to the structured initial assessment application and thus shorten the sequence of questions and answers, may be used. Other comfort features, such as the automatic insertion of structured initial assessment results into the EHR, will also be offered as soon as the technical conditions are met. The personalisation functions using data from the EHR do not give health insurance funds access to the EHR, but merely provide insured persons with technical possibilities to request and use their data.

Paragraph 4

The aim is to make it possible to set up a representative office for the digital access point function. This will allow insured persons on behalf of another person to make transfers, book appointments and use other functions. The aim of the possibility of representation in the digital start of care is to make it easier for insured persons to support their relatives and other close persons in the provision of healthcare, especially at a distance. Also in the care situation, for example, the possibility of representation can help to facilitate care processes.

In order to ensure user-friendly implementation, it should also be possible to set up a digital health care entry point as soon as the EHR representation is set up.

Paragraph 5

The identification numbers of insured persons and medical practices are needed in order for the systems involved to be clearly identified and for the processes provided for in the introduction to digital care, such as setting up the possibility of accessing the electronic health record for a medical practice or contacting the healthcare provider and the insured person before an agreed date via the TI messenger, to be carried out safely. For this purpose, at the time of confirmation of appointment, the insured person’s health insurance number on the one hand and the establishment number and telematics ID on the other hand are handed over to the doctor’s office with which an appointment has been agreed. The information that the insured person uses the TI messenger and would like to communicate about it is also provided when booking the appointment. This is provided for by the Federal Association of Statutory Health Insurance Physicians in the specifications of the interfaces of the 116117 Terminservice.

Re paragraph 6

Mirroring the obligation of the health insurance funds in paragraph 1, the Federal Association of Statutory Health Insurance Physicians is also required here to allow insured persons to use the nationwide uniform initial assessment procedure provided by the Federal Association of Statutory Health Insurance Physicians for appointment mediation in acute cases. Once the initial assessment has been completed, the results are to be transferred, in a structured form, from the initial assessment application to the functional area for digital care entry, where they can be used by insured persons for an appointment request or other follow-up processes.

Paragraph 7

If insured parties have used the nationwide uniform initial assessment procedure and an acute need for care has been identified as a result, digital switching from the start of digital

care to suitable acute care services, in particular telemedicine services, should be possible. The Federal Association of Statutory Health Insurance Physicians is therefore obliged to make the relevant appointments and offers available via the 116117 appointment interface. In this way, insured persons can be cared for efficiently and in accordance with their needs and the appointment service points of the associations of statutory health insurance physicians can be substantially relieved by the elimination of telephone mediation cases.

Re paragraph 8

Due to the necessary close interaction of the functional area for digital access to care with the electronic health record and the services and applications of the telematics infrastructure, on the one hand, and the applications of the Federal Association of Statutory Health Insurance Physicians, on the other hand, provision is made for consultation with the Telematics Society for the respective technical specifications of the health insurance funds and the Federal Association of Statutory Health Insurance Physicians.

On § 345b (data-based information on participation in clinical trials; Power to adopt ordinances)

The new Section 345b introduces a rule to make it easier for insured persons to locate and participate in clinical trials for which they are individually suitable. To this end, a procedure shall be established under which data from the electronic health record may be used with the consent of the insured persons.

Paragraph 1 provides that the information on clinical studies for which insured persons could be suitable as participants shall be displayed in the ePA front end.

Paragraph 2 clarifies that the consent of insured persons is required to compare the ePA data of insured persons with information on requirements to participate in a clinical study. The aim of this comparison is to determine for which studies insured persons could be individually suitable.

Paragraph 3 regulates what bodies organising clinical studies need to do in order to be able to contribute their studies to the matching process.

Paragraph 4 provides a legal basis for the adoption of a regulation laying down detailed procedural rules.

Too Nummer 58

Too Buchstabe a

The provision is supplemented by the newly created access facility using e-recipe tokens pursuant to Section 339(1b).

Too Buchstabe b

The deadline has been deleted as it has become obsolete due to the passage of time.

Too Nummer 59

Too Buchstabe a

To Doppelbuchstabe aa and Doppelbuchstabe bb

The term ‘use case’ has been deleted as practice has shown that each use case of the EHR should be considered in isolation and that uniform handling is not possible.

Providers must continue to include all the information objects and datasets listed in Section 342(2a), (2b) and (2c) in the electronic health record.

The conditions already contained in the second sentence, which must be met in order for the filling obligation under the first sentence to apply, are slightly adapted: The content of point 1 remains unchanged; only the ‘and’ at the end is replaced by a comma. Paragraph 2 also contains the condition that there must be no objection to access to the EHR as a whole. The second condition previously also contained in point 2 is moved to point 3 and adapted to the changes in Section 342(2)(1)(h), i.e. as far as the digitally-supported medication process or the electronic patient summary is concerned, there must also be no objection to this or these.

Too Buchstabe b

Point 3

The content of point 3 remains unchanged; only the ‘and’ at the end is replaced by a comma.

Re number 4

As a consequential amendment to adapt the legal definition in Section 341(2)(1)(d), which now includes the electronic discharge letter in addition to the electronic doctor’s letter, point 4, which refers to it, is reworded.

Re number 5

Doctors are already required to store a copy of the medical certificate attesting to the existence of incapacity for work (insured person’s certificate) in their electronic health record for the purpose of staying with the insured person, at the request of their patient, and to document the consent given in this regard in their treatment file kept locally.

Doctors are now obliged to make insured persons’ copies regularly available to their patients in the electronic health record. Patients who do not wish to do so may object to storage vis-à-vis their doctor. The objection must be recorded in the treatment file kept locally (opt-out). The regulation, on the one hand, strengthens patient autonomy and, on the other hand, contributes to reducing the burden on doctors in view of the increasing use of electronic declaration of incapacity for work and the increasing desire of patients to store data, as it removes burdensome documentation requirements. The obligation under point 5 of the first sentence of § 347(2) does not apply to the copy of the medical certificate attesting to the existence of the incapacity for work as evidence to the employer (employer’s copy) within the meaning of point 9 of the first sentence of § 73(2) SGB V in conjunction with the second sentence of § 5(1a) of the Law on the continued payment of wages (EFZG).

Too Buchstabe c

For the sake of clarity, an addition has been made to the provision to the effect that the electronic health record is to be filled in at the request of the insured person only within the limits of the data processing rights laid down in § 352.

Too Nummer 60

To Buchstabe a and Buchstabe b

The changes made to § 347(1) are reflected accordingly in the area of approved hospitals.

Too Buchstabe c

As a consequential amendment to adapt the legal definition in Section 341(2)(1)(d), which now includes the electronic discharge letter in addition to the electronic doctor’s letter, the part of the sentence referring to discharge letters is reworded before point 1.

Too Buchstabe d

For the sake of clarity, an addition has been made to the provision to the effect that the electronic health record is to be filled in at the request of the insured person only within the limits of the data processing rights laid down in § 352.

Too Nummer 61

Too Buchstabe a

The changes made to § 347(1) and § 348(1) and (2) are reflected accordingly for the area of other authorised users.

Too Buchstabe b

For the sake of clarity, an addition has also been made to the provision to the effect that the electronic health record is to be filled in at the request of insured persons only within the framework of the data processing rights laid down in § 352.

Too Buchstabe c

The changes made to § 347(1) and § 348(1) and (2) are reflected accordingly for the area of other authorised users. In addition, the newly created Section 341(2), point 14a, has been supplemented.

Too Nummer 62

Re paragraph 1

The amendment brings the rules into line with the filling rules in Sections 346 to 349. The health insurance fund’s obligation to provide information pursuant to § 343(1a), third sentence, point 10, does not need to be mentioned in § 350(1) in order to apply, so that this reference is deleted in the interests of legal regularisation.

Re paragraph 2

The time limit in the first sentence is deleted as it has become redundant as a result of the passage of time.

The newly inserted second sentence is intended to ensure that the data stored in accordance with paragraph 1 are stored in the electronic health record in a semantic and syntactically interoperable form. The determinations shall be made by the Central Federal Association of Health Insurance Funds and the Federal Association of Statutory Health Insurance Physicians in consultation with the other persons referred to in the first sentence. The purpose of storage in the EHR is to ensure that the data are made available to the insured person. The aim is to increase transparency about the benefits received by health insurance funds and to strengthen the sovereignty of insured persons.

Re paragraph 3

The health insurance fund's obligation to provide information already follows from § 343(1a), third sentence, point 10, and does not need to be mentioned in § 350(3) in order to apply, so that this reference is deleted in the interests of legal regularisation; the following paragraphs appear.

The information that the data in the electronic health record is stored by the provider of the electronic health record has been deleted, as the health insurance funds themselves are already providers of the electronic health record pursuant to Section 342(1).

Paragraph 4

In accordance with the new wording of paragraph 4, insured persons should in future be able to find an overview of the protective vaccinations received in their electronic health records. This is drawn up and continuously updated by the health insurance funds on the basis of the billing data stored with the health insurance funds. The overview shall be included in the electronic health record pursuant to Section 341(2), point 20, in an insured person's understanding and in an accessible manner, unless the insured person has objected to the transmission and storage of his billing data in accordance with paragraph 1.

As part of the digital vaccination overview, the health insurance fund must inform the insured person of upcoming protective vaccinations, which are recommended to be carried out by the Permanent Vaccination Commission set up at the Robert Koch Institute.

Paragraph 5

Paragraph 5 gives health insurance funds the power to develop and make available to insured persons additional applications on the basis of data on the benefits they receive. If the insured person's data pursuant to Section 345(1) have been made available to the health insurance funds, these data may also be used in addition. If the insured person has not objected to the transmission and storage of his or her data in accordance with paragraph 1, the data processed in that context shall be stored in the electronic health record. In this way, the added value of such applications is made directly usable in care for those with access rights under § 352. As they are stored in the electronic health record, they are also available, in particular in the event of a change of health insurance fund. The provision also strengthens competition between health insurance funds with a view to developing and innovating value-added applications that are beneficial.

Re paragraph 6

Paragraph 6 instructs the health insurance funds to inform insured persons in advance of the offer of the digital vaccination overview and other applications and of their right to object. In addition, the insured person shall have the right to object at any time to the digital vaccination overview referred to in paragraph 5 and to the further applications referred to in paragraph 6.

Too Nummer 63

In order to verify how often and to what extent insured persons have exercised their right under § 350a to have paper documents digitalised by their health insurance funds and transferred to their ePA, the Central Federal Association of Health Insurance Funds reported to the Federal Ministry of Health on 1 April 2026 in accordance with the mandate under § 350a(4). It was found that the take-up is very low and that there is no sufficient need to justify the additional costs borne by the health insurance funds for software and hardware for digitisation and recording in the ePA, so that Section 350a is deleted. Irrespective of this, insured persons can continue to upload documents to their ePA independently or through representatives.

Too Nummer 64

Too Buchstabe b

Re paragraph 1

The provision of medication data in a structured form in the EHR provides ample opportunities for better patient care. This includes the use of data by digital health applications (Diga). Subject to the patient's consent, Diga will be able to read the medication data from the ePA and use it to provide safe and personalised care to patients. Manual data input by users may be replaced by automated and correct collection. For Diga, this significantly strengthens the development perspective towards supply scenarios such as telemonitoring and digitally-supported chronic care.

Re paragraph 2

Subsequent adjustments are made as a result of the adaptation of § 342(2b) and the incorporation of the content of § 359(4) into the newly created § 352a. In addition, paragraph 2 is adapted in line with the requirements of Article 105(3), points (a) and (b), of Regulation (EU) 2025/327. In particular, it requires natural persons to be able to exercise their right of access to their personal electronic health data falling under the priority data categories referred to in Article 14(1) of Regulation (EU) 2025/327 from 26 March 2029 and from 26 March 2031 respectively (see also Article 2 of this Act). Pursuant to Section 342(2b), the Gesellschaft für Telematik (Society for Telematics) shall, with the consent of the Federal Ministry of Health, lay down the time limits for the implementation of the requirements under Section 351(2), including the date from which the data listed in paragraph 2 of the electronic health record may be processed in another Member State of the European Union by the national e-Health contact point or (from 26 March 2029) by the national contact point for digital health via the providers of the electronic health record.

Too Buchstabe c

This is a consequential adjustment due to the adaptations in Section 342(2b).

Too Nummer 65

Too Buchstabe a

Too Doppelbuchstabe aa

Under point 4 of the second sentence of Section 129(5h), assisted telemedicine measures that pharmacies may offer include, in particular, advice on the exercise of the rights of the person concerned under Sections 336 and 337, allowing access to the electronic health record and carrying out the deletion of data at the request of the insured person. The access rights of pharmacists and persons belonging to the pharmacy's pharmaceutical

staff (cf. § 352(1), first sentence, point 6), which are necessary for these measures to be available, are now added to § 352(1), first sentence, point 5(b). To accompany this, the 16th sentence of Section 129(5h) makes it clear that such access is permitted only for this purpose.

Too Doppelbuchstabe bb

In order to enable occupational physicians to include in the ePA the findings, diagnoses, treatment measures carried out and planned by them as part of preventive occupational health care, screening examinations, treatment reports and other medical information relating to examinations and treatment (data pursuant to § 341(2)(1)(a)), their processing rights will be extended accordingly.

Too Buchstabe b

With the addition, the rights of access to the medical records already provided for in the first sentence of § 352 are also declared applicable to the corresponding providers of services if they operate within the framework of Book Six, i.e. within the framework of the statutory pension insurance scheme. This includes, in particular, medical rehabilitation and follow-up services.

Too Nummer 66

Access to data from the electronic health record in cross-border care is now regulated uniformly in § 352a. Access to the electronic health record under Section 359(4) on the cross-border exchange of health data, which was previously regulated only for the electronic health record, has been moved to a new paragraph and adapted to the requirements of Regulation (EU) 2025/327. The data categories corresponding to Article 14 of Regulation (EU) 2025/327 in the electronic health record pursuant to Section 341(2) have been supplemented.

Too Nummer 67

The term ‘use case’ has been deleted as practice has shown that each use case of the EHR should be considered in isolation and that uniform handling is not possible. The separate possibility for the insured person to object to access in accordance with § 353(1) (majority of persons entitled to access in accordance with § 352) or to consent to access in accordance with § 353(4) (occupational physicians and public health service) will in future exist only with regard to the data sets and information objects pursuant to § 342(2a)(1) and (2)(a), i.e. in future there will be a possibility to object to processing or access in its entirety only with regard to the digitally-supported medication process (dgMP) and the electronic health record (EPKA). The existing system of differentiated rights of disposal of the insured person is maintained.

Too Nummer 68

Too Buchstabe a

Easy, intuitive operability and user-friendly design are key to widespread acceptance and successful use of the digital service entry point under Section 345a. Given that various telematics infrastructure services and applications are intended to work together and that technical functions must be coordinated in the event of obstacles to good integration, the Telematics Society is given a mandate to do so.

Too Buchstabe b

This is an editorial amendment.

Too Buchstabe c

Re number 7

The provision is supplemented by the newly created access facility using e-recipe tokens pursuant to Section 339(1b).

Re number 8

With regard to the digital switchover, please refer to the justification for point (a).

Too Nummer 69

Too Buchstabe a

Too Doppelbuchstabe aa

Editorial adjustment due to new point 11.

Too Doppelbuchstabe bb

The introduction of the connection of rehabilitation facilities to the telematics infrastructure in Volume VI of the Social Code makes it necessary to supplement the Deutsche Rentenversicherung Bund for the pension insurance institutions.

Too Buchstabe b

ReDoppelbuchstabe aa,

Editorial adjustment due to the restructuring of Section 31a.

To Doppelbuchstabe bb and Doppelbuchstabe cc

Editorial adjustments due to the new point 6.

Too Doppelbuchstabe dd

The provisions of the Federal Association of Statutory Health Insurance Physicians must also take into account that the medicinal product-related regulatory data and dispensing information pursuant to § 341(2)(11) must be suitable to support the cross-border treatment of the insured person pursuant to § 352a in another Member State of the European Union.

Too Buchstabe c

This is a consequential amendment resulting from the transfer of Section 359(4) to the newly created Section 352a.

Too Buchstabe d

The provisions of the Federal Association of Statutory Health Insurance Physicians for the semantic and syntactic interoperability of laboratory findings as an information object of the electronic health record must take into account that laboratory findings pursuant to Section 341(2)(1)(c) in conjunction with Section 342(2a)(2)(b) must be suitable to support the cross-border treatment of the insured person pursuant to Section 352a in another Member State of the European Union.

Too Absatz 4b

This is a correction of a spelling error and a reference error.

Too Nummer 70

This is a consequential adjustment due to the adaptations in Section 342(2b).

Too Nummer 71

This is a consequential adjustment due to the adaptations in Section 342(2b).

Too Nummer 72

Too Buchstabe a

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Buchstabe b

These are consequential adjustments due to the adaptations in Section 342(2b) and the transfer of Section 359(4) to the newly created Section 352a.

Too Buchstabe c

This is a consequential adjustment due to the deletion of the first sentence of Section 342(1).

Too Nummer 73

The provision was transferred to the newly created Section 352a and adapted to the requirements of Regulation (EU) 2025/327.

Too Nummer 74

These are, on the one hand, editorial changes resulting from the renaming of the electronic invoice as a digital patient invoice. In addition to invoice documents themselves, the digital patient invoice may also include documents justifying the invoice.

In addition, under point 4, healthcare providers who have access to insured persons' data in the Digital Patient Invoice for billing purposes are supplemented by providers of medical and assistive devices. The payers referred to in point 6 shall include the statutory health insurance funds, the other payers referred to in § 362, the German statutory accident insurance fund and the German pension insurance fund.

In addition to the use of digital patient invoicing for services that are not subject to the benefit-in-kind principle, in future use should also be possible for services that are subject to the benefit-in-kind principle. This means that in future digital patient billing can also be used for billing services provided under the benefits-in-kind principle by the statutory health insurance funds and also by the DGUV and the DRV. In this case, the bill is settled directly between the provider and the payer, which means that the consent of the insured person is not required.

In addition, health insurance funds must provide the necessary services for direct billing between pharmacies and health insurance funds using the Digital Patient Invoice. For pharmacies, the use of direct billing is voluntary.

Due to the expiry of the deadline, the deadline was removed.

Too Nummer 75

The change of heading is a consequential change due to the provisions on electronic credit transfers in § 360a and § 361d.

Too Nummer 76

On the Buchstabe a andBuchstabe b

These are adaptations of the data for the introduction of different electronic prescriptions and adaptation of the data for the deadline for connection to the telematics infrastructure for different service providers. In addition, an already expired deadline is deleted. In order to be able to understand – and, if necessary, take measures – the implementation of the electronic prescription-only medicinal products in the hospital, the German Hospital Association is also required to: December 2026 and 1st December 2027 on the share of hospital e-regulations in the total number of hospital e-regulations for the respective period from December to December.

Too Buchstabe c

These are consequential editorial amendments due to the deletion of § 311(6).

Too Buchstabe d

Too Doppelbuchstabe aa

In future, the software will no longer be able to develop the components of the telematics infrastructure that enable insured persons to access the electronic medical prescription themselves, but will instead award a contract for this and make the developed component available.

Too Doppelbuchstabe bb

In so far as a health insurance fund allows its insured persons to use the user interface (ePA app) offered for insured persons' access to the electronic health record pursuant to § 360(10) also for accessing and managing electronic prescriptions (ePA app with e-prescription functions), the health insurance fund shall ensure that, provided the necessary technical conditions are met, the insured person's ePA app also allows the cross-border exchange of data from the electronic prescription pursuant to paragraph 12(2). The deadline for implementation laid down for the Telematics Society in paragraph 12(2) does not apply to the health insurance funds.

Too Buchstabe e

The deadlines for the automatic deletion of regulations are adjusted to ensure that recovered regulations from home nursing and non-clinical intensive care are deleted only after the end of the regulation period.

Too Buchstabe f

The sentence has been deleted because the time limit set therein has expired.

Too Nummer 77

On § 360a (Electronic transmission and processing of contracted electronic credit transfers)

Paragraph 1 lays down the obligation to use the telematics infrastructure for the electronic transmission and processing of electronic credit transfers by contracted doctors. The first objective of the scheme is to provide treatment under the statutory health insurance scheme as a first stage of development. It is intended as a starting point for gradual development, to be gradually extended to other care sectors and groups of service providers. In this respect, the rules adopted in this context are aimed at providing treatment under the statutory health insurance scheme, without prejudging any subsequent extension.

This basic obligation applies only if and to the extent that the services and components required for this purpose within the telematics infrastructure are available throughout the territory in the future.

In order to give concrete expression to the rule laid down in paragraph 1, paragraph 2 requires doctors participating in panel medical care or working in institutions participating in panel medical care to issue, retrieve and use telematics infrastructure services and components for the electronic transmission of credit transfers from 1 September 2029.

This obligation shall not apply, as provided for in paragraph 3, where the electronic issuance or transmission of electronic credit transfers is not possible for technical reasons in a specific case. Insured persons may choose to be provided with the access data necessary to access their electronic credit transfer in an accessible manner, either by a paper printout or by electronic means.

Paragraph 4 requires the Telematics Society to make available, as a service of general economic interest, the components of the telematics infrastructure enabling insured persons to have access to electronic credit transfers and to ensure the functionality and interoperability of the components. The purpose of entrusting the Telematics Society is to ensure that the application becomes an integral part of the existing telematics infrastructure and thus secures acceptance among insured persons. The delegation of tasks is necessary for reasons of public health, in particular security of supply and the protection of sensitive personal data of insured persons. The experience gained from this first stage of development should serve as a basis for the further development of electronic credit transfers and their gradual extension to further areas of care.

The security of the components of the electronic credit transfer system, including the means of access for insured persons, shall be demonstrated by an external expert opinion.

The demonstration shall include ensuring the availability, integrity, authenticity and confidentiality of the components, graduated in relation to the hazard potential. The procedure and expert selection for the external security opinion is carried out by the Telematics Society in consultation with the Federal Office for Information Security. The external security opinion must be submitted to the Federal Office for Information Security for examination and confirmed by it. Only after confirmation of the external security opinion by the Federal Office for Information Security may the components be made available by the Telematics Society.

In addition, it is provided that the components of the telematics infrastructure which enable insured persons to have access to the electronic transfer and for which there is an external security report confirmed by the Federal Office for Information Security may be used by the health insurance funds as an integrated application in their user interfaces in

accordance with Section 342. The possibility of integration into the user interfaces pursuant to Section 342 provides the basis for insured persons to be able to manage their electronic credit transfers in an app in a convenient manner and without additional effort.

Paragraph 5 provides that the credit transfer data and the data on the redemption of electronic credit transfers are to be deleted with effect from 100 days after the electronic credit transfer has been redeemed, thereby ensuring compliance with data protection law.

Paragraph 6 provides for a facilitated and automated transfer of the credit transfer data and the information on the encoding of the electronic credit transfer into the electronic health record. This is to ensure that the EHR contains a continuous and up-to-date overview of issued electronic credit transfers and their redemption.

Automated data transmission is subject to the condition that the insured person has not objected to this. The opposition may be declared or revoked in two ways: via the user interface pursuant to Section 342 and at the Ombudsman's office pursuant to Section 342a. No appeal shall lie via the user interface referred to in paragraph 4, as the appeal is recorded systemically in the EHR and the user interface specific to the electronic credit transfer referred to in paragraph 4 does not have access to the EHR. An opposition declared via this surface could not technically be effectively deposited in the ePA.

The purpose of the provision is to ensure that all categories of insured persons can exercise their right to object reliably.

Paragraph 7 provides that the health care providers referred to in paragraph 2 must prove to the relevant association of statutory health insurance physicians that they are able to issue, retrieve and transmit the transfers referred to in the first sentence of paragraph 2 electronically.

Re § 360b (Agreement on Digital Needs Assessment Requirements)

The digital assessment of individual care needs constitutes, in addition to electronic referral and the possibility of digital appointments via the digital start of care under the new Section 345a, another tool to support patients in accessing medical care.

Already today, in acute cases, a digital initial assessment of patients is sometimes carried out in order to assess the urgency of the treatment and to provide medical care on this basis. This is made mandatory by the emergency reform, which provides for the introduction of acute control centres, health management systems and integrated emergency centres. These digitally-supported initial assessment procedures need to be taken into account when developing the requirements for digital needs assessment, in order to avoid contradictions in the assessment of the tools and to ensure consistent and needs-based management of patients.

The aim of the digital needs assessment is to provide patients with a comprehensive opportunity to have their medical treatment needs established in a standardised, structured, digitally-supported way, even beyond the emergency and acute cases, and to book a treatment appointment on that basis, where a corresponding medical care need is identified. This provision also serves to prepare the planned primary care system and the targeted placement provided for in that framework at the level of care appropriate to the medical concern in question. If there is no identified need for treatment by healthcare professionals, the digital needs assessment should also provide advice and information on self-care.

In addition to classifying insured persons' health conditions at an appropriate level of care, the digital needs assessment is also intended to recommend the urgency of a medical need for treatment where it exists.

The new Section 360b gives a mandate to the federal coat-contractors to develop an agreement on a digital needs assessment. This agreement is intended to form the basis for the future development and introduction of an appropriate electronic system in Germany. Further legal provisions are required for this purpose. At further stages of implementation, consideration should also be given to replacing or standardising the initial assessment systems used in outpatient emergency and acute care by or with the electronic system for digital needs assessment, so that in future only a uniform electronic assessment system will be used in outpatient care.

Too Absatz 1

The requirements and requirements for a standardised and structured digital assessment of needs are to be drawn up and agreed jointly by the Federal Association of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds. Paragraph 1 entrusts the parties to the agreement with the task of drawing up the relevant agreement. They shall be given 12 months in which to do so. The Federal Ministry of Health shall have the right to obtain ongoing information on the status of the agreement, in particular on the planned content of the agreement. In order to reflect the broadest and most up-to-date knowledge possible and also to take due account of patients' concerns, the parties to the agreement shall also be required to conclude the agreement in consultation with the organisations and associations referred to in paragraph 1.

When drawing up the agreement, account must be taken of requirements arising from other legal provisions, in particular requirements to ensure the quality of care for telemedicine services, requirements for initial assessment in the context of acute care and, in future, requirements arising from the planned reform of emergency care.

To Absatz 2 and Absatz 3

Paragraphs 2 and 3 shall set out the minimum content requirements and requirements, in particular as regards technical and professional quality and functionalities to be provided for a digital needs assessment and to be taken into account in the agreement referred to in paragraph 1. The agreement must contain specific provisions on the individual requirements and requirements for digital needs assessment in such a way that the agreement provides an appropriate basis for the subsequent commissioning of the development of a corresponding electronic system.

For example, the digital needs assessment must be feasible by the insured persons themselves, by representatives appointed by them, such as confidential counsellors or family members. The electronic system may also consist of several modules or components. This is to ensure that the electronic system can also be used, for example, for indications or for specific patient groups. At the same time, the electronic system must also enable specialist staff, for example at the appointment service points of the associations of statutory health insurance physicians. The digital needs assessment must be feasible both digitally, by telephone or on-site, for example in a doctor's surgery.

It also lays down minimum categories for the temporal classification of the urgency of the treatment needs identified and the levels of care to be provided for the classification of the identified care needs. The categories to be formed are intended to ensure that the identified supply needs can be connected to the existing supply levels; for this purpose, subcategories can also be formed under the individual general indications. Similarly, provision may also be made, for example, for the involvement of appropriate persons (so-called 'human in the loop') who, on the basis of the result of the digital needs assessment, initiate, for example, further care, e.g. appointments or the issuing of assignments to specialist care where necessary.

If the electronic system identifies a need for medical treatment but does not require treatment within the next 24 hours, the electronic system should also indicate an appropriate time corridor for the treatment. This information is intended to assist in the subsequent search for and allocation of appointments within the established medically required time frame.

The minimum categories for classifying the appropriate level of care should also include the recommendation for self-care by insured persons and the related support for self-help, for example through digitally available information from the National Health Portal or health insurance funds. When categorising care needs, provision should also be made for assignment to individual specialist groups, including psychotherapeutic care, and consideration should be given to whether the treatment needs identified are suitable for telemedicine care.

Looking ahead, account should also be taken of cases in which the digital needs assessment identifies a need for treatment that does not necessarily have to be met by doctors, but can also be met by non-medical healthcare professionals.

In addition to sensitivity and specificity, the requirements for meaningful metrics of the accuracy of the digital needs assessment must also take into account predictive values that are positive and negative, among other things.

In order for the data to be passed on or further usable, it must also be ensured that the result of the digital needs assessment, which has been determined in each case, can be transferred to the electronic health record or to the providers' practical management systems for storage and further processing and provided as information by means of an electronic credit transfer.

Too Absatz 4

The provision stipulates that the agreement must be submitted to the Federal Ministry of Health before it is published. The Federal Ministry has a right of objection and can object to the agreement submitted within three months and request adjustments to the agreement if it does not meet the standard requirements. This shall apply in particular where the content specifications and requirements for the digital needs assessment laid down in paragraphs 2 and 3 are not or not adequately reflected in the agreement. If the grounds for objection are not remedied within the time limit set by the Federal Ministry of Health for this purpose, the Federal Ministry of Health shall be authorised to determine the content of the agreements objected to. If the parties to the agreement cannot agree on an agreement, or only partially, both the parties to the agreement and the Federal Ministry of Health have the option of referring the matter to the Federal Arbitration Office under Section 89 of Volume V of the Social Code, which sets out the content of the agreement instead of the parties to the agreement. The Agreement shall enter into force upon its publication.

Too Absatz 5

The parties to the agreement are required to keep the agreement under constant review and, where necessary, to update it. This shall take into account recent scientific evidence on the digital needs assessment requirements and targets laid down in paragraphs 2 and 3, as well as supply developments related to the digital needs assessment. For an update of the agreement, which must take place at least every 12 months, the requirements of paragraph 4, in particular the obligation of the parties to the agreement to submit a complaint under paragraph 1, the right to object and the possibility of a substitute intervention by the Federal Ministry of Health, as well as the possibility of referring the matter to the Federal divorce office, shall apply mutatis mutandis.

On § 360c (providing an electronic system for digital needs assessment)

Re paragraph 1

This provision entrusts the Federal Association of Statutory Health Insurance Physicians with the task of operating, from the date provided for in paragraph 1, a nationwide uniform electronic system for assessing digital needs and making it available to the associations of statutory health insurance funds in accordance with the provisions of the agreement concluded pursuant to § 360b. The specific organisation of the development and provision of the electronic system is the responsibility of the Federal Association of Statutory Health Insurance Physicians. The electronic system shall be made available to insured persons both by telephone via the 116117-termine service and digitally via the 116117-app, the 116117-website and, as part of the digital access to care under Section 345a, via the ePA-app of the health insurance funds. Where the so-called ‘acute management centres’ of the associations of statutory health insurance physicians provided for in the planned emergency reform to improve acute care are available, the electronic system should also be made available via these acute management centres. Re paragraph 2

The expenditure incurred by the Federal Association of Statutory Health Insurance Physicians in connection with the development and provision of the electronic system for digital needs assessment shall be borne jointly by the Federal Association of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds. This includes, in particular, the financing of the electronic system, as well as the staff costs incurred, inter alia, for the monitoring and control of the system service provider and the expenditure incurred for updating and developing the electronic system or for the training of the professional staff applying it, for example in the appointment service points or, in the future, also in the planned acute management centres.

The amount of funding shall be agreed annually between the Federal Association of Statutory Health Insurance Physicians and the Central Federal Association on the basis of the cost calculation to be submitted by the Federal Association of Statutory Health Insurance Physicians in accordance with the deadlines indicated in each case. The financing is limited by the fact that the amount is to be made available in the same amount by the two parties to the agreement in accordance with § 360b.

In the event that the financing cannot be agreed or can only be agreed in part, provision is made for the amount of the agreement to be determined by the competent arbitration office.

Too Nummer 78

Access by care professionals to the electronic prescription was previously covered by paragraph 1, first sentence, point 5 (old). The new access provision for nursing professions only ensures that access is also permitted for the person in need of care to forward regulations on behalf of the person in need of care. This can be used in the future, for example, so that a nursing home can consult the prescriptions of its patients and pass them on to the pharmacy supplying the home.

In addition, the possibility of transmission under the first sentence is extended to providers of medical rehabilitation and follow-up care services under Book Six in so far as this supports the achievement of the participation objective. This includes, in particular, rehabilitation institutions that provide the above-mentioned benefits of the statutory pension insurance scheme.

Too Nummer 79

The possibility of transmission pursuant to the first sentence shall be extended to providers of medical rehabilitation and aftercare services pursuant to Book Six in so far as this supports the achievement of the participation objective. This includes, in particular, rehabilitation institutions that provide the above-mentioned benefits of the statutory pension insurance scheme.

Too Nummer 80

The rules are necessary so that, in addition to the health insurance funds, other payers can also offer the electronic prescription of digital health applications. The amendment also creates the legal framework for establishing simple redemption channels for prescriptions from digital health applications.

Too Nummer 81

On § 361c (access to prescriptions of medical aids and appliances, home nursing, non-clinical intensive care and sociotherapy in telematics infrastructure)

The provision legitimises access to and processing of data from the electronic prescription for home nursing, non-clinical intensive care, sociotherapy and medical and assistive devices for the purposes of the decision on benefits and/or the billing of the corresponding prescribed benefit for the following payers:

- statutory health insurance
- statutory accident insurance
- the payers referred to in § 362

In order to implement access by the payers in such a way that insured persons in need of care can obtain advice from the payer on their prescription from home nursing, non-clinical intensive care and sociotherapy, it must be possible for them to do so with a corresponding low threshold. Patients can then inform their payer of the existence of a regulation to which they may have access, e.g. by means of a call or via the instant messaging service pursuant to point 1 of the first sentence of Section 363a(1).

On § 361d (access to contracted electronic credit transfers in the telematics infrastructure)

The provision in Section 361d accompanies the electronic credit transfer introduced by Section 360a. The categories of persons who can access the data of insured persons in electronic credit transfers under a contract with a doctor are finally regulated. In accordance with the scope of application of § 360a, the provision relates to statutory health care as a first stage of development. If in future electronic credit transfers are extended to other care areas and groups of service providers, the group of persons with access rights must be adapted accordingly. This includes, on the one hand, doctors involved in the treatment of insured persons, with access enabling the processing of data provided by them in accordance with Paragraph 360a, to the extent necessary for the treatment of the insured person.

In addition, persons who work as professional assistants or in preparation for the profession are covered, in so far as access is necessary in the course of the activities which they are lawfully required to perform and access is carried out under the supervision of a doctor who is involved in the treatment of insured persons.

In addition, doctors who act on the basis of an electronic credit transfer are also given access to the extent that access is necessary for the treatment of the insured person. They need the necessary access data pursuant to the third sentence of Section 360a(2) in order to access the data. The fact that only the insured person can provide the access data guarantees the latter's data sovereignty.

Too Nummer 82

The reference to the rules on ombudsman bodies pursuant to Section 342a has been added. This shall also apply mutatis mutandis to private health insurance companies, to the Postal Officials' Sickness Insurance Fund, to the health care of federal railway officials, to police enforcement officers, to other civil servants with health care rights and to soldiers of the Federal Armed Forces, where these use electronic health cards or digital identities for insured persons pursuant to § 362, in so far as the rules can be applied ratione materiae to these payers. The reference is intended in particular to enable private health insurance companies to use ombudsman bodies and to join an overarching joint body, including across the system, i.e. together with health insurance funds (cf. § 342a(7)).

For the purpose of legal regularisation, the reference to § 343(1) already deleted on the basis of Article 2(2) of the Act on the acceleration of the digitalisation of healthcare (Digital Act – DigiG) is deleted. A reference to § 343(4) is added so that the obligation to provide explicit information on the digitally-supported medication process and the electronic patient summary also applies mutatis mutandis to private health insurance companies, the Postal Officials' Sickness Insurance Fund, the health care of federal railway officials, police enforcement officers, other civil servants with health care rights and soldiers of the Federal Armed Forces. This means that the obligation to provide information also applies to the sphere of these payers, so that insured persons must be informed before data sets and information objects pursuant to Section 342(2a), (2b) and (2c) can be processed comprehensively and coherently in the electronic health record.

The addition of the provision under Section 351(2) is based on the requirements and deadlines of Regulation (EU) 2025/327 and the amendments to Section 342(2b).

The newly created provision on access to data from the electronic health record in cross-border care pursuant to Section 352a applies to private health insurance companies, the Postal Officials' Sickness Insurance Fund, the health care of federal railway officials, police enforcement officers, other civil servants with health care rights and soldiers of the Federal Armed Forces if they use electronic health cards or digital identities for insured persons pursuant to Section 362.

The provisions of § 219d(6) to (9) SGB V concerning the national eHealth contact point already apply to the area of private health insurance (cf. the explanatory memorandum to the Act on better care through digitalisation and innovation (Digitale-Versorgung-Gesetz – DVG), BT-Drs. 19/13438, P. 63: "(...) Use of the eHealth National Contact Point is in principle also possible by privately insured persons (...) to the extent that the other conditions for this are established by the private health insurance companies (...)"). The explicit inclusion of such a reference clarifies this in a declaratory manner.

The inclusion of a reference to Section 9 also makes it clear that the provisions implementing Regulation (EU) 2025/327 with regard to governance (Sections 383a to 383c of Volume V of the Social Code) also apply mutatis mutandis to the area of private health insurance, i.e. that, for example, the notified bodies for digital health and the designated market surveillance authority are also responsible for the area of private health insurance.

Too Nummer 83

The insertion of Title 9 (Secure transfer procedures) is intended to systematise the rules on secure transfer procedures, which have hitherto been laid down in particular in Section 311(6), and to supplement them with new provisions, the need for which has arisen in practice as a result of the use of secure transfer procedures. In this respect, the provisions in Sections 363a to 363f echo in particular the content of the previous Section 311(6).

On § 363a (setting out secure procedures for the transmission of medical and nursing data)

Two secure means of transmission, namely the instant messaging service 'TI-Messenger' (TIM) and the secure e-mail service 'Medical Communication' (KIM), are defined as secure means of transmission in the telematics infrastructure. The instant messaging service enables, for example, the exchange of written messages and image files and, in the future, real-time video telephony. The reason for this is that these two secure transmission procedures already exist and already meet the requirements laid down by the Telematics Society for this purpose. These two secure means of transmission may be supplemented by others. The Telematics Society may, with the consent of the Federal Ministry of Health, adopt further procedures as secure transmission procedures by means of a binding decision pursuant to the first sentence of Paragraph 315(1). When drawing up the specifications and before submitting them to the Federal Ministry of Health for approval, the Telematics Society shall take particular account of the requirements of data protection and data security and the requirements of Section 363c. Pursuant to the second sentence of paragraph 2, Gesellschaft für Telematik must therefore also comply with the requirement to establish contact with the Federal Commissioner for Data Protection and Freedom of Information or with the Federal Office for Information Security.

Supply-related administrative data in the context of secure transfer procedures means any technical, organisational or procedural information necessary for the proper functioning of the transfer procedures.

The obligation to publish on the website is intended to ensure the necessary and maximum transparency.

The costs incurred by the Federal Commissioner for Data Protection and Freedom of Information for this purpose shall be reimbursed by the Telematics Society. The Gesellschaft für Telematik shall determine the details of the reimbursement of costs in agreement with the Federal Commissioner for Data Protection and Freedom of Information.

On § 363b (acceptance of telematics infrastructure components and services for secure transmission procedures)

The components or services required for the secure transmission procedures pursuant to Section 363a(1) that have a licence from the Telematics Society must be used. This should further increase the quality and reliability for users of the secure transfer procedures. In so far as the Telematics Association makes use of the possibility afforded to it by Paragraph 311(4) and (5) of central procurement and provision by means of procurement procedures in respect of components and services, authorisation shall not be granted. In this case, the security of the components and services shall be demonstrated by means of an external security opinion, demonstrating in particular that the availability, integrity, authenticity and confidentiality of the components and services is ensured (cf. § 323(2), fifth and sixth sentences).

In addition, in so far as the Telematics Company does not make use of the possibility of awarding contracts, the requirement for approval of components and services is maintained.

Re § 363c (mandatory use of secure means of transmission)

Health insurance funds are obliged to also use the instant messaging service to communicate with insured persons. Providers may also use the instant messaging service to communicate with insured persons.

Health insurance funds are in principle obliged to use the secure e-mail service pursuant to Section 363a(1)(2) for communication with health care providers. The use involves sending, receiving and displaying KIM messages. If certain service providers are not yet connected to the telematics infrastructure and therefore cannot use KIM, other means of communication may also be used.

Service providers are obliged to use the secure email service pursuant to Section 363a(1)(2) for communication with service providers. If certain service providers are not yet connected to the telematics infrastructure and therefore cannot use KIM, other means of communication may also be used.

The transmission of medical and nursing data by fax to health care providers and payers will no longer be allowed. This is subject to the condition that the secure means of transmission are available at both the sender and the recipient.

Re § 363d (content and use of secure means of transmission)

Section 363d reproduces the content of the previous provisions of the eighth to tenth sentences of Section 311(6) and the second and third sentences of Section 313(3).

The sending of messages concerning the secure transmission procedures and the use of data from the directory service pursuant to Section 313 for advertising purposes shall be prohibited.

In individual cases, it may also be necessary for providers, in compliance with data protection law, to assist in clarifying the facts, which is why this obligation has been included in the second sentence of the new Section 363d(3).

It must also be technically possible for health insurance funds to use the instant messaging service for communication with insured persons. Within the framework set by the Telematics Society, the health insurance funds are responsible for organising the accessibility and initiation of discussions.

Re § 363e (use of specialised procedures in the context of secure transmission procedures)

The new provision in Section 363e is intended to enable the Telematics Society and the stakeholders, including the ÖDG, to prepare communications services in good time and in an appropriate manner to meet the requirements of new technical procedures. Specialised procedures are standardised digital procedures within the telematics infrastructure that use secure transmission procedures, the use of which is necessary or legally required for the transmission, processing or documentation of medical or administrative information. This provision is crucial in order to implement the technical requirements and administrative processes necessary for the introduction of specialist procedures in order to support high-quality healthcare.

Thus, transparent information on the individual technical procedures is intended to support business continuity and ensure the smoothest possible integration of new technical procedures into existing communication services, as well as to avoid operational losses caused by the introduction of new technical procedures and to optimise the performance of secure procedures. To this end, it is necessary, inter alia, to obtain information on the expected number of users and details of the framework conditions and content of the specialist procedures. This will allow services to be adapted in advance of the introduction of the new technical procedures in order to ensure the best possible performance of the services and components of the telematics infrastructure concerned. This presupposes that the specifications for the specialist procedures are communicated to the Telematics Society with a corresponding advance notice.

Technical procedures are defined in agreement with the Telematics Society. They must make a significant contribution to healthcare or its administrative processes. The legally chosen thresholds for assessing the materiality of the specialised procedures take into account the impact of the specialised procedures on the overall performance of the safe procedures. Technical procedures for which a significant contribution to healthcare or its administrative processes can be identified as a result of their introduction must be reported accordingly without delay, together with the necessary information.

It clarifies the possibility for the Telematics Society to require the mandatory use of the identifier referred to in paragraph 2 in its specifications pursuant to § 311(1) for individual procedures pursuant to § 363a and technical procedures, in order to facilitate the processing and allocation of technical procedures within the telematics infrastructure and among users and to ensure the interoperability of systems and technical procedures among themselves. In particular, double use of identical markings in different procedures and semantic inaccuracies should be avoided.

On § 363f (provision of medical and nursing data with appropriate private terminals)

This provision creates the possibility for private mobile devices to be used by hospital service providers for the exchange of health data in the hospital. Use is subject to certain requirements to ensure data protection and data security.

Too Nummer 84

This is a correction of a drafting error.

Too Nummer 85

The deadline of the Federal Ministry of Health for the supervisory review is extended to three months. The complexity of the technical regulations, as well as the extensive participation of third parties, is difficult to describe over a period of one month. This is particularly challenging if the scrutiny periods conflict with holidays or holidays.

Too Nummer 86

This is a necessary consequential amendment due to the deletion of § 311(6).

Too Nummer 87

Contracted doctors and panel dentists use appointment booking platforms to facilitate scheduling and manage appointments. Insured persons can also benefit from the fact that, in addition to tried-and-tested appointment mechanisms, there are other appointment procedures that are independent of, for example, the opening time of the practices or limited telephone resources. Against the background of the increasing importance of appointment booking platforms, it is important that contracted doctors, panel dentists and

panel dentists, as well as insured persons, can trust these platforms equally. To this end, compliance with data protection, information security and accessibility requirements is as essential as tailoring appointments to specific medical needs and not to irrelevant considerations. As part of the proof of compliance with data protection requirements, appropriate evidence must be provided to show that the appointment booking platforms fully meet all data protection requirements. This includes compliance with the purpose limitation of data processing, which may only be carried out for the purpose of appointment intermediation. With regard to accessibility, the generally applicable legislation must be taken into account.

The Federal Associations of Statutory Health Insurance Physicians and the Central Federal Association of Health Insurance Funds agree on requirements that must be taken into account by health care providers when using digital appointment booking platforms in the statutory health insurance system. The agreement shall first lay down basic technical and procedural requirements. It also specifies how to demonstrate that data protection requirements are met and that state-of-the-art information security is ensured. In addition, the definition of interoperability requirements is based on the implementation of open and standardised interfaces. Where available, standards published on the platform pursuant to Section 385 of Volume V of the Social Code shall be provided for. The requirements apply to all providers and institutions participating in panel and dental care, including, for example, authorised doctors and institutions and contracted psychotherapists. No distinction is made with regard to validity according to whether these are private-sector appointment-matching platforms or, for example, those provided by the associations of health insurance funds for the free allocation of appointments, in addition to separately regulated placement cases.

The agreement must also specify security of supply and quality of supply. Among other things, it must be ensured that persons with statutory health insurance have access to medical care on a needs-based and equal basis. For example, it cannot be ruled out that appointments will be given to affected groups of people on a secondary basis because of higher treatment costs expected as a result of characteristics such as age or pre-existing medical conditions. If appointments are prioritised on the basis of health status, priority must be given solely on the basis of up-to-date technical-medical standards in order to ensure equal and needs-based care. Appointments based on any payments made by patients or providers or third parties to the appointment booking platform and based on which prioritisation is carried out shall also not be permitted; similarly, appointments aimed at optimising remuneration and, for example, giving priority to appointment requests for extra-budgetary services. Appointments based on the behavioural profiles of the insured person must also be excluded.

It shall be ensured that the forward booking platforms used by service providers are free of advertising. In addition, the agreement shall lay down provisions to prevent insured persons who do not have access to digital appointment booking platforms from being disadvantaged in accessing panel and dental care (e.g. by setting maximum limits on appointment booking possibilities via online platforms or by setting minimum telephone access requirements). In order to ensure the quality of supply, provisions may also be made to counteract over- and under-supply in connection with the use of digital forward booking platforms. The agreement shall lay down the procedure for verifying compliance with the requirements for digital appointment booking platforms by the Federal Association of Statutory Health Insurance Physicians. In particular, the procedure must ensure that the digital forward booking platforms comply with the technical requirements and the quality of supply requirements to be defined by the parties to the agreement.

The agreement referred to in paragraph 1, like the other agreements in Section 6 of Chapter 11 of the Social Security Code, is an annex to the Federal Shelter Agreement. Since the regulatory mandate to be laid down in this agreement goes considerably beyond purely technical requirements, paragraph 2 does not, exceptionally, refer to the

conciliation body of the Telematics Society pursuant to § 319, which is otherwise responsible for technical agreements on telemedicine, in the event that the parties fail to reach agreement in whole or in part, but instead opens the way to the Federal Arbitration Office pursuant to § 89(2). The necessary technical expertise is incorporated into the procedure by the Federal Office of Arbitration in an appropriate manner.

Too Nummer 88

The amendment extends the existing obligation to integrate open and standardised interfaces into information technology systems in statutory health insurance, which are used to process patients' personal data, to include an interface for electronic programs that are authorised for the creation of electronic credit transfers pursuant to § 312. The obligation does not apply to dental and hospital information technology systems.

The scheme thus serves to increase the user-friendliness of practice management systems in the field of statutory health insurance and thus contributes in general to the functioning of digital processes and the simplification of care processes.

Too Nummer 89

The current total ban on billing for services provided by panel doctors and panel dentists using a non-certified IT system will be replaced by a staggered billing ban and a specific self-regulatory agreement. Section 372(3) to (5) continues to link the criminalisation of services provided by panel doctors and panel dentists to the use of certified systems and thus serves to enforce the mandatory requirements laid down pursuant to Section 385(2), first sentence, point 1.

Re paragraph 3

Section 372(3) imposes an obligation on the associations of statutory health insurance physicians to reduce the remuneration for services provided by statutory health insurance physicians and dentists by up to 20 % if management providers use information technology systems to which binding provisions under Section 385(2), first sentence, point 1, of Volume V of the Social Code apply, but which have not, or have not successfully, undergone a conformity assessment procedure under Section 387 of Volume V of the Social Code.

The reduction of the remuneration is an appropriate and proportionate means of ensuring compliance with the mandatory provisions under Section 385(2), first sentence, point 1, of Volume V of the Social Code. It applies directly to remuneration and thus creates a direct economic incentive for service providers to use certified information technology systems. Compared to regulatory sanctions – such as the previous absolute prohibition on billing – the gradual reduction is the more lenient but at the same time effective means. It takes into account the fact that an immediate complete refusal of remuneration for service providers relying on non-compliant systems could lead to a disproportionate burden and thus risk supply shortages.

The detailed design and implementation of the reduction shall be governed by an agreement between the Central Federal Association of Health Insurance Funds and the Federal Associations of Statutory Health Insurance Physicians. This form of joint self-government is in line with the well-established system of SGB V and ensures that the rules can be adapted to the practical realities of statutory medical care. The flat-rate reduction may not exceed 20 % of the remuneration. Within this framework, it is up to the contracting parties to agree on appropriate arrangements which, on the one hand, provide the necessary incentive for compliance and, on the other hand, do not create a burden on individual service providers that threatens their existence.

The deadline of 31 October 2027 provides sufficient time for the Parties to develop a workable procedure, while ensuring that the sanctions mechanism takes effect in a timely manner. If an agreement is not reached within the time limit, the arbitration office determines the content of the contract in accordance with Section 89 of Volume V of the Social Code; the time limit for assessment is two months in each case.

Under point 1 of the third sentence, the agreement must lay down specific provisions on the amount and calculation of the reduction. A progressive increase should be foreseen, taking into account two factors: the duration of the use of a non-certified system and the number of non-compliant but mandatory requirements. This is in line with the objective of allowing a reasonable period of time for providers who make a recognisable effort to bring their systems up to the required level, without immediately burdening them with the full amount of the reduction. At the same time, the incentive to switch quickly to a certified system will be increased.

The arrangements for calculating the reduction referred to in point 2 of the third sentence shall include, in particular, technical processing through the associations of sickness insurance funds, the dates on which the reduction is to be carried out and the obligations to provide information to the service providers concerned. A clear procedural regime is needed to ensure legal certainty for all stakeholders and minimise the administrative burden. The obligation on health care providers to provide evidence through the system they use to the associations of health insurance funds under point 3 of the third sentence is a necessary condition for the sanction mechanism to be enforceable. Only if the Associations of Statutory Health Insurance Physicians receive reliable information on the certification status of the systems used can they apply the reduction properly.

The arrangements to be agreed under point 4 of the third sentence for the withdrawal and withdrawal of a certificate take account of the fact that service providers may be affected by factors for which they are not responsible. In such cases, they should be granted a transitional period of nine months, without penalty, after the withdrawal or revocation has been published on the platform in accordance with point 5 of the second sentence of Section 385(1) of Volume V of the Social Code. This deadline is reasonable, as a change in the IT system used requires a technical and organisational change, with nine months corresponding to a typical procurement and implementation period for IT systems in medical practices. The non-punitive transitional period applies only to cases where the loss of certification is due to circumstances at the manufacturer’s or supplier’s premises, not to cases where a system has not undergone a conformity assessment procedure in the first place.

Point 5 of the third sentence provides for the possibility of transitional periods during which service providers may continue to use a non-certified system beyond the period laid down by the statutory ordinance pursuant to the first sentence of Paragraph 385(1) in conjunction with point 1 of the first sentence of Paragraph 385(2) of the SGB V without the reduction being applied. This provision serves the principle of proportionality. It is conceivable that in certain supply segments or for certain types of systems, a sufficient number of certified alternatives are not or not yet available on the market. In such situations, direct application of the penalty mechanism would not be appropriate and could jeopardise security of supply. The agreement must clearly define the factual conditions for granting an exemption.

Paragraph 4

The obligation to regularly review and, if necessary, adapt the agreement on a biennial basis, starting on 31 October 2029, takes into account the dynamic nature of the healthcare IT landscape. As technical standards, market conditions and supply realities are constantly changing, it is necessary to regularly review the effectiveness and appropriateness of the penalty mechanism.

The system of continued application in the event that an adjustment agreement is not concluded within the prescribed period avoids loopholes and ensures the continuity of the penalty mechanism. At the same time, it creates an incentive for the parties to negotiate expeditiously, as the existing agreement continues to apply until agreement is reached.

Paragraph 5

Paragraph 5 stipulates that the funds resulting from the reduction in remuneration are to be used by the contracting parties to promote the digitalisation of panel and dental care, in particular to further develop digital care processes and digital practice organisation.

This earmarking ensures that the penalty mechanism not only fulfils a fiscal function, but directly contributes to achieving the overarching legislative objective of digitalisation and interoperability in the healthcare sector. The funds withheld are therefore not withdrawn from the health system, but returned to its further development.

Too Nummer 90

From 1 January 2028, tools and implants that make their data available to insured persons on mobile applications and, in addition, transfer the data to a backend, shall allow insured persons to use their data also in digital health applications. Manufacturers shall make available an interoperable backend interface specified by the Telematics Society.

Taking into account the lessons learned from the specification work, a number of clarifications and additions are made and the paragraph as a whole is redrafted.

As part of the supply of assistive devices and implants that transfer data from insured persons to a backend, different combinations of devices and applications from the same manufacturer or also from different manufacturers or companies are possible and used in the supply. Accordingly, it is clarified which of these situations are covered by the obligation to implement the interface and which are not.

Where data is transferred from an assistive device or implant to a device or application of a connected undertaking, the obligation to provide the interface shall also apply to the connected undertaking.

Where data are transferred from an assistive device or implant to a device or application of another undertaking which is not a related undertaking and whose data processing is outside the control of the manufacturer of the assistive device or implant, the other undertaking is obliged to implement the interface only if the other undertaking is itself a manufacturer of an assistive device or implant which is obliged to implement the interface or if the other undertaking transmits the data to contracted doctors or hospitals.

Other clarifications are also provided:

— Clarification that the interoperable interface shall be implemented in accordance with the specifications set out in paragraph 4.

— Clarification that the use of the interface for digital health applications is free of charge. The costs incurred by manufacturers of assistive devices and implants shall be taken into account in the pricing arrangements for assistive devices and implants.

— Clarification that the obligation to implement the interface also includes the obligation to make test environments and test data permanently available so that manufacturers of digital health applications wishing to use the interface can reliably make the data available to insured persons.

— For the use of the interface by digital health applications and the mutual identification of products, it is necessary for digital health applications to be able to access and retrieve information from the register of assistive interfaces referred to in paragraph 2 and, conversely, for assistive devices to be able to access and retrieve information from the register of digital health applications referred to in § 139e. These possibilities will be created.

— Clarification that the specifications referred to in paragraph 4 include not only technical but also operational requirements. The reliable quality of service of the interface that this ensures is essential for the use of the data in the context of care and for the secure provision of care to insured persons, for example in the context of monitoring scenarios.

— Clarification that compliance with the interface must be demonstrated by manufacturers to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products and Medical Devices) by submitting a confirmation of gematics and that the gematics offers a confirmation procedure.

— Obligation on the GKV-Spitzenverband to draw up a directive setting out the details of the verification by the sickness insurance funds of the obligation to transpose.

Too Nummer 91

Too Buchstabe a

Since specialised outpatient palliative care is fundamentally different in some aspects from the other areas covered by paragraph 4(5), the relevant umbrella organisations for hospice work and palliative care at federal level should be involved in the procedure for concluding the agreement under paragraph 4(5).

Too Buchstabe b

The arrangements referred to in paragraphs 3 and 4 shall provide for a conflict resolution mechanism in the form of arbitration by an arbitrator. If the parties to the agreement do not agree on an arbitrator, the latter shall be appointed by the Federal Social Security Office within one month. In order to ensure that arbitration proceedings run expeditiously in the interests of legal certainty, it is also provided that actions and objections against the appointment of the arbitrator by the Federal Office for Social Security and against the determination of the content of the agreement do not have suspensory effect. Actions against the determination of the content of the agreement shall be brought against the other party to the agreement.

Too Nummer 92

The purpose of the amendment is to bring the wording into line with the terminology of Section 15(2) of Volume VI of the Social Code. The Law on improving transparency in old-age insurance and rehabilitation and modernising social security elections of 17 August 2021 (BGBl. I, p. 154) laid down a statutory definition of ‘approved rehabilitation institution’. Substantive changes are not linked to recasting.

The deletion of the words ‘from 1 January 2021’ is for editorial correction. That date relates exclusively to the initial entry into force of the regulation and no longer has any independent significance for the current application of the law. The substantive legal situation remains unchanged.

Too Nummer 93

The previous lump sum for the e-doctor's letter was a start-up funding to establish the e-doctor's letter. Pursuant to § 295(1c), doctors and institutions participating in statutory medical care are obliged, by 30 June 2024 at the latest, to ensure the willingness to receive electronic medical certificates in statutory medical care by using the KIM (Medical Communications) Intelligence Service for the transmission of the electronic medical certificate as a secure transmission procedure. Additional financing of the electronic medical certificate is therefore no longer necessary. For this reason, the transmission of faxes should no longer be remunerated. Moreover, these are consequential editorial amendments.

Too Nummer 94

A new Ninth Section is added to Chapter 11 (telematics infrastructure) as a regulatory section for regulations implementing Regulation (EU) 2025/327 that cannot be supplemented in existing standards.

Sections 383a to 383c of Volume V of the Social Code implement key provisions of Regulation (EU) 2025/327 on governance in general and specifically in the area of primary use of health data.

Sections 383a and 383b of Volume V of the Social Code implement Section 2 of Chapter II (in particular the designation obligation under the first sentence of Article 19(1)) and Section 4 (in particular the designation obligation under the first sentence of Article 43(2)) of Regulation (EU) 2025/327. It requires each Member State to designate at least one digital health authority responsible for the implementation and enforcement of Chapter II of Regulation (EU) 2025/327 and at least one (market surveillance) authority responsible for the implementation of Chapter III of Regulation (EU) 2025/327.

Section 383c of Volume V of the Social Code implements Article 92(1) and Article 95 of Regulation (EU) 2025/327, which provide for the possibility of setting up sub-groups of the EHDS Board and of setting up the steering groups for MyHealth@EU and HealthData@EU

On § 383a (Digital Health Bodies; central Complaints Board)

Digital health authorities under Regulation (EU) 2025/327 are in particular responsible for the implementation and enforcement of Chapter II of Regulation (EU) 2025/327 at national level, in accordance with the first sentence of Article 19(1) of that Regulation.

Too Absatz 1

The Federal Ministry of Health is entrusted with the tasks of a digital health body pursuant to Article 19(2), points (a), (c) and (f), of Regulation (EU) 2025/327. As the regulatory authority, the Federal Ministry of Health is responsible for ensuring that rules and mechanisms are adopted and technical solutions implemented in order to guarantee the rights and obligations provided for in Chapters II and III of Regulation (EU) 2025/327 (point (a)) and that those technical solutions comply with the requirements of Chapters II and III and Annex II to Regulation (EU) 2025/327 (point (c)). The Federal Ministry of Health is assisted in the implementation of technical solutions by the Telematics Society. Through the supervision of the Central Federal Association of Health Insurance Funds, the German Liaison Body for Health Insurance – Abroad (DVKA), the Federal Ministry of Health is also responsible for supervising the national contact point for digital health with regard to the proper performance of its tasks and its technical functioning; in the further development of MyHealth@EU, the Federal Ministry of Health cooperates with other

digital health authorities, in particular the Gesellschaft für Telematik (Society for Telematics), and the European Commission (point (f)).

The Telematics Society shall be entrusted with the tasks of a digital health authority referred to in Article 19(2), points (b), (d), (e), (g), (h) and (j) to (m), of Regulation (EU) 2025/327.

In accordance with Article 19(2)(k) of Regulation (EU) 2025/327, the Telematics Society (as the body responsible for drawing up guidelines for the safe operation of the telematics infrastructure and monitoring the implementation of these guidelines pursuant to Section 311(1)(1)(c) of Volume V of the Social Code) cooperates with the market surveillance authorities, in particular the Federal Office for Information Security as the German market surveillance authority (see Section 383b of Volume V of the Social Code), participates in activities to manage the risks of EHR systems and serious incidents, and monitors the implementation of corrective measures pursuant to Article 44 of Regulation (EU) 2025/327.

Too Absatz 2

Because of its central position in the field of digital healthcare in Germany, Gesellschaft für Telematik is entrusted with coordinating the tasks and powers of the digital health authorities in order to have an overall view of the fulfilment of these tasks. This position also enables the Telematics Society to draw up the report on the activities of the digital health authorities pursuant to the first and second sentences of Article 20 of Regulation (EU) 2025/327, which requires agreement with the Federal Ministry of Health.

Section 383b implements Articles 21 and 22 of the EHDS Regulation and creates a single point of contact for complaints regarding the provisions of Chapter II of Regulation (EU) 2025/327.

Article 21(1) of Regulation (EU) 2025/327 provides for the right of any natural or legal person to lodge a complaint with the competent digital health body concerning the provisions of Chapter II of Regulation (EU) 2025/327 in relation to the provisions of that Chapter, provided that their rights or interests are negatively affected.

Too Absatz 3

Paragraph 3 interprets the right to lodge a complaint under Article 21 of Regulation (EU) 2025/327 in a user-friendly manner by providing that the coordinating body established within the Telematics Society pursuant to Section 307(5) of Volume V of the Social Code takes over the role of the single point of contact for complaints with regard to the provisions of Chapter II of Regulation (EU) 2025/327, so that the Telematics Society, as the coordinating body pursuant to the fourth sentence of Article 19(1) of Regulation (EU) 2025/327, also has an overview of all complaints procedures. Irrespective of the provisions of Chapter II of Regulation (EU) 2025/327, which they allege have not been complied with, complainants may submit their complaint to the coordinating body set up within the Telematics Society pursuant to Section 307(5) of Volume V of the Social Code. The complainant is thus relieved of the responsibility test.

Pursuant to paragraph 3, if the complaint concerns the rights of natural persons under Articles 3 and 5 to 10 of Regulation (EU) 2025/327, the coordinating body set up at the Gesellschaft für Telematik pursuant to § 307(5) SGB V shall forward the complaint to the competent supervisory authority under the GDPR for processing in accordance with the first sentence of Article 21(2) of Regulation (EU) 2025/327. This facilitates the practical exercise of the right to lodge a complaint and enables complainants to effectively exercise their right to lodge complaints in relation to the provisions of Chapter II of Regulation (EU) 2025/327.

Complaints by natural persons other than those referred to in Articles 3 or 5 to 10 of Regulation (EU) 2025/327, as well as complaints by legal persons, shall be examined and handled by the coordinating body set up within the Telematics Society pursuant to Section 307(5) of Volume V of the Social Code.

Re § 383b (market surveillance authority)

In accordance with the obligation laid down in the first sentence of Article 43(2) of Regulation (EU) 2025/327 for Member States to designate a market surveillance authority, the newly inserted Section 383b of Volume V of the Social Code stipulates that the Federal Office for Information Security is the market surveillance authority.

In accordance with Article 3(3) of Regulation (EU) 2019/1020 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (Market Surveillance Regulation), the activities carried out and measures taken by market surveillance authorities are to ensure that EHR systems regulated in Chapter III of Regulation (EU) 2025/327 comply with the requirements laid down therein and that the public interest covered therein is protected.

If the Federal Office for Information Security has reason to believe that EHR systems are non-compliant or that an EHR system presents a risk to the health, safety or rights of natural persons or to the protection of personal data, the Federal Office for Information Security has a wide range of powers under Chapter III of Regulation (EU) 2025/327 (in particular under Article 43 et seq. of Regulation (EU) 2025/327).

In accordance with Article 43(6) of Regulation (EU) 2025/327, the Federal Office for Information Security is to cooperate with the market surveillance authorities of the other Member States and with the European Commission. The Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security) informs the Gesellschaft für Telematics (Society for Telematics) as a digital health authority of serious incidents involving EHR systems that pose a risk, such as interoperability, safety and patient safety, of any corrective action taken and of any recall or withdrawal of such EHR systems from the market (cf. Article 44(9) of Regulation (EU) 2025/327).

In addition, the cost-sharing mechanism is laid down. The details shall be laid down by the Telematics Society in agreement with the Federal Office for Information Security. It is assumed that this will be reimbursed on the basis of activities actually incurred; the current estimate is a full-time equivalent.

On § 383c (sub-groups of the European Health Data Space Board; Steering Groups)

The representatives of Germany in the EHDS Board referred to in Article 92(1) of Regulation (EU) 2025/327 and in European sub- or complementary governance bodies, in particular in sub-groups of the EHDS Board referred to in Article 92(6) of Regulation (EU) 2025/327 and in the steering groups for MyHealth@EU and HealthData@EU referred to in Article 95 of Regulation (EU) 2025/327, shall be designated or confirmed by the Federal Ministry of Health.

The representatives in sub-groups of the EHDS Board referred to in Article 92(6) of Regulation (EU) 2025/327 and in the steering groups for MyHealth@EU and HealthData@EU referred to in Article 95 of Regulation (EU) 2025/327 shall, as far as material matters are concerned, reach an agreement with the Federal Ministry of Health before voting. Important matters also include important or fundamental decisions, such as the adoption of a work programme for the year in question or those which have a financial impact on the Member States or a binding impact on national infrastructure, etc.

Too Nummer 95

Too Buchstabe a

The German healthcare system is characterised by historically developed and often proprietary IT systems and thus an overall highly complex IT landscape. The exchange of information necessary for holistic, digitally-supported care is thereby restricted and exacerbated by increasing digitalisation. In order to counteract this effect and bring complexity to a manageable level, there is a need for common guidelines, principles and rules to be agreed upon by all interacting IT systems. The Digital Supply and Care Modernisation Act (Digitale Versorgungs- und Pflege-Modernisierungs-Gesetz) and the resulting Health IT Interoperability Governance Regulation (Gesundheit-IT-Interoperability-Governance-Verordnung – GIGV) have already introduced the concept of specification, which was further clarified in the course of the Digital Act. Specifications first describe defined, standardised documented requirements, which vary in different forms depending on the application context.

The requirements themselves concern both technical, semantic and syntactic interoperability requirements for information technology systems. These are supplemented by requirements relating to the qualitative and quantitative functions of an information technology system. In accordance with the definition of interoperability under Section 384 sentence 1 point 1, this describes the ability of two or more information technology systems to work together as intended – i.e. also to enable the seamless data and information exchange process across systems, in accordance with points (c) and (a). However, this should not be exclusively reflected in the definition of interface requirements. Cooperation between primary systems and the EHR, for example, can be ensured by means of specifications at interfaces, data exchange formats, etc. However, the proper cooperation for the seamless data and information exchange process also requires, for example, the definition of qualitative functions: such as the maximum charging times for the primary systems to fill the ePA (performance and reliability requirements). Qualitative and quantitative functions therefore relate, in particular, to the ability of an information technology system to reflect, to a defined standard, the essential documentation obligations of health care providers and thus to make those systems usable in practice and within the rapid workflow of health care providers and to ensure integration with telematics infrastructure applications. In view of the relevance of the qualitative and quantitative functions of an information technology system in the area of documentation obligations for the provision of medical services, these can be identified as core functions of an information technology system.

Too Buchstabe b

The definition of the conformity assessment procedure was introduced in the Digital Act. With reference to the extension of the competence of the competence centre on health interoperability with regard to the qualitative and quantitative functions of information technology systems (see the explanatory memorandum with regard to § 384 sentence 1 point 7).

Too Nummer 96

Too Buchstabe a

Too Doppelbuchstabe aa

Paragraph 1, second sentence, point 7 constitutes a follow-up adjustment with regard to the extension of the scope, tasks and competences of the Competence Centre for Interoperability in Health Care (see the explanatory memorandum with regard to Section 384, first sentence, point 7).

Too Doppelbuchstabe bb

The tasks of the competence centre for interoperability in health will be extended to include support for the implementation and maintenance of an interoperability agenda to be drawn up by the Federal Ministry of Health. With the interoperability agenda, the Federal Ministry of Health provides a structured, continuously updated overview of the interoperability requirements and basic interoperability paradigms required for end-to-end digital care, and determines the order in which these are to be implemented across sectors. The Agenda thus provides transparency and predictability for all healthcare stakeholders on the requirements in force and to be met in the future, and allows limited implementation capacity to be focused on areas with the greatest benefits for care and patient safety.

Too Buchstabe b

Too Doppelbuchstabe aa

The definition of the conformity assessment procedure was introduced in the Digital Act. With reference to the extension of the competence of the competence centre on health interoperability with regard to the qualitative and quantitative functions of information technology systems (see the explanatory memorandum with regard to § 384 sentence 1 point 7).

Too Doppelbuchstabe bb

Under the Digital Act, the competence centre for interoperability in the health sector has already been tasked with setting up an appeal body on the platform pursuant to § 385(1), second sentence, point 5. Where information technology systems are certified after completion of the conformity assessment procedure pursuant to Section 387(3), but a breach of both the specified interoperability requirements and the requirements relating to qualitative and quantitative functions is demonstrated or there is a suspicion of a breach, a complaint may be notified to that body.

Too Nummer 97

Re § 386a (obligation of interoperability)

Re paragraph 1

The provision is aimed at the interoperability obligations of manufacturers, which, among other things, have a direct impact on the implementation of the right to interoperability of insured persons under § 386. Manufacturers of information technology systems within the meaning of point 3 of the second sentence of § 384 shall make their patients' personal health data available to healthcare providers in interoperable format without delay and free of charge upon their request. Service providers, in turn, are obliged to provide individual patient data if necessary or requested (see also Section 386(1)). However, the immediate exchange of data requires that the data is in an interoperable format. In order to fulfil his obligation towards patients, the provider depends on the nature of his primary system. As a result, manufacturers and suppliers of information technology systems are required to create the necessary conditions for this, thereby enabling the service provider to have access to their patients' data on a non-discriminatory basis and free of charge, or to make data available in an interoperable manner from the system provided by the manufacturer, by means of appropriate interfaces, free of charge. The obligation of interoperability also exists without a specific request for information from an insured person pursuant to § 386(2) and is not limited in frequency. It shall be made available without undue delay if, depending on the complexity of the data provision, it is made available without undue delay.

The arrangements put in place help, inter alia, to improve the switching process of the providers' practice management system and to ensure that, even after switching, the provider can fully comply with its documentation and archiving obligations or, with reference to the right of insured persons to provide the data in an interoperable format, can also fully comply with this obligation, i.e. by providing the full data of the patient. Non-discriminatory access is imperative for this, as otherwise it could be restricted or prevented by technical measures taken by the manufacturer. This is particularly true for cloud computing services. The provision also ensures that the provision and implementation of binding requirements must in future be free of charge. Hospitals in particular are expected to benefit significantly from this.

The scheme does not cover manufacturers of digital health applications. By allowing data to be transferred to the EHR, healthcare-related data will be made available to both insured persons and healthcare providers in an interoperable format. In that regard, there is no need for a separate claim on the part of the service provider.

Re paragraph 2

Paragraph 2 defines the format to be followed by the manufacturers referred to in paragraph 1. The interoperable format shall be deemed to be all the mandatory requirements laid down in the statutory ordinance pursuant to the first sentence of § 385(1) in conjunction with point 1 of the first sentence of § 385(2).

Re paragraph 3

Service providers shall have the right, in accordance with paragraph 1, to obtain, at their request and without undue delay and free of charge, the personal health data of patients covered by statutory health insurance from manufacturers of information technology systems within the meaning of point 3 of the second sentence of § 384. In order to assert this right, healthcare providers have the possibility to seek the assistance of the respective association of social security doctors, in line with the right to interoperability of patients. This requires the prior consent of the health care providers to request the personal health data of the health care provider's patients from the manufacturers on their behalf. The aim of the scheme is to provide appropriate assistance to health care providers in enforcing their rights. The data are not sent to the combined transport undertaking and may not be used by it for its own purposes.

Paragraph 4

The failure to make their patients' personal health data available at the request of healthcare providers can cause these monetary damage. For example, the service provider may suffer monetary damage as a result of the need for additional expenditure to migrate the data from an old Practical Management System (PVS) to a new PVS. In addition, opportunity costs may arise as user-driven information technology systems cannot or only to a limited extent be integrated into the workflow of service providers. The provider may also incur costs when making the relevant data available to patients, unless the data can be made available in an interoperable format, as the provider is obliged to make the data available to the patient free of charge in an interoperable format (cf. § 386(2)).

The regulation therefore makes manufacturers of information technology systems more responsible. A balance shall be struck between the rights and obligations of the various actors in the field of information technology systems.

If the manufacturer fails to comply with its obligation to make data available to the Consultant in an interoperable format, the latter shall have the right to compensation for any damage suffered. The amount of damage relates to the actual costs incurred, for

example, as a result of the use of external services for data migration as part of the system change. Other use cases include, for example, costs incurred for necessary measures used for archiving data (to be carried out by the Consultant on a mandatory basis) or the local withdrawal of data from a cloud provider.

On § 386b (digital consultancy)

In the established sector, there is a growing need for holistic advice and support on the digitalisation of practices. This shows, among other things, the high demand for show practices, some of which are already offered by the associations of social security doctors, in which doctors in private practice can in principle find out about the digitalisation of practices. However, the need often goes beyond this initial, principled and ad hoc advice. In line with this need, the Associations of Statutory Health Insurance Physicians are given the opportunity to make further offers to service providers in connection with digitalisation. This may include, for example, general switching advice (PVS switching) or implementation of the measures demonstrated in the show practices. A criteria-based comparison of key product characteristics of information technology systems can also be created on the basis of voluntary information provided by manufacturers (e.g. in terms of functionalities, costs) in order to allow line providers to make informed modernisation decisions of their practices. The Associations of Statutory Health Insurance Physicians could carry out a technical weighting of the criteria in this regard. Other examples may include skills-building training on digitalisation or how to set up and initialise digitalisation projects. This should enable the Association of Statutory Health Insurance Physicians to provide comprehensive advice to its members. Explicit product advertising is not permitted.

On § 386c (anti-circumvention)

Section 386c of Volume V of the Social Code serves to ensure the effective implementation of the requirements for interoperability, data access and data usability in the healthcare sector laid down in Chapter 12. The legislative objective pursued by Paragraph 384 et seq., namely the cross-sectoral and interoperable availability of health-related data, can be achieved only if circumvention practices that are liable to affect the exercise of the rights of health care providers and insured persons established in Paragraphs 386 and 386a are excluded. Manufacturers of information technology systems regularly have effective control over technical interfaces, data formats and contractual arrangements for system use. In the absence of such legislation, there would be a risk that the envisaged rights of access, transfer or use would be restricted by technical, economic or contractual measures, thereby depriving them of their effectiveness. In that regard, Paragraph 386c of SGB V establishes a binding legal framework to ensure the effectiveness of the rules.

Re paragraph 1

Paragraph 1 lays down a general prohibition on circumvention. Manufacturers of information technology systems in the health sector shall not take or refrain from taking measures that are likely to prevent, impede or unduly delay the exercise of the right to interoperability by insured persons and healthcare providers. The concept of appropriateness makes it clear that it does not cover disabilities that have actually occurred, but rather measures that, in terms of their objective effect, are liable to affect the exercise of the right provided for by law; there is no need for an intention to obstruct. The situations listed in points 1 to 5 give concrete expression to the general prohibition of circumvention in typical cases.

Point 1 prohibits the levying of charges, fees or indemnities for making data available in an interoperable format. This prevents access rights provided for by law from being

restricted by economic barriers to access. The provision covers all forms of pecuniary charge, irrespective of their specific designation.

Point 2 prohibits contractual arrangements that restrict the disclosure of data to healthcare providers or insured persons or make it subject to additional conditions. This applies regardless of whether such clauses are included in licensing agreements, terms of use or other arrangements. Manufacturers' contractual freedom is limited by the data access rights granted by law.

Point 3 prohibits technical restrictions on the speed or scope of data output beyond what is technically necessary. The criterion of 'technically necessary' takes account of the fact that certain limits inherent in the system cannot be avoided. On the other hand, deliberate throttling measures that go beyond that level are to be classified as aggravating acts. Technical measures remain permissible to the extent that they are necessary for reasons of system security, stability or integrity.

Point 4 clarifies that data shall be provided in a format that allows complete semantic reconstruction by other information technology systems permitted by this book. A mere formal provision of data is not sufficient if its actual usability cannot be guaranteed due to proprietary structures, inadequate documentation or a lack of semantic interoperability. The provision takes account of the fact that interoperability requires not only technical portability, but also the material and functional usability of data.

Point 5 prevents the withholding of such data elements which, although not defined in a binding manner, are necessary to fulfil the documentation and archiving obligations incumbent on service providers. This prevents the practical relevance or usability of datasets from being limited by the selective provision of data.

Re paragraph 2

The first sentence of paragraph 2 lays down specific information requirements for manufacturers vis-à-vis service providers using these systems. The objective of the scheme is to provide early transparency on the state of implementation of legal requirements and to allow service providers to prepare in a timely manner for becoming mandatory requirements under the IOP Governance Regulation. The obligation to notify at least three months before binding provisions take effect takes account of the fact that service providers depend to a significant extent on the technical and organisational capacity to implement the systems in place. The purpose of early information is to reduce uncertainties as to compliance with legal requirements and to improve planning certainty for the service providers concerned.

The second sentence regulates the service provider's extraordinary right of termination in the event that the manufacturer indicates that it will not be able to meet the relevant requirements or that it will not be able to do so on time. The right of termination may be exercised without notice and at no cost within three months of receipt of the information. The purpose of the provision is to protect service providers from being permanently locked in to information technology systems that do not meet the legal requirements and to enable them to switch to appropriate systems in good time. At the same time, it creates an incentive for manufacturers to implement the legal requirements on time.

Too Nummer 98

With the entry into force of the Digital Act, a uniform conformity assessment procedure was set up at the Competence Centre for Interoperability as the central body pursuant to Section 385(1), second sentence, point 7, in order to verify the interoperability requirements. The competence centre may assess compliance itself or entrust this to a body accredited within the meaning of Section 385(8). As a result of the now extended

tasks of the Competence Centre, as a result of the changes made during the current legislative procedure to include, prioritise, develop or have developed by third parties requirements for specifications for qualitative and quantitative functions of information technology systems and to recommend that the Federal Ministry of Health make them binding, the scope of the conformity assessment procedure is extended accordingly.

The framework conditions for the conformity assessment procedure introduced by the Digital Act remain in place and are simply applied by analogy to the extended scope. The aim is to ensure that IT systems comply with all relevant requirements so that, in terms of qualitative and quantitative functionalities, it can be ensured that in future healthcare providers will only use systems that, for example, have sufficient performance or can ensure a smooth and efficient operation of the ePA of patients treated by a healthcare provider. Conformity assessment therefore leads directly to an improvement in the supply of insured persons.

Too Nummer 99

Too Buchstabe a

In order to ensure interoperability and standardisation and increase the quality of information technology systems, they may in future be placed or kept on the market only if they not only meet the interoperability requirements but also meet the other requirements in terms of quality and quantity. The competence centre on health interoperability shall be responsible for the unambiguous definition of the scope in relation to the mandatory requirements stemming from a specification and established for mandatory implementation. In the event of substantial changes to existing systems affecting not only interoperability but also the other requirements mentioned above, a new conformity check will be required. Compliance with both interoperability and qualitative and quantitative requirements is crucial for the seamless integration of PVS and the effective exchange of health data. This will improve the quality of healthcare towards modern and data-driven medicine.

Too Buchstabe b

This is a consequential amendment; reference is made in this regard to the justification for the amendment of the first sentence of Section 388(1).

Too Nummer 100

The first sentence remains unchanged.

The new second sentence provides legal certainty for established maintenance and support processes and at the same time strengthens the level of protection of the systems used. It states that access for maintenance and support purposes alone is not to be regarded as processing within the meaning of the first sentence if state-of-the-art technical measures ensure that the data cannot be accessed or otherwise processed. Section 393 of Volume V of the Social Code links its requirements to the processing of social data and health data by means of the cloud computing service pursuant to the first sentence of paragraph 1. If access is technically designed in such a way that the data are kept closed, there is already no access to the protected dataset; the requirements of paragraphs 2 to 4 shall remain unaffected and need not be met separately for such access.

The provision is deliberately designed to enable this. It allows continuous maintenance and support operations, including site-independent maintenance and support operations, without lowering the level of safety: The point of reference for privileged treatment is not the purpose of access, but only the technically proven inaccessibility of the protected data. The requirement of the state of the art ensures that the requirements for the arrangements

evolve with the level of safety that can be achieved at any given time and do not fall short of the state of the art of current and best practices. Encryption is privileged only if the accessing entity does not have the means to decrypt it; mere organisational or contractual assurances are not sufficient. Technologically open, equivalent safeguards to encryption may be considered, such as trusted execution environments, effective separation of maintenance collection from productive data assets, or tokenisation; the list is not exhaustive and open to future technical developments.

This takes into account the work-sharing design of modern cloud architectures, where security-related decisions can be taken not only at the level of the infrastructure manager, but also at the application or platform level. The clarification also serves to distinguish cloud-specific security risks from general remote access, maintenance and support constellations. Remote access for maintenance, support or error analytics purposes should not be subject to stricter requirements simply because the data concerned is stored in a cloud infrastructure. In particular, the migration of existing IT systems from on-premises to cloud environments should not lead to a different security assessment of established support and maintenance processes solely due to the change of hosting model.

The privilege applies exactly as far as technical protection is concerned. The security logic of the provision, based on the C5 certificate issued by the Federal Office for Information Security, is maintained in full; The second sentence concerns only accesses that do not technically reach the protected dataset. If state-of-the-art access does not consistently ensure that the data remains locked, the rule with all requirements applies in full. The provisions of paragraph 8 shall remain unaffected.

Too Nummer 101

If, in a particular case, the Telematics Society suspects an administrative offence under Section 397(2a)(2), (3) or (4), it shall inform the Federal Office for Information Security accordingly. In this way, it can be ensured that the Federal Office for Information Security, as the administrative fine authority pursuant to Section 397(4), becomes aware of all facts that may justify an administrative offence pursuant to Section 397(2a)(2), (3) or (4).

Re paragraph 3

If an objection arises in proceedings concerning an administrative offence pursuant to Section 397(2a)(2), (3) or (4) and the Federal Office for Information Security becomes involved pursuant to Section 76(1) or (3) in conjunction with the first sentence of Section 63(3) of the Administrative Offences Act, the latter shall coordinate continuously with the Telematics Society as part of its participation in the main proceedings. This ensures that the specific expertise of the Telematics Society in the area of telematics infrastructure, including with regard to risks to its functioning and safety and relevant safety deficiencies, is taken into account in the administrative offence proceedings. In addition, as soon as the Federal Office for Information Security becomes aware of the judgment or other decisions closing the proceedings in accordance with Section 76(4) of the Administrative Offences Act, it must immediately inform the Telematics Society.

Too Nummer 102

Too Buchstabe a

Under the first sentence of Section 329(2), in addition to significant disruptions, identified vulnerabilities and security incidents must now be reported immediately to the Telematics Society; the addressees of the standard are also required to take appropriate measures to remedy the malfunction. In addition, providers of operating services pursuant to Section 323 and providers and manufacturers of information technology systems with the

technical interfaces and modules necessary for the use of telematics infrastructure in the healthcare sector will be added to the circle of addressees of the standard. With the new provision in Section 329(2a), the Telematics Society can now also, in the event of significant disruption, request information on the possible causes of the disruption and on the measures taken to remedy it from the providers and manufacturers referred to in paragraph 2, who are then obliged to provide full and immediate information. The adjustments to the obligations also have an impact on the offences subject to fines in such a way that infringements of all the above obligations by all the addressees referred to are now punishable by fines pursuant to Section 397(2a)(2). The new obligation on the providers and manufacturers referred to in Section 329(2) to provide information pursuant to the second sentence of Section 329(2a) is also subject to a fine as a result of an amendment to Section 397(2a)(4). The possibility of imposing administrative fines thus significantly expanded is capable of preventing breaches of obligations by the aforementioned participants in the telematics infrastructure and can therefore contribute to strengthening the telematics infrastructure as a secure digital platform in the health sector for the exchange of sensitive health data. Since the Telematics Company's power to issue binding orders to the suppliers and manufacturers referred to in Section 329(2) is now governed by the third sentence of Section 329(3), the penalty for an infringement of that provision is adjusted.

In addition, the unlawful charging of costs for the integration of components and services into information technology systems pursuant to Section 332a(2) is punishable by a fine.

Section 386a(1) of Volume V of the Social Code requires manufacturers of information technology systems in the health sector to make their patients' personal health data available to health care providers, upon their request, without undue delay and free of charge, in an interoperable format and to enable health care providers to access patient data in accordance with this book in an interoperable format. Section 397(2a)(7) of Volume V of the Social Code flanks this obligation under administrative law: Anyone who, contrary to Section 386a of Volume V of the Social Code, fails to ensure both the provision of and access to data, or fails to do so correctly, completely, in the manner provided for or in good time, is guilty of an administrative offence. The provision is intended to ensure that health care providers are able to fulfil their obligation under Section 386(2) of Volume V of the Social Code to provide interoperable data to insured persons in good time.

Too Buchstabe b

In the absence of specific legislation, the general rule of jurisdiction laid down in Section 36 of the Administrative Offences Act (Gesetz über Ordnungswidrigkeiten, OWiG) has hitherto applied to the prosecution of administrative offences under Section 397(1)(2) to (5). Under Section 36(1)(1) OWiG in conjunction with Section 112(1)(1) of Volume IV of the Social Security Code, the health insurance funds, as insurance institutions, are therefore the competent administrative authorities. On the basis of this current system, situations may arise where several sickness insurance funds are responsible for prosecuting an administrative offence at the same time. In the interests of legal certainty and efficient processing of proceedings, responsibility for prosecuting administrative offences under Section 397(1)(2) to (5) should be pooled uniformly with bodies responsible for the entire Federal Republic which are already responsible for prosecuting administrative offences. To this end, the special jurisdiction rule in Section 397(4) is supplemented by the administrative offences set out in points 2 to 5 of paragraph 1.

The offence referred to in paragraph 1(2) shall be aimed at the non-discriminatory integration of all authorised components and services and at the operability and development of the telematics infrastructure. Since the Federal Office for Information Security is closely involved in the approval process (see Section 325(3)), it is appropriate

to assign to it the responsibility for prosecuting administrative offences pursuant to paragraph 1(2).

The situations referred to in points 3 and 4 serve to protect the insured person's right to informational self-determination and to protect the insured person against the misuse of his or her data. The Federal Commissioner for Data Protection and Freedom of Information is the supreme federal authority responsible for the protection of the right to informational self-determination, so it is appropriate to assign it also responsibility for the prosecution of administrative offences pursuant to paragraph 1(3) and (4). Since the offence under Section 397(1)(5) also serves to protect against abusive data processing, it is also appropriate here to assign competence to the Federal Commissioner for Data Protection and Freedom of Information.

Too Nummer 103

The group of persons entitled to apply is extended to include those responsible under data protection law.

Too Nummer 104

This is a consequential amendment to adapt the legal definition in Section 341(2)(1)(d), which now includes the electronic discharge letter in addition to the electronic doctor's letter.

It is also a consequential amendment to the amendment of the agreement rule to a consultation rule in § 311(2) and a consequential amendment due to the deletion of the first sentence of § 342(1).

Re Artikel 2 (Further amendment of Volume V of the Social Code)

Too Nummer 1

Pursuant to Article 24(3) of Regulation (EU) 2025/327, in addition to the national contact points for digital health of the Member States of the European Union, a national contact point for digital health of a third country or a participant in MyHealth@EU authorised by a system established at international level by an international organisation may also become a national contact point for digital health provided that it meets the requirements of MyHealth@EU for the purposes of the exchange of personal electronic health data pursuant to Article 23 of Regulation (EU) 2025/327, that the transfer resulting from the connection to MyHealth@EU complies with the rules laid down in Chapter V of the GDPR and that the requirements in terms of legal, organisational, operational, semantic, technical and cybersecurity measures are equivalent to those applicable to Member States when operating the MyHealth@EU-Dienste. It will also make it possible to connect European Economic Area (EEA) countries. The European Commission verifies compliance with these requirements by means of conformity checks (cf. Article 23(3), first subparagraph, of Regulation (EU) 2025/327 above) and, based on the outcome of the conformity checks, decides, by means of implementing acts, to connect or disconnect the national contact point for digital health of the third country or the system established at international level by an international organisation to MyHealth@EU, where applicable (cf. Article 23(3), second subparagraph, of Regulation (EU) 2025/327). The European Commission shall establish, maintain and make publicly available the list of national contact points for digital health of third countries or systems established at international level by international organisations connected to MyHealth@EU in accordance with Article 23(3) of Regulation (EU) 2025/327 (see Article 23(3), third subparagraph, of Regulation (EU) 2025/327). MyHealth@EU is therefore intended to support the exchange of personal electronic health data not only with national contact points for digital health of Member States of the European Union, but also with national contact points for digital health of

relevant third countries and with systems established at international level by international organisations, in order to contribute to the continuity of healthcare (see fourth sentence of recital 35 of Regulation (EU) 2025/327). Therefore, § 219d(8) SGB V also provides for the possibility of cross-border data exchange with the national contact points for digital health of third countries connected to MyHealth@EU A legal definition of 'MyHealth@EU-Mitgliedstaat' is introduced, which includes, in the context of MyHealth@EU, in addition to the Member States of the European Union, third countries whose national contact points for digital health have been added by the European Commission to the list of national contact points for digital health of third countries referred to in Article 24(3), third subparagraph, of Regulation (EU) 2025/327.

Too Nummer 2

This is a consequential amendment due to the adaptation of § 352a.

Too Nummer 3

First, since Regulation (EU) 2025/327 refers to national contact points for digital health, the renaming of the national contact point for eHealth as the national contact point for digital health, which took place on 26 March 2029, is reflected in the text of the standard. On the other hand, as from the above-mentioned date, in addition to Member States of the European Union, Contracting States to the Agreement on the European Economic Area (EEA) and third countries (which are neither Member States nor Contracting States) connected to MyHealth@EU and included in the relevant Commission list pursuant to Article 24(3) of Regulation (EU) 2025/327 are also to be involved in the cross-border exchange of the electronic health record data referred to in § 352a.

To Nummer 4 and Nummer 5

These are consequential amendments due to the adaptation of § 352a.

Too Nummer 6

Since Regulation (EU) 2025/327 refers to national contact points for digital health, on the one hand, the national contact point for eHealth will be renamed as of 26 March 2029 and further developed into a national contact point for digital health that meets the requirements of Regulation (EU) 2025/327. In addition, as of the above-mentioned date, States Parties to the Agreement on the European Economic Area (EEA) and third States (other than Member States and States) connected to MyHealth@EU and included in the relevant Commission list pursuant to Article 24(3) are also to be involved in the cross-border exchange of regulatory and dispensing data. The Member States, as well as the Contracting States to the Agreement on the European Economic Area (EEA) and third States (which are neither Member States nor Contracting States) are collectively referred to as connected States.

Too Buchstabe b

Too Nummer 7

Since Regulation (EU) 2025/327 refers to national contact points for digital health, on the one hand, the national contact point for eHealth will be renamed as of 26 March 2029 and further developed into a national contact point for digital health that meets the requirements of Regulation (EU) 2025/327. In addition, as of the above-mentioned date, States Parties to the Agreement on the European Economic Area (EEA) and third States (other than Member States and States) connected to MyHealth@EU and included in the relevant Commission list pursuant to Article 24(3) are also to be involved in the cross-border exchange of regulatory and dispensing data. The Member States, as well as the

Contracting States to the Agreement on the European Economic Area (EEA) and third States (which are neither Member States nor Contracting States) are collectively referred to as connected States.

Re Artikel 3 (Further amendment of Volume V of the Social Code)

From 26 March 2031, in addition to the categories of data already mentioned in Section 219d(8)(1) to (3), pursuant to Article 14(1), points (d), (e) and (f), of Regulation (EU) 2025/327, data on medical imaging and related imaging-based findings (i.e. reports from imaging diagnostics pursuant to Section 347(2)(2) in conjunction with Section 341(2)(1)(a) SGB V), data on the results of medical examinations, including laboratory and other diagnostic results and related reports (i.e. data on laboratory findings pursuant to Section 347(2)(1) in conjunction with Section 341(2)(1)(a) SGB V and reports on findings from invasive or surgical measures and from non-invasive or conservative measures pursuant to Section 347(2)(3) in conjunction with Section 341(2)(1)(a) SGB V), and data on discharge reports (i.e. discharge letters pursuant to Section 348(3)(1)). Half sentence in conjunction with § 341(2)(1)(d) SGB V) can be sent via MyHealth@EU (cf. Article 105(3) (b) of Regulation (EU) 2025/327).

Re Artikel 4 (Amendment of Volume VI of the Social Code)

Too Nummer 1

This is a consequential amendment to the new Section 32a.

Too Nummer 2

Providers of medical rehabilitation and aftercare services in the rehabilitation of the statutory pension insurance are to be subject to an obligation to connect to the telematics infrastructure from 1 January 2029. Pre-connection will also remain possible. This applies in particular to rehabilitation institutions which provide services for the statutory pension insurance scheme, in so far as, on the basis of the provisions of Book Five, they do not yet have the obligation to be connected to the telematics infrastructure and may be charged to the statutory pension insurance scheme.

The mandatory connection also serves to implement Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space (EHDS Regulation). It provides that natural persons have access to their electronic health data. This also includes data on medical rehabilitation and follow-up care provided by the statutory pension insurance scheme. The integration of the service providers concerned into the telematics infrastructure enables the secure electronic processing of the data necessary for that purpose.

The providers of medical rehabilitation and after-care services under Book Six are in part identical to those under Book Five or Book Seven, since in some cases similar or identical services are provided. Rehabilitation institutions are partially covered by both the statutory health insurance and the statutory pension insurance. Some of the persons or bodies which also provide services under Book Five are therefore already connected to the telematics infrastructure. It is therefore reasonable that the telematics infrastructure and its applications can be used in the pension insurance system as a whole. There is no need to refer to the rules on the reimbursement of costs incurred by service providers in connection with the connection to the telematics infrastructure (Section 378(2) of Volume V of the Social Code), as these are already included in the rules on costs set out in Section 381 of Volume V of the Social Code. The provisions of paragraphs 2 and 3 ensure that the rules and standards of telematics infrastructure referred to in SGB V also apply in the field of statutory pension insurance. By applying the provisions of Book Five mutatis mutandis, differences in the use of telematics infrastructure are avoided. This also applies

to the scope of the e-Regulation and the use of secure means of transmission. Use is already largely technically possible today. As soon as full technical use is possible, it should also be used in the interests of largely uniform applicability.

Re Artikel 5 (Amendment of Volume 7 of the Social Code)

Too Nummer 1

Too Buchstabe a

Paragraph 360 of Book Five shall apply to the service providers referred to in Paragraph 27(1) and to the accident insurance institutions as soon as the regulation of services referred to in Paragraph 27(1)(4) is carried out electronically and the service provider is connected to the telematics infrastructure. The second sentence of § 27(1) provides that all service providers who provide services for statutory accident insurance and for whom the SGB V does not already provide for a possibility of connection to the telematics infrastructure (TI) are obliged to be connected until 1 January 2027. For providers of sociotherapy services, the deadline for the connection obligation in Section 360(8) of Book Five has been adjusted. This is taken into account by dynamic reference to § 360(8) of Book Five.

Too Buchstabe b

The removal of the TI lump sum for providers of statutory accident insurance who do not at the same time provide statutory medical care under Book Five corrects unjustified burdens on statutory accident insurance institutions. Service providers are, in principle, engaged in business activities and decide on their own responsibility as to the scope of their activities. Providers who do not participate in statutory health insurance have deliberately chosen not to provide care to the general population and therefore do not participate in the financing mechanisms provided for therein, including the reimbursement of TI's costs. This means that they take investment decisions – for example for joining the TI – autonomously and without any entitlement to solidarity-based funding.

Too Nummer 2

This concerns, on the one hand, the clarification of the provision already in force in Paragraph 27(1) and, on the other hand, a consequential editorial provision resulting from the deletion of Paragraph 350a of the SGB V.

On Artikel 6 (amendment of Volume 11 of the Social Code)

Too Nummer 1

The table of contents had to be adapted as a result of the subsequent changes.

Too Nummer 2

The addition of point 8 in the first sentence adds to the competence of the Federal Medical Service the power to lay down uniform national rules on digital data exchange procedures between medical services and, in particular, care funds and service providers. This addition is made with the aim of making digital standards for data exchange by the medical services mandatory in the field of social care insurance too.

The Directive shall specify technical transmission methods, formats, interfaces, transmission frequencies or qualitative requirements. Taking into account the state of the art, priority shall be given to the use of established applications of the telematics infrastructure. The provisions on the database referred to in § 114(1a) shall remain

unaffected. Existing schemes, if any, can be continued and further developed as long as they are efficient and cost-effective.

The standardisation of data transfers contributes to the homogeneity of digital structures, accelerates processes and thus contributes to the digital transformation of healthcare. In doing so, it also strengthens the cost-effectiveness and quality of care for insured persons.

Too Nummer 3

This is an addition to the already existing § 25b SGB V in the list in § 94(1) SGB XI.

Too Nummer 4

This is a consequential adjustment due to the deletion of Section 311(6) of Volume V of the Social Security Code and the re-systematisation of the rules on secure procedures for the transmission of medical data in Sections 363a to 363f of Volume V of the Social Security Code.

Too Nummer 5

On § 106c (integrating medical services into telematics infrastructure)

This is a consequential amendment as a result of the newly inserted Sections 363a et seq. of Volume V of the Social Security Code and the newly inserted Directive competence pursuant to Section 53d(3), first sentence, point 8. The Federal Medical Service is to regulate the details, in particular justified exceptions to the use of telematics infrastructure in specific cases, by means of guidelines.

Re § 106d (mandatory use of secure means of transmission)

The Instant Intelligence Service remains a voluntary application for service providers. Within the framework conditions laid down by the Society for Telematics, the organisation of the accessibility and initiation of discussions is also left to the service providers, in line with the procedure followed by the care funds.

Care funds are obliged to use, in principle, the secure e-mail service referred to in Section 363a(1)(2) of Volume V of the Social Code for communication with service providers. If certain service providers are not yet connected to the telematics infrastructure and therefore cannot use KIM, other means of communication may also be used.

Service providers are obliged to use the secure e-mail service referred to in Section 363a(1)(2) of Volume V of the Social Code for communication with service providers. If certain service providers are not yet connected to the telematics infrastructure and therefore cannot use KIM, other means of communication may also be used. In the event that the data and communication platform pursuant to § 114(1a) also provides for the connection of service providers, there is no obligation to use KIM for communication in this context.

The transmission of medical and nursing data by fax to health care providers and payers will no longer be allowed. This is subject to the condition that the secure means of transmission are available at both the sender and the recipient.

Too Nummer 6

Too Buchstabe a

This is a consequential amendment following the deletion of point 7.

Too Buchstabe b

This is a deletion of administrative offence proceedings for reasons of cutting red tape.

The Federal Social Security Office has hitherto been responsible for conducting administrative offence proceedings under Section 121(1)(7) of Volume XI of the Social Code against private insurance undertakings that fail to comply properly with their reporting obligation to the Central Office for Private Care Provision. The burden of this administrative task is disproportionate to the legislative purpose of the procedure for imposing fines. The Central Office for Private Care Preparation only informs the Federal Social Security Office of incorrect datasets that have been identified as incorrect in the automated procedure. In these cases, the Central Office for Private Care Provision does not pay any supplement. Consequently, in these cases there is no monetary loss as a result of the payment of unjustified allowances and no administrative burden as a result of the recovery of unjustified payments from the Central Office for Private Care Provision. The prosecution of the corresponding administrative offences therefore has no bearing on the operation of the supplement procedure. On average, the fines collected are negligible and have little punitive effect on private insurance companies. In recent years, only in a few cases has it been possible to issue a fine notice at all.

The discontinuance of the misdemeanour proceedings will result in direct relief.

On Artikel 7 (Act on the Use of Health Data for Public Interest Purposes and Data-Based Development of Health Care)

The Health Data Utilisation Act will be re-adopted. The significant extension of the scope of the standards contained makes it necessary to break them down into sections.

Re Abschnitt 1 (General provisions)

Section 1 contains general rules, such as the rules on the purpose of the Act, definitions and other general rules.

On § 1 (purpose of the law; Scope of application)

To Absatz 1 and Absatz 2

Paragraphs 1 and 2 correspond to paragraphs 1 and 2 of the current § 1, with the clarification that not only research purposes but also other secondary uses in the public interest should be made possible. The Health Data Usage Act is aimed at the re-use of data collected for other purposes. Therefore, the concept of further use is also taken into account.

Too Absatz 3

The new rules in Section 2 of DGNG implement Regulation (EU) 2025/327 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Regulation (EU) 2025/327) as far as secondary use (Chapter IV) is concerned. This is now included in paragraph 3 of the provision on scope.

Too Absatz 4

Corresponds to current paragraph 3. It is clarified that GDNG also takes precedence over the provisions of the Genetic Diagnostics Act in so far as the same facts are regulated. Section 2 of DGNG carries out the secondary use procedure in accordance with Chapter IV of Regulation (EU) 2025/327. This includes genomic, genetic and other omic data (cf. Article 51(1), points (f) and (g), of Regulation (EU) 2025/327). These provisions of European law take precedence over their application. On the basis of the opening clauses in Article 51(4) of Regulation (EU) 2025/327, it is possible to derogate from the objection principle in Regulation (EU) 2025/327 and to withdraw a consent requirement here (see Section 21). Consent must meet the requirements of Article 9(2)(a) GDPR and Article 7 GDPR. This means, in particular, that it must be explicit, voluntary and revocable at any time. The EHDS process covers more data categories than genetic analyses and investigations, which is why, in order to ensure a uniform implementation of the EHDS process for all data categories and purposes covered, it needs to be regulated in GDNG. In so far as secondary use is concerned in accordance with the provisions of the GDNG, it therefore takes precedence. The Genetic Diagnostics Act has been amended accordingly. However, priority applies only in so far as GDNG regulates a situation. This means, in particular, that the requirements of the gene diagnostic set on the doctor-patient ratio and the use of the samples continue to apply. In addition, in accordance with the procedure set out in Regulation (EU) 2025/327 and Section 2 of DGNG, access to the data shall be given priority only in the case of a request under that procedure. Other access procedures, such as under § 303e SGB V or § 64e SGB V, remain unaffected and coexist with the EHDS procedure.

Too Absatz 5

As Section 2 has added another comprehensive administrative procedure, this provision clarifies that the provisions of the applicable Administrative Procedure Act apply to administrative proceedings under the Health Data Usage Act. This includes the rules on ancillary provisions, withdrawals and revocations of administrative acts.

Re § 2 (Definitions)

The definitions are derived from the reference to Regulation (EU) 2025/327 (as amended).

At the same time, the ‘General Data Protection Regulation’ short citation for Regulation (EU) 2016/679 is introduced.

The current points 1, 2, 3, 4 and 8 of Section 2 are superfluous due to the alignment of the terminology with Regulation (EU) 2025/327 and should be deleted due to the prohibition on repetition and deviation. In so far as DGNG refers to data users who are not health data users within the meaning of Regulation (EU) 2025/327, the term ‘recipient’ within the meaning of the GDPR is used or a different wording is chosen.

Points 5, 6 and 7 shall become points 1, 2 and 3.

Basic research in the field of life sciences is added to the concept of health and care research for clarification and clarification purposes.

On § 3 (research code; Power to adopt ordinances)

The new Section 3 introduces a research indicator for the health sector. The research identifier is a national identifier or other identifier of general importance within the meaning of Article 87 GDPR. Paragraph 3 sets out the conditions necessary to ensure appropriate safeguards for the rights and freedoms of the data subject. Meaningful re-use of health data regularly requires the linking of data from different data silos. This research metric is

necessary to enable such a link, in particular pursuant to § 10 GDNG in the context of the implementation of the EHDS secondary use procedure. This is because, in addition to the necessary legal basis for linking, clear, uniform features in datasets are needed on the technical side in order to correctly attribute information on the same natural person from different datasets. The research metric thus serves as an ‘unique identifier’, enabling secure and privacy-preserving interconnection. At the same time, however, the research indicator is also a necessary basis for enforcing the opposition as a key data subject right in the context of the EHDS secondary use procedure. The unique research metric allows datasets captured by contradictions to be filtered out before being made available. Despite its function as an ‘unique identifier’, it is precisely not the aim of the research metric to enable the identification of individuals. On the contrary, the research code serves precisely to replace, when making data available, characteristics that make it easier to re-identify data subjects.

Too Absatz 1

Paragraph 1 provides for the general introduction of the research identifier as a unique, pseudonymous identifier for natural persons. The term ‘research metric’ will be legally defined and its role and objective will be defined. The research code is therefore designed in such a way that it does not allow the identification of the health insurance number or the re-identification of the person behind it.

Too Absatz 2

Paragraph 2 regulates the definition of the research metric. The research code is then compiled on the basis of the unchangeable part of the health insurance number in accordance with the second sentence of Section 290(1) of Volume V of the Social Code. The coordinating health data access body pursuant to § 7 GDNG is responsible for designing the technical procedure for drawing up the data. This technical procedure shall be established in consultation with the Federal Office for Information Security and the Federal Commissioner(s) for Data Protection and Freedom of Information. The technical procedure for compiling the research code from the unchangeable part of the health insurance number is shared with the health data holders and other bodies involved in re-use. The design of the research metric should take into account its cross-checking and linkage with other, sector-specific or cross-sector identification metrics or metrics. This should also take into account the possibility of integrating the European Digital Identity Wallet in accordance with Regulation (EU) 910/2014.

Too Absatz 3

Paragraph 3 requires health data holders to use this technical process to create the relevant research metrics for the personal electronic health data in their possession and assign them to the respective datasets. In order to enable them to do so, the second sentence allows them to process the unmodifiable part of the health insurance number. They may therefore, in principle, collect this date and use it to generate the research metric.

Too Absatz 4

Paragraph 4 specifies the extent to which the research metric may be processed. The processing of the research metric is thus permitted to the extent that it is permitted and necessary to combine data from different health data holders on the basis of a legal basis in the GDNG or on the basis of another legal basis. The research metric can also be used for consent-based research with datasets to be linked, provided that consent includes linking the datasets.

Too Absatz 5

Paragraph 5 creates a regulatory power for the Federal Ministry of Health in consultation with the Federal Ministry of Research, Technology and Space and the Federal Ministry of Digital and State Modernisation. This may, for example, regulate the technical procedure and also technical requirements for the design of the research indicator.

Re § 4 (processing of data on deceased persons)

As regards the use of personal data under DGNG, the question has been raised in practice whether this includes the use of data of deceased persons. The background is that the GDPR does not apply to data of deceased persons. The purpose of the rule is to clarify that the data of deceased persons may also be included in the context of the use of personal data under DGNG.

It is not the intention of these rules to impose additional conditions for the isolated use of data of deceased persons within and outside DGNG. In particular, no independent requirements comparable to data protection law are laid down for the processing of such data.

Paragraph 2 deals with the effects of death on oppositions. Under the first sentence, oppositions lodged previously continue to apply. In this way, the will of the deceased continues to be taken into account even after the death. In this way, individuals who lodge an objection can be sure that their data will not be processed even after their death. In accordance with the second sentence, the introduction of new objections by successors in title is also excluded. This provision also preserves the will of the deceased.

On § 5 (data protection supervision of cross-border health research projects)

Corresponds to the current § 5 with editorial adjustments.

On Abschnitt 2 (implementation of Chapter IV of Regulation (EU) 2025/327)

The newly inserted Section 2 implements Chapter IV of Regulation (EU) 2025/327 on the secondary use of electronic health data.

On § 6 (health data access bodies)

Too Absatz 1

Paragraph 1 specifies that the tasks referred to in Articles 55, 57, 58 and 59 of Regulation (EU) 2025/327 shall be carried out by a coordinating health data access body and domain-specific health data access bodies in accordance with the new Section 2 in DGNG. The aim of the division of tasks is to ensure efficient and resource-efficient implementation with clear divisions of responsibilities and efficient processes, avoiding double burdens on all stakeholders.

Too Absatz 2

Paragraph 2 provides for the cooperation of the coordinating health data access body and the domain-specific access bodies in the performance of their tasks in order to ensure a consistent application of Regulation (EU) 2025/327. This serves to implement the sixth sentence of Article 55(1) of Regulation (EU) 2025/327.

Mutual assistance can take the form, for example, of inputting information and documentation and also reaching out to health data holders. In particular, this includes providing the information to enable the coordinating health data access body to fulfil its

information, transparency and oversight obligations. This therefore includes, in particular, information on the facts of applications, requests and authorisations, but also reports of infringements of which the domain-specific access points have become aware. Where possible, notifications of application procedures should be able to be reported to the register of applications in an automated manner. Health data access bodies may provide each other with assistance in carrying out their tasks. For example, an access point for other access points may take over the provision of the secure processing environment. In cases where the competence of a domain-specific access point is justified by the fact that a request falls predominantly within its competence, other access points, where relevant concerned, may provide assistance by taking over the data request from the data holders within their domain.

On § 7 (coordinating health data access body)

Too Absatz 1

Paragraph 1 corresponds to the former Section 3(1), with the adaptation that the data access and coordination body for health data is now named as the coordinating health data access body in line with the terminology of Regulation (EU) 2025/327.

Too Absatz 2

Paragraph 2 serves to implement the third sentence of Article 55(1) of Regulation (EU) 2025/327. Regulation (EU) 2025/327 leaves it to the Member States to establish either one or more access points. Where several health data access bodies are designated, the Member State shall designate one access body as a coordinating body. The law designates the coordinating health data access body as a coordinating body and entrusts it, in particular, with the tasks of the national contact point for secondary use referred to in Article 75(1) of Regulation (EU) 2025/327.

Too Absatz 3

Paragraph 3 sets out the tasks from the list of tasks of the health data access body set out in Regulation (EU) 2025/327 that need to be performed centrally in one place, as they are cross-system in nature and require a particular degree of uniformity or neutrality and independence. These are, in particular, coordination and information tasks.

Too Nummer 1

Point (1) implements Article 57(1), first sentence, point (e), of Regulation (EU) 2025/327. The obligation shall include the maintenance of a management system to record and process health data access applications, health data requests, the decisions on those applications and requests, as well as the data permits issued and the health data requests processed, containing at least information on the name of the health data applicant, the purpose of access, the date of issuance, the duration of the data permit and a description of the health data access application or health data request.

As the processing of applications and requests is not normally to be carried out by the coordinating access body, this entails the obligation to forward applications received in their single application portal to the relevant competent health data access body. Where possible, this should be done automatically on the basis of the information in the application.

In order to be able to fill the management system with the necessary information, the domain-specific health data access bodies handling the applications and requests shall return the relevant information, in particular on the decisions taken, to the coordinating health data access body. This should also be done in an automated manner.

Too Nummer 2

Point (2) implements Article 57(1), first sentence, point (f), of Regulation (EU) 2025/327. The obligation includes the maintenance of a public information system to comply with the obligations set out in Article 58 of Regulation (EU) 2025/327. This requires the coordinating health data access body to make publicly available information on the conditions under which electronic health data is made available for secondary use. Again, the domain-specific access points provide the necessary information. The information system shall also include, in accordance with Article 58(2) of Regulation (EU) 2025/327, the information on and the possibility to submit the statement of objection referred to in Article 71 of Regulation (EU) 2025/327 and the declarations of non-knowledge referred to in the third sentence of Article 58(3) of Regulation (EU) 2025/327. The coordinating access point should therefore refer to the register pursuant to § 16 on its website.

Too Nummer 3

Point (3) implements Article 57(1), first sentence, points (g) and (h), of Regulation (EU) 2025/327. The obligation includes cooperation at Union and national level to establish common standards, technical requirements and appropriate measures for accessing electronic health data in a secure processing environment, as well as cooperation at Union and national level and advice to the Commission on techniques and best practices for secondary use and management of electronic health data. The cooperation shall take into account the objective set out in Article 75(11) of Regulation (EU) 2025/327 to promote the interoperability of HealthData@EU with other relevant common European data spaces in accordance with Regulations (EU) 2022/868 and (EU) 2023/2854.

Too Nummer 4

Point (4) implements Article 57(1), first sentence, point (i), of Regulation (EU) 2025/327. The obligation shall include facilitating cross-border access to electronic health data for secondary use hosted in other Member States through the HealthData@EU referred to in Article 75 and cooperating closely with each other and with the Commission.

Too Nummer 5

Point (5) implements Article 57(1), first sentence, point (j), of Regulation (EU) 2025/327. The obligation shall include the publication by electronic means of (i) a national dataset catalogue containing detailed information on the source and type of electronic health data referred to in Articles 77, 78 and 80 of Regulation (EU) 2025/327, as well as the conditions for making electronic health data available, (ii) all health data access applications and health data requests without undue delay after the first receipt, (iii) all issued data permits or approved health data requests and refusal decisions, including their justification, within 30 working days from the issuance, approval or refusal, (iv) actions related to non-compliance pursuant to Article 63 of Regulation (EU) 2025/327, (v) the results communicated by health data users pursuant to Article 61(4) of Regulation (EU) 2025/327, (vi) an information system to comply with the obligations of Article 58 of Regulation (EU) 2025/327, and (vii) information, at least on an easily accessible website or web portal, to connect national contact points for secondary use of a third country or a system established at international level by an international organisation to HealthData@EU once the third country or international organisation becomes an authorised participant of HealthData@EU. Points (i) to (iii) correspond to the information also available in the management system referred to in point 1. Point (vi) presents the information referred to in point 2. The national dataset catalogue shall also be made available to the single information point referred to in Article 8 of Regulation (EU) 2022/868. This is laid down in Section 2(3)(2) of the Data Governance Act. The national dataset catalogue should be searchable, machine-readable and aligned with European standards.

Too Nummer 6

Point (6) implements Article 59 of Regulation (EU) 2025/327. Access points must publish an activity report every two years and send it to the European Commission. This obligation falls on the coordinating access point in accordance with Article 59(1), second sentence, of Regulation (EU) 2025/327.

Too Absatz 4

As a rule, the other tasks of the health data access body, in particular those of processing, deciding and making data available, are to be performed by domain-specific health data access bodies pursuant to § 9. However, scenarios can be envisaged in which there is no domain-specific access point for the relevant application or in which the competence of the coordinating health data access body is justified for other reasons (cf. § 10). In these cases, the coordinating health data access body has residual competence, unless competence is established at another access body (including at Land level). If and to the extent that a domain-specific access point (in the Land administration) has been established, § 7(4) GDNG applies. This separation of administrative levels, particularly in the case of complaints, fines and fees, prevents improper mixed management.

Too Nummer 1

Point (1) of the implementation of Article 57(1), first sentence, point (a), of Regulation (EU) 2025/327. As far as legally and technically possible, all processes should be automated. This includes the tasks referred to in points (a)(i) to (iii) of the first sentence of Article 57(1) of Regulation (EU) 2025/327, in accordance with Articles 67, 68 and 69 of Regulation (EU) 2025/327, with supervision limited to monitoring and reporting of non-compliance, as the supervisory measures are to be laid down centrally by the coordinating health data access body. It shall also be ensured that personal health data are not made available by persons in so far as they exercise their right to object under Article 71 of Regulation (EU) 2025/327 through the possibility to object established under this Act. Access shall be granted in secure processing environments in accordance with Article 73(1) and (2), first sentence, of Regulation (EU) 2025/327 and Section 13 of this Act. Health data holders provide information to access bodies where necessary for the processing of applications, cf. Section 12(1).

Too Nummer 2

Point (2) implements Article 57(1), first sentence, point (b), of Regulation (EU) 2025/327 and clarifies that health data access bodies may process personal data in the context of making them available to health data users. This also includes the link referred to in Paragraph 11 of that law.

Too Nummer 3

Point (3) implements Article 57(1), first sentence, point (c), and Article 52 of Regulation (EU) 2025/327. Health data access bodies shall take the necessary measures to preserve the confidentiality of intellectual property rights and legal data protection, as well as the confidentiality of trade secrets in accordance with Article 52. The adoption of such measures shall be subject to health data holders having indicated in the national dataset catalogue that their data is subject to restrictions based on intellectual property, trade secret protection or legal data protection law pursuant to Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004.

Too Nummer 4

Point (4) implements Article 57(1), first sentence, point (d), of Regulation (EU) 2025/327. The obligation shall include cooperation with and supervision of health data holders to ensure consistent and accurate implementation of the rules on data quality and utility labels set out in Article 78 of Regulation (EU) 2025/327, including, and in particular, notification to the coordinating health data access body, as any revocation measures of the label referred to in paragraph 3, point (11), shall lie with the coordinating health data access body.

Too Nummer 5

Point (5) implements Article 57(1), first sentence, point (l), of Regulation (EU) 2025/327. This includes all other tasks related to enabling the secondary use of electronic health data. This includes, but is not limited to, advising health data holders and users.

Too Nummer 6

Point (6) implements Article 57(1), first sentence, point (k), of Regulation (EU) 2025/327. This includes in particular those obligations which are not already fulfilled with the information requirements pursuant to paragraph 2, points 2 and 5. This is essentially the information to the general public on the tasks and benefits of the health data access bodies under Article 58(4) of Regulation (EU) 2025/327, as the information to health data holders on material findings reported by health data users will be regularly provided by the domain-specific access bodies (see paragraph 4, point (12)).

Too Nummer 7

Point (8) implements Article 57(2) of Regulation (EU) 2025/327. Access bodies shall cooperate with data protection supervisory authorities, the EHDS Board, all relevant stakeholders and other relevant national competent bodies where relevant, including national competent authorities for the supervision of data altruism organisations under Regulation (EU) 2022/868, competent authorities under Regulation (EU) 2023/2854 and national competent authorities under Regulations (EU) 2017/745, (EU) 2017/746 and (EU) 2024/1689, where relevant.

Too Nummer 8

Point (8) implements Article 57(3) and (4) of Regulation (EU) 2025/327, according to which health data access bodies may support public sector bodies when they access electronic health data pursuant to Article 14 of Regulation (EU) 2023/2854 or when they need technical assistance to process the data after obtaining data pursuant to Article 15, point (a) or (b), of Regulation (EU) 2023/2854.

Too Nummer 9

Point (9) implements Article 62 of Regulation (EU) 2025/327. Access points may charge fees in accordance with Article 62 of Regulation (EU) 2025/327. The intention is to have a centralised fee system linked to the application management system referred to in paragraph 3, point (1).

Too Nummer 10

Point (10) implements Article 63 of Regulation (EU) 2025/327. Health data access bodies may take enforcement measures pursuant to Article 63 of Regulation (EU) 2025/327 to carry out their monitoring and supervisory tasks. To ensure consistency and comparability of enforcement actions, those tasks shall, where possible, be carried out by the

coordinating health data access body as a neutral body. This is to ensure that existing good cooperation between domain-specific health data access bodies and in particular health data holders is not jeopardised by enforcement actions of the domain-specific access body. However, it is possible to envisage scenarios in which the domain-specific access points are sufficiently equipped by the public authorities to carry out these tasks under their own responsibility. In that case, the task and the other tasks referred to in paragraph 4 may be assigned by means of a statutory ordinance pursuant to § 22(1)(2). In these cases too, access points must cooperate in order to ensure the uniform application of the law.

Too Nummer 11

Point (11) implements Article 64 of Regulation (EU) 2025/327. Health data access bodies shall have the power to impose administrative fines pursuant to Article 64 of Regulation (EU) 2025/327 for infringements of Regulation (EU) 2025/327. In order to ensure uniformity and comparability of administrative fines, those tasks shall, where possible, be carried out by the coordinating health data access body as a neutral body. The domain-specific access points shall assist the coordinating access point in carrying out its task by providing the necessary information. However, it is possible to envisage scenarios in which the domain-specific access points are sufficiently equipped by the public authorities to carry out these tasks under their own responsibility. In that case, the task and the other tasks referred to in paragraph 4 may be assigned by means of a statutory ordinance pursuant to § 22(1)(2). In these cases too, access points must cooperate in order to ensure the uniform application of the law.

Too Nummer 12

Point (12) implements Article 58(3) of Regulation (EU) 2025/327. Where a health data access body is informed by a health data user of a substantial finding concerning the health of a natural person pursuant to Article 61(5) of Regulation (EU) 2025/327, the health data access body shall inform the health data holder of that finding. However, this applies only to the extent that a comparison with the register pursuant to § 16 has not revealed that there is a declaration of non-knowledge for the relevant dataset.

Too Nummer 13

Point 13 implements the second sentence of Article 73(2) of Regulation (EU) 2025/327. Health data access bodies shall review the electronic health data included in a download request to ensure that health data users are only able to download non-personal electronic health data, including electronic health data in an anonymised statistical format, from the secure processing environment.

Too Nummer 14

Point (14) implements Article 73(3) of Regulation (EU) 2025/327. It requires health data access bodies to ensure that audits of the secure processing environments are carried out on a regular basis. They may also use third parties to carry out the audits. If these audits identify deficiencies, risks or vulnerabilities in the secure processing environments, necessary corrective actions shall be taken. Where the coordinating access point is responsible for audits and where the audits concern secure processing environments under the responsibility of other domain-specific access points, the financing of the audit by those access points shall be ensured.

Too Nummer 15

Point (15) implements Article 78(4) of Regulation (EU) 2025/327. Health data holders may affix a data quality and utility label to their datasets in accordance with Article 78 of

Regulation (EU) 2025/327. Where a health data access body has reason to believe that a data quality and utility label may be inaccurate, it shall assess whether the dataset covered by the label meets the quality requirements that are part of the elements of the data quality and utility labels referred to in Article 78(3) of Regulation (EU) 2025/327 and shall revoke the label if the data do not meet the quality requirements. In so far as the coordinating access point retains responsibility, it must be informed of possible infringements by the domain-specific access points in order to be able to fulfil its verification obligation.

Too Nummer 16

Point (16) implements Article 81 of Regulation (EU) 2025/327. Under that provision, natural and legal persons have the right to lodge a complaint with a health data access body in relation to the rules laid down in Chapter IV of Regulation (EU) 2025/327. The coordinating health data access body is the contact point for this at federal level and puts in place the relevant tools and procedures.

§ 8 (Further tasks of the coordinating health data access body; Power to adopt ordinances)

Too Absatz 1

Points 1 and 2 of paragraph 1 correspond to the current Section 3(2)(9) and (10) and have been adapted only in terms of terminology. The remaining points of the current Section 3(2) have been deleted as they are no longer necessary as a result of the implementation of Regulation (EU) 2025/327.

Too Absatz 2

Paragraph 2, points 1 and 2, corresponds to the current Section 3(3), points 1 and 2, and has only been amended in terms of terminology and drafting. Point 3 could be deleted due to the adaptation of the procedure.

Too Absatz 3

Paragraph 3 corresponds to the current Section 3(4), but has also been amended in terms. It also implements Article 55(4) and corresponds to the legal idea of Recital 65 of Regulation (EU) 2025/327, according to which health data access bodies shall also cooperate with stakeholders, including patient organisations, to contribute to and monitor a consistent application of Chapter IV of Regulation (EU) 2025/327. The working group shall be given an advisory role in relation to the design, further development and evaluation of the tasks of the coordinating health data access body. Limiting the working group to an advisory role serves, inter alia, to implement Article 55(5) of Regulation (EU) 2025/327, which requires ensuring that the staff of health data access bodies act independently.

On § 9 (domain-specific health data access bodies)

§ 9 implements Articles 55, 57, 58 and 59 of Regulation (EU) 2025/327. Pursuant to Article 55(1) of Regulation (EU) 2025/327, Member States may designate one or more health data access bodies to be responsible for carrying out the tasks and obligations referred to in Articles 57, 58 and 59. Therefore, in order to prevent a bottleneck effect and not to have all applications handled by a single body, there should be other health data access bodies with defined areas (domains) (domain-specific health data access bodies). With domain-specific access points, the construction and development of the health data infrastructure for the implementation of the EHDS is to build on existing infrastructure and make use of existing actors in the performance of tasks. This will allow existing resources

to be used. At the same time, it also serves to ensure the necessary expertise in processing applications.

Too Absatz 1

In order to ensure sufficient (data-related) expertise in tasks related to the processing of applications and to keep pathways to health data holders or intermediaries short, these should be fulfilled as close to data as possible, i.e. close to health data sources and holders(structures). To this end, there should therefore be other health data access bodies with defined areas (domains) (domain-specific health data access bodies). For example, FDZ Health and the Centre for Medical Registries are to assume this role for the respective domains of cash and registry data. In the field of university medicine, it is appropriate to name the university medicine network for the data held there.

Too Absatz 2

Paragraph 2 provides that the principle for the distribution of tasks of health data access bodies is that the domain-specific health data access bodies perform the tasks set out in Section 7(4) of this Act for those applications and requests that fall within their remit. The scope of competence derives from the statutory ordinance pursuant to Section 22(1)(2), which transfers the respective tasks to the domain-specific health data access body. The responsibility referred to in paragraph 2 shall be established where a request falls within the sole or predominant competence of the relevant domain-specific access point. Thus, if a request is limited to or focused on the data of a particular source or category, the access point is competent to deal with the request. The competence shall be decided by the coordinating health data access body upon receipt of the application. Before (automated) determining responsibility and forwarding applications, the coordinating health data access body shall coordinate with the domain-specific health data access bodies concerned.

On § 10 (health data access bodies' procedures for health data access applications and health data queries)

Too Absatz 1

Paragraph 1 lays down the general rule that an application is received by the coordinating access point and then forwarded to the competent domain-specific access point. The competent domain-specific access point shall then perform the tasks relating to the processing of applications, decision-making and data request and provision. In order to reduce red tape and speed up access, this entire procedure should be automated as much as possible.

Too Absatz 2

By way of derogation from paragraph 1, where only a domain-specific access point is competent on the basis of sole or predominant concern, the decision-making competence of the coordinating health data access body shall extend to cases where (i) there is no competent domain-specific access point; (ii) the request falls under the competence of more than one domain-specific access point without one of them being predominantly affected; or (iii) while the competence of a domain-specific access point is affected, other areas are also predominantly affected for which there is no domain-specific access point. In such cases, the domain-specific access points shall be involved in the procedure and may issue a recommendation for a decision. However, the coordinating access point shall not be bound by this decision. This is particularly the case where several recommendations differ and a single decision can only be reached by departing from the recommendation.

Too Absatz 3

Paragraph 3 provides for a further derogation from the rule that domain-specific access points are responsible for cases of so-called ‘own applications’. The first sentence states, first of all, that the body or organisational unit performing tasks of a health data access body is not itself authorised to submit health data access applications or health data requests. However, this applies only to the organisational unit to which these tasks are delegated and not to other organisational units of the institution, if any.

Where another organisational unit of an entity where a health data access body is established submits a health data access application or a health data request, the decision-making power referred to in the second sentence shall be exercised by the coordinating health data access body. This is to ensure that the decision can be taken independently.

Following the regulatory logic of the second sentence, the coordinating access body cannot be competent if a request for access to health data or a request for health data is made from the Federal Institute for Medicinal Products and Medical Devices. In such cases, the Federal Ministry of Health shall decide in accordance with the third sentence.

Too Absatz 4

Paragraph 4 clarifies that only the decision on a health data access application or health data request in the cases referred to in paragraphs 2 and 3 shall not be taken by the domain-specific access bodies. This is to ensure a consistent and neutral decision on applications and health data requests. Once the decision has been taken, the decision should be implemented as close as possible to the data in order to keep the routes as short as possible. Other tasks pursuant to § 7(4), in particular the request for data and making available, are therefore still carried out in these cases by domain-specific access points. In such cases, the access points concerned must cooperate to link and make the data available.

On § 11 (linking, pseudonymisation and making available)

For data from different sources to be usefully used, it must be possible to link them, including at the level of individuals, where necessary. Regulation (EU) 2025/327 requires that this is possible (technically and legally) (cf. Article 78(2), point (f), of Regulation (EU) 2025/327). Pursuant to Article 57(1), first sentence, point (b), of Regulation (EU) 2025/327, health data access bodies are to process electronic health data in the context of making data available, for example by receiving, combining, preparing and assembling, pseudonymising or anonymising data. § 11 implements these Articles.

Too Absatz 1

Paragraph 1 clarifies that for the preparation and making available of the data of a health data access application or health data request, the linking of the data in question is allowed to the extent necessary to fulfil the right to access data. In such cases, the link must also be made. The competent health data access body shall link the data of different health data holders using the research identifier referred to in Section 3, which shall be provided to it when the data are made available.

Too Absatz 2

Where a request for non-anonymised data has been approved, the data shall be provided in pseudonymised format. Paragraph 2 requires access bodies to carry out (re-) pseudonymisation before making the data available to health data users in a secure processing environment. Even if the first pseudonymisation has already taken place

through the supply of data sets using the research code (see § 12), further pseudonymisation is necessary to safeguard the interests of the persons concerned. Datasets made available to health data users shall no longer contain the research metric. In order to ensure the reporting of material findings in accordance with Article 58(3) of Regulation (EU) 2025/327, the access point shall be able to reconnect the pseudonymised datasets for the provision to the respective research metrics. The pseudonyms should therefore be kept.

Too Absatz 3

The provision in paragraph 3 is an additional data processing power for data access points. The information on the so-called bias resulting from the failure to provide conflicting data is in many cases important in order to be able to assess the data. For this reason, access bodies are entitled to identify the bias for the provided dataset and communicate it to the health data user.

Re § 12 (Obligations of health data holders)

Section 12 implements Article 60 of Regulation (EU) 2025/327.

Too Absatz 1

Paragraph 1 clarifies that health data holders shall provide access bodies, including, where appropriate, upon request, with additional information necessary for the performance of their tasks under this Act, in particular when processing applications pursuant to Section 7(4).

Too Absatz 2

Paragraph 2 takes into account the principle of data minimisation. For example, the health data access body receives datasets with a unique identifier that allows it to link pursuant to § 11(1). However, the data shall only be made available to the extent necessary to fulfil the data request. This should be specified in the requirement and information should also be provided on requirements for pseudonymising the data set to be supplied. This ensures that directly identifying data (such as name or address) that are not necessary for linking and data dissemination are not provided. It takes into account the protection of data subjects and does not share information that is not necessary for the purpose of secondary use.

Too Absatz 3

Existing infrastructure should be used to fulfil data provision obligations where possible and appropriate. For example, paragraph 3 requires health data holders already connected to the telematics infrastructure to make their data available through the telematics infrastructure. At the same time, this also means that, where appropriate, the relevant access points must also connect the secure processing environments to the telematics infrastructure, where possible and appropriate.

Too Absatz 4

Paragraph 4 clarifies that the obligations under Regulation (EU) 2025/327 also apply to health data holders that have concluded data delivery agreements with third parties (including, where relevant, exclusive ones).

Re § 13 (safe processing environments)

The provision implements Article 73 of Regulation (EU) 2025/327. No explicit reference to and repetition of the provisions of the GDPR is made, as these provisions are applicable as directly applicable law in any case. In particular, the requirements for the security of processing set out in Article 32 GDPR must be taken into account.

Too Absatz 1

The first sentence of paragraph 1 clarifies that the determining health data access body shall determine in which secure processing environment data is made available to health data users. The second sentence implements Article 67(2), point (i), of Regulation (EU) 2025/327. This requires applicants to provide a description of their requirements for the secure processing environment. In doing so, they may also identify a particular provider. However, they are not entitled to have the data actually made available in the secure processing environment of that provider. This applies in particular where other equivalent processing environments exist.

Too Absatz 2

Paragraph 2 clarifies that secure processing environments do not need to be built and operated by the access points themselves. They may also use the services of third parties for this purpose. The second sentence clarifies that health data holders can also offer secure processing environments.

Too Absatz 3

Paragraph 3 clarifies that health data users may also bring their own data into a secure processing environment, provided that they have indicated it accordingly in the application and that it has been approved (cf. Article 67(1), point (f), of Regulation (EU) 2025/327). This is particularly important for health data users who have collected data on the basis of consent and who wish to use this data for other purposes in accordance with the EHDS procedure and, where appropriate, also to link it to other data. In order for these to be linked, they must be made available to the health data access bodies referred to in § 12, which can link them, make them sufficiently pseudonymous and then be made available in a secure processing environment. It must be ensured that the link does not increase the risk of identification for the persons concerned.

On § 14 (fees and expenses; Power to adopt ordinances)

The provision implements Article 62 of Regulation (EU) 2025/327. This means that access bodies charge fees to health data users. Costs referred to in Article 62(2) of Regulation (EU) 2025/327 incurred by health data holders for the compilation and preparation of the electronic health data to be made available for secondary use shall be collected by health data holders as expenses and paid to the health data holders upon receipt.

Too Absatz 1

Paragraph 1 provides the legal basis for charging fees and expenses.

Too Absatz 2

The first sentence of paragraph 2 provides that the Federal Ministry of Health, in consultation with the coordinating health data access body and the domain-specific federal health data access bodies, shall adopt the Special Fees Regulation pursuant to Section 22(4) of the Federal Fees Act (Bundesgebührengesetz, BGebG). Fees shall be

transparent and fair. Where an implementing act pursuant to Article 62(5) of Regulation (EU) 2025/327 is adopted, the provisions of that act shall be taken into account.

The scheme covers all current and future public services for which fees may be charged. The details for the Fees Regulation are set out in the BGebG and the General Fees Regulation. It is intended, in particular, to cover the incurrence of fees, the levying of fees, the reimbursement of expenses, the person liable to pay the fees, fee exemptions, fee reductions, the due date, deferral, write-off, remission, late-payment penalties, limitation periods and reimbursement.

The collection of a display by health data holders for their expenses, inter alia, presupposes that they are not already to be included in the fee because they are usually associated with it (second sentence of Paragraph 9(1) of the BGebG: According to official justification (BT-Drs. 17/10422, p. 103) makes it clear that the costs of the public service are to be taken into account in the calculation of charges only in so far as they are not charged as expenses. In that regard, in the interests of administrative simplification and legal certainty, the second sentence lays down the principle that the fee must include the costs normally associated with the public service that can be attributed individually. According to that provision, additional reimbursement of expenses under Paragraph 12 of the BGebG is to be made only in cases where costs cannot be included in the calculation of the fee on the basis of the particular characteristics of the service concerned, for example because they have different invoice items on a case-by-case basis or because they vary significantly in individual cases. The burden on health data holders for compiling and preparing the electronic health data to be made available for secondary use is likely to be of a regular nature.

Re § 15 (data protection information obligations)

The provision regulates more detailed information requirements under data protection law in connection with secondary use.

Too Absatz 1

The first sentence of paragraph 1 clarifies that health data holders must comply with their data protection information obligations under Article 13 GDPR also with regard to possible processing under Regulation (EU) 2025/327. This applies independently, but in particular when they collect and process data based on consent under Article 9(2)(a) GDPR. Since, at the time of data collection, only uncertain and even potential data processing is involved, a generic, albeit clear, reference to the EHDS will have to be sufficient. In order to relieve the burden on health data holders and also not to overburden the information notices to data subjects while keeping them consistent, the coordinating access body will provide templates for use by health data holders. This is part of their tasks under Article 58 of Regulation (EU) 2025/327.

Too Absatz 2

By way of derogation from paragraph 1, paragraph 2 removes the information obligation of health data holders pursuant to Article 13(3) GDPR and Article 14(4) GDPR for electronic health data already collected at the date of entry into force of this Act. This also applies if the data were processed on the basis of consent pursuant to Article 9(2)(a) of the DGS Regulation. This limitation of the right under Articles 13 and 14 is made pursuant to Article 23(1)(e) GDPR. This is to avoid overburdening health data holders with the otherwise necessary tracing and re-contacting of data subjects. Otherwise, the considerable bureaucratic and administrative burden placed on health holders, particularly in the field of healthcare and long-term care, would seriously jeopardise their provision. The information to the persons concerned in those ‘legacy datasets’ is to be fulfilled by the coordinating health data access body through the transparency and information obligations of

Regulation (EU) 2025/327, in particular pursuant to Article 57(1), first sentence, points (j)(ii) to (vii), (58) and (59). There should be public information campaigns, cf. Article 58(4) of Regulation (EU) 2025/327. Such restriction of data subjects' rights shall be supplemented as part of the information to be provided in accordance with Article 58 of Regulation (EU) 2025/327.

Too Absatz 3

Paragraph 3, in turn, clarifies that health data users do not have information obligations under Articles 13 and 14 GDPR towards data subjects in the context of the secondary use procedure under Chapter IV of Regulation (EU) 2025/327. This already does not exist under Article 11(1) GDPR, as health data users only receive anonymised or pseudonymised data and therefore cannot identify the data subjects. Health data users therefore also have no possibility to identify the data subjects and contact them for the purpose of information, which also means that the obligation to provide information does not apply (cf. Article 14(5)(b) GDPR). Re-identification by health data users is also specifically excluded under Regulation (EU) 2025/327 and is also punishable under that law. The data subjects shall be fulfilled by the coordinating health data access body through the transparency and information obligations of Regulation (EU) 2025/327, in particular pursuant to Article 57(1), first sentence, points (j)(ii) to (vii), (58) and (59), for which the health data users shall also provide information.

On § 16 (Data Subjects Enforcement Register; Power to adopt ordinances)

The scheme implements Article 71 of Regulation (EU) 2025/327 and ensures the right to non-knowledge of significant findings. A register will be set up to enforce these data subjects' rights. The provision is based on the rules on the organ donation register. The register will be set up in a forward-looking manner. There may therefore be no need for centralised data retention. The possibilities to expand and interconnect with other data infrastructures and spaces will be taken into account.

Too Absatz 1

The first sentence of paragraph 1 entrusts the Federal Ministry with the task of entrusting an appropriate body with the establishment and operation of a register for the implementation and enforcement of data subjects' rights under Regulation (EU) 2025/327. The second sentence lists the requirements to be met by the entrusted entity. In doing so, the institution shall have sufficient financial, organisational, technical and human resources to be able to ensure the performance of the tasks conferred by law pursuant to paragraph 2. The independence, neutrality, data protection and data security required for this key task must be ensured in the entrusted entity in order to ensure trust in this body. The entrusted entity shall establish and maintain the register.

Too Absatz 2

Paragraph 2 provides that persons who have reached the age of 15 may submit declarations to the register, consult them, amend them or withdraw them. This includes the statement of opposition pursuant to Article 71 of Regulation (EU) 2025/327 as a total opposition (paragraph 1) or partial opposition (paragraph 2) and the statement in the exercise of the right to non-knowledge of material findings pursuant to the third sentence of Article 58(3) of Regulation (EU) 2025/327 (paragraph 3). The granularity of the partial opposition shall be limited to the purposes set out in Regulation (EU) 2025/327. By reference to the purpose, the contradiction can be precisely 'matched' with the data permits. For example, the contradiction is clear and can also be implemented in an interoperable manner in the other EU Member States, as the data permits are made uniform. A different or further granularity would, on the one hand, jeopardise enforceability and, on the other hand, also lead to overburdening and, if necessary, fait acquiescence on

the part of the persons concerned. The granularity of the opposition chosen here therefore balances the right to informational self-determination of the persons concerned and the need for a functioning secondary use procedure.

The second sentence provides that the right is to be exercised by legal representatives for persons who have not reached the age of 15. The third sentence specifies the bodies to which such declarations may be made: Declarations may be made to the register referred to in the first sentence at the Ombudsperson's Office in accordance with Section 342a of Volume V of the Social Code or, where available, via electronic health records in accordance with Section 342(1) of Volume V of the Social Code. The latter two means of declaration are already known to persons insured under the statutory health insurance scheme as a result of the appeal proceedings against the electronic health record. The provision deliberately leaves open how the declaration can be made (written, (remotely), orally, electronically). The aim is to develop low-threshold, simple and accessible procedures that enable all persons concerned, including vulnerable groups, to submit declarations. If a declaration is not made to the register, the recipients of the declaration must (automatically) forward the declaration to the register. The precise procedure for submitting, consulting, amending and revoking declarations remains to be determined. Requirements for data protection and security shall be taken into account when defining the procedure. This should also take into account the possibility of integrating the European Digital Identity Wallet in accordance with Regulation (EU) 910/2014. Where possible, it should be possible for declarations to be made in a standardised, machine-readable form for automated testing procedures designed without the use of consent-based tracking technologies.

Too Absatz 3

Paragraph 3 specifies which personal data of the declarant must and may be collected and processed by the register. In addition to the declaration itself (point 1) and the date and time at which the declaration was made, amended or revoked (point 2), these are the fixed part of the health insurance number pursuant to Section 290(1) of Volume V of the Social Code (point 3), the research code pursuant to Section 3 (point 4) and the data required for authentication pursuant to paragraph 2 (point 5). This data is necessary to enable the declarant to authenticate himself/herself and then to make his/her declaration. The health insurance number (KVNR) is required for the registry to generate the research identifier so that, in the case of data provision, any objections received can be assigned to the correct datasets, or can be assigned if a declaration of non-knowledge has been made in respect of a dataset before the health data holder concerned has a material finding. In the case of (old) datasets for which it is not possible to generate a research identifier due to the lack of a KVNR, it may therefore not be possible to assign them. For example, Article 71(8) of Regulation (EU) 2025/327 also allows for the non-enforcement of the right to object where it requires additional information to identify the data subject that health data holders are not or no longer required to hold. In order to reduce the burden on health data holders, enforcement of the right to object is therefore linked to the research indicator based on the KVNR, which is in any case available to a large number of health data holders. The data processed pursuant to paragraph 3 may be processed only for as long as, and to the extent that, it is necessary for the purposes for which it is processed (cf. Article 5 GDPR). This means, for example, that directly identifying data necessary for the authentication of the declarant or the KVNR are not permanently stored in the register.

Too Absatz 4

Paragraph 4 sets out the cases in which the data stored in the register may be processed. According to the first sentence, point 1, they may be processed to determine whether the electronic health data of the person who made the declaration can be made available to health data users pursuant to Article 68(7) of Regulation (EU) 2025/327 or used for health data requests pursuant to Article 69 of Regulation (EU) 2025/327, or whether there is an

objection. Under point 2 of the first sentence, they may be processed to determine whether the person who made the declaration wishes to be informed of material findings. In addition, the processing may and must also take place in order to enforce the declared will. The necessary technical procedure for this has yet to be defined. It is possible, for example, to incorporate the information as a kind of 'filter' into the data provision process, which the data passes through at two points in time: upon acceptance of the data requested and provided by the data holders to the access body and again shortly before the data is made available to the health data user.

The second sentence clarifies in which cases the partial opposition must be observed: If an application or the data permit based on it mentions only one purpose, all data shall be omitted from the persons who objected to that purpose. Where several purposes are stated in an application or in the data permit based on it, all data shall be omitted from the persons who objected to one of those purposes. This applies even if the application is also made for purposes which have not been contested by the persons concerned.

The third sentence provides that the authentication and enforcement procedure is to be carried out in an automated search procedure. Procedure to be defined. Data protection and security must be respected.

Too Absatz 5

Paragraph 5 provides that the data may also be processed for the purpose of drawing up an annual report.

Too Absatz 6

Paragraph 6 empowers the Federal Ministry to regulate further details on the authentication procedure, the required data sets, the authentication and enforcement procedure and the requirements for the annual report.

On § 17 (Competent data protection supervisory authority and cooperation with health data access bodies)

The provision serves, inter alia, to implement Article 65 of Regulation (EU) 2025/327. According to Regulation (EU) 2025/327, including Article 65 of Regulation (EU) 2025/327, competent supervisory authority under the GDPR shall cooperate with the health data hub in the enforcement of Regulation (EU) 2025/327 in a cooperative and trusted manner within their respective competences. The associated powers and procedures are largely derived from the corresponding European and national data protection provisions, which apply mutatis mutandis, unless otherwise provided for in Regulation (EU) 2025/327 or in this Act.

Too Nummer 1

Pursuant to Article 65 of Regulation (EU) 2025/327, the designation of the prospective authority responsible for monitoring and enforcing the application of the GDPR for the application of the right to object pursuant to Article 71 of Regulation (EU) 2025/327 is a matter for the Member States. The Member State may therefore designate one or more authorities as the competent body. The national legislature remains free to lay down rules on the competence of the data protection supervisory authorities under Regulation (EU) 2025/327 with regard to the right to object. The European legislator is neutral with regard to the national division of powers of supervision in accordance with the spirit and purpose of the provision and leaves this decision to the Member States. In the exercise of its legislative powers under Article 74(1)(1) and Article 74(1)(11) of the Basic Law (Law on the Economy), the Federal Government establishes a special competence of the Federal Commissioner(s) for Data Protection and Freedom of Information under the first sentence

of Article 87(3) of the Basic Law by means of Section 1 of this Act. The Federal Commissioner for Data Protection and Freedom of Information has the expertise necessary for the swift identification and assessment of data protection issues and the processing of facts, and can thus significantly contribute to a swift assessment of data protection issues in the context of the right to object under Article 71 of Regulation (EU) 2025/327.

Too Nummer 2

The competence to monitor and enforce the processing of personal data remains with the supervisory authorities of the GDPR (see recital 65 of the EHDS Regulation). The designation of the prospective authority responsible for monitoring and enforcing the application of the GDPR is a matter for the Member States. The Member State may therefore designate one or more authorities as the competent body. The national legislature remains free to lay down rules on the competence of the data protection supervisory authorities under the EHDS Regulation, by way of derogation from the general allocation of competence for non-public bodies under Section 40 of the Federal Data Protection Act. The European legislator is neutral with regard to the national division of powers of supervision in accordance with the spirit and purpose of the provision and leaves this decision to the Member States. In the exercise of its legislative competence under Article 74(1)(1) and Article 74(1)(11) of the Basic Law (Law on the Economy), the Federal Government establishes a special competence of the Federal Commissioner(s) for Data Protection and Freedom of Information under the first sentence of Article 87(3) of the Basic Law. The Federal Commissioner for Data Protection and Freedom of Information has the expertise necessary for the swift identification and assessment of data protection issues and the processing of facts, and can thus significantly contribute to a swift assessment of data protection issues.

On § 18 (enforcement powers under Articles 63 and 64 of Regulation (EU) 2025/327)

The scheme implements Articles 63 and 64 of Regulation (EU) 2025/327.

Too Absatz 1

Paragraph 1 clarifies that the competent health data access body, as part of its supervisory function, may take measures necessary for the enforcement of Regulation (EU) 2025/327.

Too Absatz 2

Article 63(3) and (4) require the measures to be taken in accordance with national law, which requires the provision in paragraph 2. It provides that the enforcement measures are to be taken in accordance with the Administrative Enforcement Act, in so far as Regulation (EU) 2025/327 itself does not regulate the procedure. Article 63(4) of Regulation (EU) 2025/327 requires Member States to lay down rules on the amount of periodic penalty payments. The amount of the possible penalty payment is EUR 500.000.

On § 19 (procedure for complaints under Article 81 of Regulation (EU) 2025/327)

The provision implements Article 81 of Regulation (EU) 2025/327. The provision is based on the provisions implementing the GDPR in the Federal Data Protection Act (Bundesdatenschutzgesetz), in particular Section 14(1)(6) and (3) of the Federal Data Protection Act (Bundesdatenschutzgesetz).

Too Absatz 1

The coordinating access point shall be the federal contact point for complaints pursuant to Article 81 of Regulation (EU) 2025/327. Paragraph 1 specifies that the information to the complainant on the progress and outcome of the investigation pursuant to Article 81(2) of Regulation (EU) 2025/327 must be provided within a reasonable period of time. This applies in particular where the handling of the complaint requires the involvement of other health data access bodies or other supervisory authorities, such as under the GDPR or Regulation (EU) 2023/2854, thereby delaying the procedure.

Too Absatz 2

Paragraph 2 serves to implement Recital 99 of Regulation (EU) 2025/327, according to which health data access bodies shall take measures to facilitate the submission of complaints, such as providing a complaint form, which may also be completed electronically, while not excluding the possibility to use other means of communication.

Too Absatz 3

While the principle is that the coordinating health data access body should serve as a single point of contact for complaints under Article 81 of Regulation (EU) 2025/327, it may happen that a complaint is received by a domain-specific access body. In order to meet the complainants' legal interest in bringing proceedings, in these cases the complainants submit the complaint to the coordinating health data access body for further processing. However, the aim is to establish a low-threshold, centralised complaint mechanism at the coordinating health data access body so that health data access bodies are not burdened with tasks outside this process.

Re § 20 (Electronic communication)

Communication, including the transmission of statements, information and documents, between health data access bodies and between health data access bodies and natural or legal persons on the basis of Regulation (EU) 2025/327 or this Act shall, where possible, be carried out electronically.

§ 21 (Specific rules for electronic health data referred to in Article 51(1), points (f) and (g), of Regulation (EU) 2025/327)

Regulation (EU) 2025/327 provides a legal basis for the secondary use of personal electronic health data under Article 9(2), points (g) to (j), of the GDPR to enable the processing of special categories of data in relation to legitimate purposes (see Recital 52 of Regulation (EU) 2025/327). EU Member States should therefore maintain or introduce further conditions (restrictions or consent requirements) for secondary use within the scope of Regulation (EU) 2025/327, in accordance with Article 9(4) of the GDPR, unless explicitly permitted by Regulation (EU) 2025/327 (see Recital 52 of Regulation (EU) 2025/327). By way of derogation from this principle, the opening clause in Article 50(4) of Regulation (EU) 2025/327 allows EU Member States to set stricter requirements for the categories of data referred to therein. This includes genetic, genomic and other omics data referred to in Article 51(1), points (f) and (g), of Regulation (EU) 2025/327. In order to take into account the particular sensitivity and sensitivity of these data, a consent requirement should apply to these data, by way of derogation from the principle of consent-free secondary use. In Germany, genomic data have already been made available for secondary use with the consent of the insured persons via the pilot project pursuant to § 64e SGB V. The procedures for data provision and processing laid down therein remain in place for the duration of the pilot project.

Too Absatz 1

Paragraph 1, point (1), provides that the processing of the electronic health data under Article 51(1), point (f), of Regulation (EU) 2025/327 for secondary use is only allowed if there is a corresponding consent under Article 9(2), point (a), of the GDPR. According to point 2, the same applies to proteomic and transcriptomic products referred to in Article 51(1), point (g), of Regulation (EU) 2025/327, as they present a risk comparable to that referred to in point 1. Therefore, this requirement under point 3 also applies to other data referred to in Article 51(1), point (g), of Regulation (EU) 2025/327, to the extent that the re-identification risk to data subjects posed by the processing of those data corresponds to that of the data under points 1 or 2.

Too Absatz 2

Consent under paragraph 1 must already be obtained at the level of health data holders, as they collect the data. Consent must comply with the requirements of Article 9(2)(a) GDPR. Care should be taken not to overburden data subjects with unnecessary bureaucracy and voluminous information material. In order to minimise red tape and ensure consistency for health data holders, the coordinating access body referred to in paragraph 2 shall provide templates. This can be done on the basis of the information and consent documents drawn up as part of the medical information initiative and agreed with the data protection authorities of the Federal Government and all the Länder, which are already used nationwide and are used in the pilot project pursuant to § 64e SGB V for secondary use.

On § 22 (Further power to enact regulations; Loan-to-value)

The provision governs the authorisation to adopt an EHDS implementing regulation in order to regulate further details on the implementation of the secondary use procedure.

Too Absatz 1

Too Nummer 1

The Federal Government shall be authorised to transfer the coordinating health data access body to another federal public body.

Too Nummer 2

Point 2 regulates the possibility of delegating tasks under Section 7(4) to certain bodies, in part or in full, under certain conditions. This allows the administration to be decentralised and thus relieved of the burden.

The transfer takes place by way of a statutory instrument. In this context, associations and legal persons governed by private law with partial legal capacity may, by way of delegation, delegate the performance of some or all of the tasks referred to in § 7(4)(1) to (9) and (12) to (15) for an area to be determined (point (a)) or provide that public bodies or individual organisational units of the same individual or all of the tasks referred to in § 7(4) for an area to be determined (point (b)). Paragraph 2 is a way of alleviating the burden on the public administration and, in the case of point (a), the use of far-reaching private resources. The delegation of tasks shall be for a specific area to be defined. This can be determined in particular on the basis of certain categories of data – e.g. ‘genome data’ or ‘from medical registers’ – or data from certain categories of health data holders – e.g. ‘public health insurance fund data’ or ‘data from manufacturers of medicinal products and medical devices’, but other criteria are also conceivable, provided that the responsibility can be sufficiently determined in this way.

Tasks may be delegated only to persons governed by private law in so far as they cannot necessarily be carried out by a public authority. Therefore, the powers to impose fines and enforcement measures are excluded.

Too Nummer 3

By way of derogation from the third sentence of Section 10(3), the statutory ordinance may stipulate that decisions on applications and requests from the Federal Institute for Medicinal Products and Medical Devices are to be taken by a domain-specific access point, which may not then be located at the Federal Institute for Medicinal Products and Medical Devices. In this way, a conflict of interest within the Federal Institute for Medicinal Products and Medical Devices can be prevented without the need to refer the matter to the Federal Ministry of Health.

Too Nummer 4

Point 4 provides that if, pursuant to point 1, another body is designated to take over the tasks of the coordinated health data access body, it may also be specified that the decision on applications from the Federal Institute for Medicinal Products and Medical Devices is to be taken again by the coordinated health data access body. In such cases, there is no risk of a conflict of interest between the Federal Institute for Medicinal Products and Medical Devices.

Too Nummer 5

Too Buchstabe a

In the context of the implementation of Regulation (EU) 2025/327, point (a) serves as a measure to reduce red tape and compliance burden for health data holders, but also budgetary expenditure for health data access bodies. In the event that the same set of data is available to different health data holders to the extent and quality requested and approved, the provision for the cost-effective implementation of the process shall be made in such a way that it is made available by the most appropriate health data holder. This may be the case, for example, where datasets – distributed where appropriate – are available from many different health data holders, e.g. health care providers, but also – already merged – from one health data holder, e.g. a registry.

Too Buchstabe b

Point (b) implements Article 60(5) of Regulation (EU) 2025/327. The EHDS Implementing Regulation may address specific requirements for trusted open databases referred to in Article 60(5) of Regulation (EU) 2025/327.

Too Buchstabe c

Point (c) implements the opening clause in Article 50(3) of Regulation (EU) 2025/327. There should be health data intermediaries to relieve the burden on health data holders. The Statutory Instrument may provide that the obligations of certain health data holders are fulfilled by health data intermediaries pursuant to Article 50(3) of Regulation (EU) 2025/327. In order to also ensure data-related advice without imposing an additional burden on data holders, health data intermediation bodies may also be entrusted with advisory tasks pursuant to the first sentence of Section 6(2).

Too Buchstabe d

Point (d) implements the opening clause of Article 72 of Regulation (EU) 2025/327.

Should it become apparent in the data infrastructure landscape that the design of the trusted data holder can contribute to easing the burden on the infrastructure, the possibility of regulating a corresponding definition procedure should already be enshrined. Regulation (EU) 2025/327 provides comprehensive guidance on the requirements for trusted data holders. The remainder of the procedure may be regulated by regulation.

Too Nummer 6

The provision implements Article 68(6) of Regulation (EU) 2025/327.

Too Nummer 7

The selection procedure for the secure processing environment, as well as requirements for third parties offering secure processing environments, can be regulated under the EHDS Implementing Regulation.

Too Absatz 2

A loan as referred to in point (2)(a) of paragraph 1 shall be permitted only if it can be demonstrated that the resources for the effective performance of the delegated tasks and exercise of the delegated powers referred to in the first sentence of Article 55(2) of Regulation (EU) 2025/327 are ensured by the person to be loaned.

The second sentence governs the supervision of the person to be lent. Depending on the designated domains, these may include, in addition to the Federal Ministry of Health, other federal ministries, insofar as the domain falls within their respective competences.

The third and third sentences lay down the liability of the person who lends and the possibility for the legal entity to have recourse to it in the event of intent or gross negligence.

On § 23 (evaluation of the coordinating health data access body)

The number of applications received under the procedure laid down in Chapter IV of Regulation (EU) 2025/327, the sectors from which they originate and the processing costs involved cannot be predicted reliably at present; this also opens up the permanent staffing and job needs of the coordinating health data access body. The rules resolve this by evaluating the actual needs on the basis of reliable data. The funding can thus be made sustainable, cost-reflective and independent of the initially uncertain volume of applications.

The objective of the scheme (subject of evaluation) is to ensure that the data access procedure laid down in Chapter IV of Regulation (EU) 2025/327 is carried out in a non-bureaucratic, timely and European-ready manner by an effective, needs-based coordinating health data access body. In the long term, funding should ensure that needs are met.

The indicators set out in are intended to be the basis for evaluation and cost allocation.

The coordinating health data access body shall be required to collect and report history data. An obligation to collect data from day 1 onwards is mandatory, as the volume of applications and the need for jobs cannot yet be predicted with certainty; without it, the evaluation in 2031 would not be meaningful.

Re Abschnitt 3 (Special data use procedures)

After Section 2 has regulated the implementing rules for the EHDS secondary use procedure, Section 3 regulates further data use procedures that regulate alternative data access mechanisms in addition to the EHDS secondary use procedure.

On § 24 (further processing of supply data for quality assurance, patient safety promotion and research purposes)

The provision corresponds to the previous § 6 GDNG with editorial adjustments.

The insertion in paragraph 1, point 2, clarifies that permitted data processing for medical, rehabilitative and nursing research also covers the development of AI models and AI systems in the field of health. The research purpose in Article 53 of Regulation (EU) 2025/327 also includes corresponding processing operations. Possible processing operations for the development of AI models and AI systems include, in particular, the training, testing and validation of such systems and models.

Re § 25 (processing of health data with the authorisation of the data protection supervisory authority)

The newly inserted provision allows the relevant data protection supervisory authority to authorise data processing for a health and care research project. An authorisation may be granted upon request. The request shall be made by data controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679. Due to the exceptional nature of the provision, the data protection supervisory authorities are not obliged to grant authorisations. They enjoy a wide margin of discretion in their resolutions. The newly inserted provision creates a permit within the meaning of Article 9(2)(j) GDPR for the use of health data for research projects. In that regard, it is not the authorisation of the competent data protection supervisory authority that constitutes the necessary basis in the law of a Member State, but the provision itself. Where more than one controller is involved and more than one data protection supervisory authority is responsible for those parties, the approval of all supervisory authorities shall be required. Applicants must demonstrate in their request a legal basis under Article 6(1) GDPR (e.g. a legal mandate or a legitimate interest). This provision creates a flexible but at the same time legally certain mechanism for data use. An authorisation cannot be granted on a flat-rate basis for data processing by a controller, but must relate to a distinct and specific health and care research project.

This creates a derogation to cover specific needs in the area of health research, in addition to data access mechanisms in FDP Health or data access under Chapter IV of Regulation (EU) 2025/327.

Paragraph 2 lays down requirements for an authorisation. In particular, the interest of processing must prevail. At the same time, ancillary provisions may be laid down. This ensures that appropriate technical and organisational measures are complied with in the context of the health and care research project as part of the permit granting process. The data protection supervisory authority will therefore have an extended control option.

In accordance with paragraph 3, the application shall include comprehensive information necessary for the data protection supervisory authority to take an informed decision on the authorisation.

Paragraph 4 regulates the relationship of the provision with other data access mechanisms. The provision is designed as a derogation. On the one hand, the provision is not intended to undermine exhaustive special rules. For example, access to the data of the Health FDZ outside the procedure laid down in Section 303a et seq. cannot be authorised under this provision by the competent data protection supervisory authority. In

addition, the provision is intended to be subsidiary to other specific data access regulations. An authorisation may therefore only be granted if the necessary access to data cannot be adequately achieved by other data access mechanisms in terms of the volume of data, the time frame and the form in which the data are to be made available. In particular, the provision takes precedence over the provisions on access to health data in Regulation (EU) 2025/327, the further processing of care data under § 24 GDNG (§ 6 GDNG (old version)) and the planned data access mechanisms in the Medical Register Act. If, for example, access to data under Chapter IV of Regulation (EU) 2025/327 is suitable for meeting the needs of the health and healthcare research project, no authorisation may be granted under this provision.

On § 26 (linking data from the Research Data Centre with data from the clinical cancer registries of the countries; Power to adopt ordinances)

This is the regulation linking data from the Health FDZ to data from the clinical cancer registries of the Länder, which was previously regulated in § 4 GDNG. It is taken over, with minor changes, as a further rule for a data access procedure for section 3 GDNG.

As is also apparent from the explanatory memorandum to the Law on the improved use of health data, which the old Paragraph 4 of the GDNG was intended to be a transitional provision. The aim was to test the linking of health data from different data-holding entities before the linking will be regularly possible in the context of the implementation of Regulation (EU) 2025/327. As the latter will now take place with the adaptations in this law, this transitional provision will also be repealed with effect from 1 January 2030.

On Abschnitt 4 (precautionary measures and public interest orientation)

Section 4 sets out rules to safeguard data access procedures and to ensure that data access remains in line with the public interest.

Re § 27 (requirement to register and publish)

This is the rule on the obligation to register and publish research projects, which was previously laid down in § 8 GDNG. It is included in with amendments. The background to this adjustment is, on the one hand, that the provision is to be supplemented by a division into several paragraphs. On the other hand, the obligation of confidentiality hitherto laid down in Paragraph 7 of the GDNG and the criminal provision previously laid down in Paragraph 9 of the GDNG, which essentially refers to Paragraph 7, are intended to be immediately consecutive.

In addition to these changes to the place of regulation and structuring, substantive changes have also been made to the previous regulation, which are described in more detail below.

Too Absatz 1

Paragraph 1 is based on the former § 8, first sentence, GDNG. It still describes the scope of the scheme.

The place where the registration and the deposit of the results are to take place has been changed. Instead of a primary clinical trial registry recognised by the World Health Organisation, registration with the coordinating health data access body is to take place in the future. This amendment is made because Regulation (EU) 2025/327 already provides for a registration and result notification system. The obligations therein are to be fulfilled at the coordinating health data access body. In order to avoid duplication of structures, the registration and deposit of the results with this body should therefore also take place in future for other data access mechanisms.

Too Absatz 2

Paragraph 2 has been amended only slightly compared to the second sentence of Section 8 GDNG. The new wording ‘other legislation’ aims to clarify that the registration of the application provided for in Regulation (EU) 2025/327 and the publication of the results also make (re)registration under this standard unnecessary.

Too Absatz 3

In paragraph 3, in comparison with the third sentence of § 8 GDNG, the deadline for those responsible for a research project to deposit their research results has been reduced from 24 months to 18 months. This shortening aligns the deadline with the deadline for the notification of results provided for in Regulation (EU) 2025/327. In addition, the body with which the publication of the results must be filed will be adjusted.

Too Absatz 4

In paragraph 4, compared to the previous § 8 sentence 4, the references to have been adapted to take account of the reorganisation.

Re § 28 (Confidentiality obligations)

Corresponds to former § 7 with two amendments.

These are, on the one hand, editorial adjustments as a consequential amendment replacing the term ‘data users’. The term was previously legally defined in § 2 No 4 GDNG. The background to this is the adaptations to Section 2 GDNG, in which reference should now also be made to the definitions in Regulation (EU) 2025/327. Regulation (EU) 2025/327 also defines the very similar term ‘data user’, which, however, only covers data users under the Chapter IV procedure under Regulation (EU) 2025/327. In order to avoid interpretation difficulties and legal uncertainty, the term ‘data user’ will be removed throughout DGNG and replaced by other terms. In that provision, the term ‘data users’ is replaced by the term ‘natural persons’.

The scope of the provision has also been extended. Previously, there was a duty of confidentiality under § 7 GDNG only if data were made available for scientific research purposes. As data has been made available not only for scientific research purposes, but also for other purposes, both in the context of the implementation of the EHDS secondary use process and on the basis of other legal bases in DGNG, it will also be necessary to include other purposes. In this respect, the new wording has also extended the scope to these purposes. On the other hand, the scope is further clarified and only cases where natural persons process health data on the basis of GDNG are covered. The scope has thus been adjusted in a number of respects compared to the previous version.

Re § 29 (criminal provisions)

This is the former Section 9, with minor adjustments required for reasons of legal system. The qualifying criteria and the application requirement should not apply to cases of infringement of the prohibition on re-identification, in order to ensure consistency with Section 22 of the Federal Statistics Act in such cases. Furthermore, the range of penalties for the offence is to be brought into line with that laid down in Section 203(6) of the Criminal Code.

§ 30 (Penalty provisions relating to Regulation (EU) 2025/327)

The scheme implements the requirements of Article 99 of Regulation (EU) 2025/327. According to recital 106 of Regulation (EU) 2025/327, Member States should take all

necessary measures to ensure compliance with the provisions of Regulation (EU) 2025/327, including by laying down effective, proportionate and dissuasive penalties for infringements. When deciding on the amount of the penalty for each individual case, Member States should take into account the limits and criteria set out in this Regulation. Re-identification of natural persons should be considered a serious breach of this Regulation. For re-identification, the criminal provisions already exist in Section 29 of this Act. Penalties are also not necessary to the extent that they are already punishable by fines under Articles 63 and 64 of Regulation (EU) 2025/327.

Too Absatz 1

Paragraph 1 establishes that a health data holder or health data user shall be considered to be acting improperly when acting in breach of an enforceable order pursuant to Article 63 of Regulation (EU) 2025/327.

Too Absatz 2

Article 99 of Regulation (EU) 2025/327 requires penalties to be effective, proportionate and dissuasive. In serious cases, the fine may therefore be as high as fifty thousand euros.

Re § 31 (Application of the provisions on administrative fines and criminal proceedings)

The scheme implements Article 64 of Regulation (EU) 2025/327. In that regard, Article 64(7) of Regulation (EU) 2025/327 sets out the mandate for Member States to ensure ‘adequate procedural safeguards’. Such an instruction already existed in Article 83(8) GDPR. Following its implementation in Section 41 of the Federal Data Protection Act (Bundesdatenschutzgesetz), the provision therefore contains the necessary references to general law to ensure procedural safeguards.

Too Absatz 1

Pursuant to Section 2 of the Administrative Offences Act (Gesetz über Ordnungswidrigkeiten – OWiG), the OWiG applies to administrative offences under federal and Land law. The first sentence of paragraph 1 of this Act states that the OWiG is in principle also applicable mutatis mutandis to infringements under Article 64(4) and (5) of Regulation (EU) 2025/327, which is directly applicable national law. Section 17 OWiG, also in conjunction with Section 30(3) OWiG, and Section 30(1) and (2) OWiG do not apply, because the European law on penalties regulated in Regulation (EU) 2025/327 contains exhaustive and priority rules in this regard.

Too Absatz 2

The penalty procedure itself is not regulated by Regulation (EU) 2025/327. Paragraph 2 therefore provides that, in principle, the provisions of the OWiG apply mutatis mutandis to proceedings to penalise an infringement under Article 64(4) and (5), and expressly states that this also applies to the provisions of the general laws on criminal procedure, which apply mutatis mutandis by virtue of Paragraph 46(1) of the OWiG. According to the second sentence of paragraph 2, Paragraphs 35 and 36 of the OWiG do not apply, since it already follows from Article 64 that the health data access bodies are competent to impose administrative fines. Similarly, Sections 87, 99 and 100 OWiG do not apply, as Regulation (EU) 2025/327 does not provide for the possibility of recovery, so the recovery procedure under Section 22 OWiG has no legal basis. Unlike Section 41 of the Federal Data Protection Act, the application of Sections 56 to 58 of the OWiG is not excluded, as Regulation (EU) 2025/327 does not provide for a warning. The third sentence of paragraph 2 provides that, in the interim proceedings, the public prosecutor’s office may

discontinue the proceedings only with the consent of the coordinating health data access body which issued the penalty notice. This takes into account the importance of the administrative fines in Regulation (EU) 2025/327 and the independence of the coordinating health data access body.

On § 32 (fines against public authorities)

This provision clarifies that no fines are imposed on public bodies within the meaning of Section 2(1) and (2) of the Federal Data Protection Act.

Re Artikel 8 (Amendment of the Health Data Utilisation Act)

This Article specifies the deletion of the requirement to link data from clinical cancer registries with data from FDZ Health. The Article shall enter into force on 1 January 2030. The reason for this time limit is that, by March 2029, the secondary use procedure under Chapter IV of Regulation (EU) 2025/327 will be carried out, which will also enable cancer registry data and FDZ Health data to be linked. § 26 GDNG was created as a transitional provision to test data linking. As the EHDS secondary use procedure has created a long-term regime, § 26 may cease to apply once the EHDS secondary use procedure is ongoing. Between March 2029 and the beginning of 2030, there will be a multi-month period during which both data linking mechanisms will be applicable. This transitional phase is necessary to allow data linking also in case of possible delays in the implementation of the EHDS.

Re Artikel 9 (Amendment of the Medicinal Products Act)

Too Nummer 1

These are consequential amendments due to the deletion of Section 40b(6).

Too Nummer 2

Too Buchstabe a

The amendments to Article 3 are measures to reduce red tape. The amendment deletes the provision in Section 40b(6) AMG, which lays down a requirement for consent for the processing of personal data in the context of clinical trials.

The legal basis under data protection law and the necessary information and transparency measures for the processing of personal data derive from the GDPR even in the absence of the special rule in Section 40b(6). The additional regulation of data protection consent in the context of clinical trials is not necessary.

Too Buchstabe b

This is a consequential amendment due to the deletion in point (a).

Too Nummer 3

These are consequential amendments due to the deletion of Section 40b(6).

Re Artikel 10 (Amendment of the Genetic Diagnostics Act)

Regulation (EU) 2025/327 provides a legal basis for the secondary use of personal electronic health data under Article 9(2), points (g) to (j), of the GDPR to enable the processing of special categories of data in relation to legitimate purposes (see Recital 52 of Regulation (EU) 2025/327). EU Member States should therefore maintain or introduce

further conditions (restrictions or consent requirements) for secondary use within the scope of Regulation (EU) 2025/327, in accordance with Article 9(4) of the GDPR, unless explicitly permitted by Regulation (EU) 2025/327 (see Recital 52 of Regulation (EU) 2025/327). By way of derogation from this principle, the opening clause in Article 50(4) of Regulation (EU) 2025/327 allows EU Member States to set stricter requirements for the categories of data referred to therein. This includes genetics referred to in Article 51(1), point (f), of Regulation (EU) 2025/327. In order to take into account the particular sensitivity and sensitivity of these data, a consent requirement should apply to these data, by way of derogation from the principle of consent-free secondary use. This is regulated in Section 21 of the GNDG. A reference to this is therefore included in § 11(4). In order to reduce the administrative burden on service providers, information on this should be provided as part of the information provided. Consent for secondary use is voluntary and separate from consent for genetic testing and analysis.

Re Artikel 11 (Amendment of the BSI Act)

This is a consequential adjustment due to the deletion of Section 311(6) of Volume V of the Social Code and the re-systematisation of the rules on secure procedures for the transfer of medical data in Sections 363a to 363f of Volume V of the Social Code.

On Artikel 12 (Amendment of the Second Farmers' Health Insurance Act)

In order for the provisions of Chapters 11 and 12 of Volume V of the Social Code to continue to apply to agricultural health insurance, the reference to the corresponding provisions in Volume V of the Social Code needs to be adapted.

On Artikel 13 (Amendment to the Digital Health Applications Regulation)

This is a consequential amendment to Section 351(1)(2) and (3) of Volume V of the Social Code.

Too Nummer 2

Re Artikel 14 (Amendment of the Telematics Charges Regulation)

This is a consequential amendment to § 374a(5) SGB V and § 328(1) SGB V: A charging framework shall be established for the verification of the compliance of the interface by the mesh.

On Artikel 15 (expiry)

Article 8 re-establishes the GDNG. The previous GDNG will therefore cease to apply when this Act is promulgated.

Re Artikel 16 (entry into force)

Too Absatz 1

The provision governs the entry into force of the articles, with the exception of Article 1(104)(b)(aa) and Articles 2, 3 and 8.

Too Absatz 2

This is a correction of an editorially incorrect amendment order from the Digital Act. The amendment to Article 1(94)(b)(bb) was not feasible. The amendment will therefore enter into force retroactively from the entry into force of the Digital Act.

Too Absatz 3

With effect from 26 March 2029, the national contact point for digital health shall become operational (see the amendment to § 219d SGB V provided for in Article 1). It is therefore necessary at this stage to delete the parts or sentences relating to the National Contact Point for eHealth in its previous form.

Too Absatz 4

With paragraph 4, Article 8 shall enter into force on 1 January 2030, with the result that § 26 GDNG shall enter into force on 31 January 2030. Expires on December 2029.

Too Absatz 5

From 26 March 2031, it shall be possible to submit additional categories of data via MyHealth@EU Therefore, the extension of the catalogue of data categories in § 219d(8) SGB V will enter into force on that date.