Social Code Book V – Statutory health insurance

(Sozialgesetzbuch Fünftes Buch – Gesetzliche Krankenversicherung, SGB V)

Book Five of the Social Code - Article 1 of the Act of 20 December 1988 (Federal Law Gazette I, p. 2477, 2482), as last amended by Article 3 of the Act of 22 March 2024 (Federal Law Gazette 2024 I No. 102)

Section 64e
Model project for comprehensive diagnostics and therapy identification through genome sequencing in cases of rare and oncological diseases; power to issue ordinances

(1) By 1 April 2024, the National Association of Statutory Health Insurance Funds (Spitzenverband Bund der Krankenkassen) will enter into a uniform contract with the healthcare providers deemed eligible to take part in the model project in accordance with subsection (4) sentence 2 for the implementation of a model project for comprehensive diagnostics and therapy identification through genome sequencing in cases of rare and oncological diseases; the contract will have binding effect for the health insurance funds. In derogation of section 63 (5), the term of the model project will be at least five years. Before concluding the contract, the German Hospital Federation must be given an opportunity to issue an opinion. The Association of Private Health Insurance Funds can accede to the contract by notifying the National Association of Statutory Health Insurance Funds and the healthcare providers pursuant to sentence 1. If the Association of Private Health Insurance Funds intends to terminate the contract, it must notify the National Association of Statutory Health Insurance Funds and the healthcare providers pursuant to sentence 1. If a healthcare provider intends to terminate the contract, it must notify the National Association of Statutory Health Insurance Funds and the Association of Private Health Insurance Funds, provided that the latter has acceded to the contract. Termination pursuant to sentences 5 or 6 will not affect the validity of the contract for the other contractual partners. Healthcare providers whose eligibility to take part in the model project is determined in accordance with subsection (4) sentence 2 after the contract pursuant to sentence 1 has been concluded can accede to the contract by notifying the National Association of Statutory Health Insurance Funds of their accession.
(2) The model project comprises uniform, quality-assured and standardised diagnostics and personalised therapy identification through genome sequencing to be provided according to the latest standards prevailing in science and technology for the insured person taking part in the model project in accordance with subsection (5) in cases of rare or oncological diseases.

The service must be provided in compliance with the Genetic Diagnostics Act (Gendiagnostikgesetz) and with data protection regulations and includes in particular

1. the appropriate reviewing, based in as far as possible on evidence-based guidelines, of the medical indication for genome sequencing and consideration of other diagnostic or therapeutic options in multidisciplinary case conferences at which all medical fields relevant for the respective case are represented,

2. standardised phenotyping,

3. sequencing, which can also comprise parallel examinations of all coding sequences,

4. bioinformatic assessment,

5. clinical interpretation,

6. notification of findings after implementation of the sequencing and

7. implementation of uniform re-evaluation cycles.

In addition to the genome sequencing of the insured person, part of the diagnostics may involve the genome sequencing of one or both biological parents of the insured person, provided that the biological parent consents or both the biological parents consent. Genome sequencing pursuant to sentence 3 should be decided on in a multidisciplinary case conference pursuant to sentence 2 no. 1 if it is necessary in order to facilitate or substantially improve the diagnostics of the insured person. Genome sequencing pursuant to sentence 3 comprises the measures listed in sentence 2 nos. 2 to 5 as well as the services needed to obtain the requisite samples.
Responsibility for the measures and services pursuant to sentence 5 lies with the health insurance fund of the insured person taking part in the model project. The data collected in the course of diagnostics and therapy identification must be documented by the healthcare providers in the data infrastructure pursuant to subsection (9) within three months.
(3) The healthcare providers eligible to take part in the model project include:

1. Hospitals, in particular university clinics, that have a centre for rare or oncological diseases which meets the quality requirements in Appendix 1 or 2 of the decision of the Federal Joint Committee regarding the first version of the regulations on specifying the special tasks of centres and focus areas pursuant to section 136c (5), or

2. Oncological centres organised in networks, in particular the German Network for Personalised Medicine (Deutsches Netzwerk für Personalisierte Medizin), the National Network Genomic Medicine Lung Cancer (Nationales Netzwerk Genomische Medizin Lungenkrebs), the German Consortium for Hereditary Breast and Ovarian Cancer (Deutsches Konsortium Familiärer Brust- und Eierstockkrebs), the German Cancer Consortium (Deutsches Konsortium für Translationale Krebsforschung) and the National Center for Tumor Diseases (Nationales Centrum für Tumorerkrankungen).

(4) An application for the healthcare providers to take part in the model project can be submitted to the National Association of Statutory Health Insurance Funds, providing evidence that the prerequisites in subsection (3) are met. The National Association of Statutory Health Insurance Funds will assess whether the prerequisites in subsection (3) are met and decide by way of an administrative act whether the healthcare provider that has submitted an application is eligible to take part in the model project. If further documentation is required in order to make a final decision regarding the application, the National Association of Statutory Health Insurance Funds will request such documents from the healthcare provider. The National Association of Statutory Health Insurance Funds will publish the names of the healthcare providers taking part in the model project on its website.

The healthcare providers must agree, in their application to take part, to their names being published pursuant to subsection (4).
(5) Insured persons can take part in the model project if

1. they have been diagnosed with or require assessment of a rare or oncological disease that corresponds to an indication agreed in accordance with subsection (7) sentence 1 no. 1,

2. based on the treatment history, it is recommended that they take part in the model project by

   a) the healthcare provider treating the insured person, or

   b) a healthcare provider deemed eligible to take part in the model project in accordance with subsection (4) sentence 2.

Participation in the model project is recommended if state-of-the-art genome sequencing could be expected to provide key insights in relation to the diagnosis or clinically relevant added value for the treatment of the insured person. The recommendation to take part in accordance with sentence 1 no. 2 b) should be confirmed by at least one multidisciplinary case conference convened by the healthcare provider in accordance with sentence 1 no. 2. Information as set out in the requirements in subsection (7) sentence 1 no. 2 regarding the treatment history by the treating healthcare provider to the healthcare provider taking part in the model project as well as information regarding the insights gained from diagnostics and therapy identification by the healthcare provider taking part in the model project to the treating healthcare provider must be ensured.
(6) The healthcare providers, genomic data centres, clinical data nodes as well as data services are authorised to process the personal data required to carry out their tasks in accordance with subsections (10) to (10c). Use of the data for the purposes listed in subsection (9c) sentence 7 no. 1 and subsection (11) sentence 3 no. 4 requires the prior written or electronic consent of the insured persons vis-à-vis the healthcare providers in line with data protection regulations, in particular the rights of the data subject pursuant to Articles 12 to 22 of 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 (General Data Protection Regulation) (OJ L 119 of 4 May 2016, p. 1; L 314 of 22 November 2016, p. 72; L 127 of 23 May 2018, p. 2; L 74 of 4 March 2021, p. 35) as amended. In the case of genome sequencing pursuant to subsection (2) sentence 3, the consent referred to in sentence 2 must be declared individually by the biological parent or by both biological parents, in derogation of sentence 2. The platform operator will ensure that the insured persons' declaration of consent referred to in sentence 2 is structured in an accessible and standardised format in line with data protection regulations. This must be done in agreement with the Federal Commissioner for Data Protection and Freedom of Information as well as the Federal Government Commissioner for Patient Affairs.
(7) In the contract pursuant to subsection (1) sentence 1, the contractual partners must make arrangements regarding the following in particular:

1. the indications in the area of rare and oncological diseases for which there are clinical or scientific findings suggesting that individual and genetic information influence the diagnosis and the therapy decision,

2. the information duties pursuant to subsection (5) sentence 4,

3. the prerequisites for ending comprehensive diagnostics and therapy identification in the model project, for referring the insured person back to outpatient or inpatient care for further treatment within the framework of standard care as well as regarding the possibility for insured persons to continue to avail of continuous re-

evaluation in accordance with subsection (2) sentence 2 no. 7 within the framework of the model project, the results of which must be taken into consideration in treatment in standard care,

4. additional quality requirements for the healthcare providers that ensure the quality of the services to be provided and the safety of the insured persons,

5. requirements for coordinating and structuring processes at the healthcare providers, including stipulations on re-evaluation cycles as well as on the active collaboration of the healthcare providers in a network,

6. uniform use by the healthcare providers of the insured persons' declaration of consent referred to in subsection (6) sentence 4,

7. possibilities for the healthcare providers taking part in the model project to cooperate in regard to providing the services and measures referred to in subsection (2) sentence 2,

8. uniform rules for the remuneration for the services to be provided within the framework of this model project,

9. measures to ensure the cost-effectiveness of the services to be provided within the framework of this model project,

10. ensuring that the healthcare providers are connected to the data infrastructure in accordance with subsections (9) to (11b),

11. measures to provide the data collected by all of the healthcare providers taking part in the model project in the course of diagnostics and therapy identification in the genomic data centres and the clinical data nodes,

12. the consequences of terminating a healthcare provider, in particular with regard to handling the data already generated by that healthcare provider.

The contract must be entered into according to the latest standards prevailing in science and technology. The contract must be modified by the contractual partners to keep abreast of the latest standards prevailing in science and technology or if the interim reports pursuant to subsection (13) sentence 3 show a need for modifications. In derogation of subsection (1) sentence 3, consensus must be reached with the German Hospital Federation in relation to the contractual content referred to in sentence 1 nos. 2 and 3. The organisations recognised in accordance with the ordinance issued on the basis of section 140g must be consulted before the contract according to subsection (1) sentence 1 is concluded. The organisations will appoint qualified persons for this purpose. Section 116b (6) sentences 13 to 15 apply accordingly, subject to the proviso that the morbidity-related overall remuneration must be adjusted for the services provided within the framework of the model project in accordance with subsection (2). For the remuneration of services provided within the framework of the model project by the healthcare providers deemed eligible to take part in the model project in accordance with subsection (4) sentence 2, section 120 (2) sentence 1 applies accordingly; the details regarding the procedure for billing must be set out in the agreement pursuant to section 301 (3). Section 136c (5) sentence 3 and section 140a (2) sentence (7) apply accordingly.

(8) If a contract pursuant to subsection (1) sentence 1 has not been concluded in full or in part by 1 April 2024, the contractual content will be stipulated within a period of three months by an arbitrator to be appointed jointly by the contractual partners. If the consensus required in accordance with subsection (7) sentence 4 cannot be reached, the arbitrator will stipulate the contractual content referred to in subsection (7) sentence 1 nos. 2 and 3 after consulting with the German Hospital Federation. Half of the cost of the arbitration procedure will be borne by the National Association of Statutory Health Insurance Funds, with the other half

borne by the healthcare providers deemed eligible to take part in the model project in accordance with subsection (4) sentence 2. Legal actions that relate to the stipulation of the contractual content must be taken against one of the two contractual partners and not against the arbitrator.
(9) The Federal Institute for Drugs and Medical Devices (platform operator) will be in charge of setting up and operating a centralised platform for the model project. The platform operator is subject to the principle of secrecy of social data in accordance with section 35 of Book One. The platform operator must ensure through the qualifications of its staff and through its material resources, technical equipment and facilities that it can fulfil its tasks. In particular, the platform operator must

1. authorise and monitor the clinical data nodes, genomic data centres and data services and set out requirements for quality testing and quality assurance of the data to be stored in the genomic data centres in accordance with subsection (10a) sentence 4 and in the clinical data nodes in accordance with subsection (10b) sentence 4,

2. set up and keep up-to-date a public registry of applications with information on the authorised users submitting applications, on the projects for which data were requested and on the results of those projects,

3. develop the model project further,

4. inform the public about the model project,

5. provide data and make them accessible for the authorised users on application.

An administrative office to operate the platform and carry out the tasks pursuant to sentence 4 will be set up at the platform operator. In its terms of business and use, the platform operator will set out in more detail how the administrative office is organised and functions as well as how the tasks pursuant to sentence 4 are structured, in particular regarding the prerequisites for approval as well as the nature, scope and procedures for monitoring pursuant to sentence 4 no. 1. These terms require the approval of the Federal Ministry of Health in consultation with the Federal Ministry of Education and Research.
(9a) In consultation with the Federal Ministry of Health and the Federal Ministry of Education and Research, the platform operator will establish an advisory board which it will chair as well as a number of working groups. The advisory board will advise the platform operator on carrying out its tasks in accordance with subsection (9) sentence 4 nos. 1 to 4 and subsection (9c) sentences 12 and 13. The working groups will assist the advisory board in carrying out its task; its members will work on a voluntary basis. The platform operator will appoint qualified expert members and deputy members for the advisory board. Each will be appointed for a period of one year. The platform operator will ensure that the advisory board is composed of representatives from:

1. the Federal Ministry of Health,

2. the Trust Centre,

3. the healthcare providers,

4. the operators of the genomic data centres and clinical data nodes,

5. the statutory health insurance,

6. the relevant federal organisations for representing the interests of patients and self-help organisations for the chronically ill,

7. health research.

Representatives from the Federal Ministry of Education and Research as well as from the Association of German University Hospitals can take part in the meetings of the advisory

board in an advisory capacity. More details on the tasks and composition of the advisory board and of the working groups must be set out in the terms of business and use pursuant to subsection (9) sentence 6.
(9b) In consultation with the Federal Ministry of Health and the Federal Ministry of Education and Research, the platform operator will establish a scientific committee which it will chair. The scientific committee will advise the platform operator and assist it in carrying out its tasks in accordance with subsection (9) sentence 4 no. 5. Subsection (9a) sentences 4, 5 and 8 apply accordingly.
(9c) The Robert Koch Institute will establish a Trust Centre for the model project. Subsection (9) sentences 2 and 3 apply accordingly. The Trust Centre must in particular

1. generate a random transaction number for the data submitted to it pursuant to subsection (10) sentence 1 no. 1 and submit the number to the respective healthcare provider,

2. generate a genomic dataset pseudonym for the transaction number submitted to it pursuant to subsection (10a) sentence 4 no. 1 and submit this to a genomic data centre,

3. generate a clinical dataset pseudonym for the transaction number submitted to it pursuant to subsection (10b) sentence 4 no. 1 and submit this to a clinical data node,

4. for case identification as referred to in sentence 7 no. 1, generate a random transaction number for the data submitted to it pursuant to subsection (10) sentence 3 no. 1 and submit the number to the requesting healthcare provider together with the contact details for the requested healthcare provider,

5. for case identification as referred to in sentence 7 no. 1, determine the working number from the data submitted to it pursuant to subsection (10) sentence 3 no. 2 and submit the number to the requested healthcare provider,

6. to inform the treating healthcare provider as referred to in sentence 7 no. 2, determine the working number from the data submitted to it pursuant to subsection (10) sentence 4 and submit the number to the treating healthcare provider.

After submission, the transaction number must be erased at the Trust Centre, the healthcare providers, genomic data centres and clinical data nodes. The process of pseudonymisation must, according to the state of the art prevailing at the time, preclude unlawful identification of the patients concerned. The process of pseudonymisation is determined by the Trust Centre in agreement with the Federal Commissioner for Data Protection and Freedom of Information and the Federal Office for Information Security. The Trust Centre is authorised to restore the case reference of the data and to submit the data to the extent necessary

1. for case identification by a requesting healthcare provider or

2. to inform the treating healthcare provider of an insured person.

It is necessary to restore the case reference and submit data for case identification if, based on the clinical diagnostic assessment of the requesting healthcare provider, the treatment of an insured person calls for consultation and contact with a requested healthcare provider in the model project who has a similar case. It is necessary to restore the case reference and submit data in order to provide information to the treating healthcare provider of an insured person if projects carried out using pseudonymised individual datasets pursuant to subsection (11a) result in information that is relevant for the care of an insured person in the model project. The respective authorised user must inform the platform operator of this without delay. The platform operator must submit the information and the relevant pseudonyms to the respective treating healthcare provider without delay using a corresponding data service. In agreement with two representatives to be appointed by the

clinical cancer registries of the Länder pursuant to section 65c, the platform operator and the Trust Centre must present to the Federal Ministry of Health by 31 May 2025 a concept for linking and processing pseudonymised data from the model project and the clinical cancer registries of the *Länder* in accordance with section 65c. In agreement with the Health Data Lab and the Trust Centres involved, the platform operator must present to the Federal Ministry of Health by 31 May 2026 a concept for linking and processing pseudonymised data from the model project and the Health Data Lab (Forschungsdatenzentrum Gesundheit).
(10) For each participating insured person, the healthcare providers submit for the purposes referred to in subsection (11) sentence 3

1. the working number created by them and the health insurance number of the insured person as defined in section 290 to the Trust Centre,

2. the transaction number and the genome sequencing data to a genomic data centre,

3. the transaction number, the clinical data and the data from the respective consent to a clinical data node.

The clinical data include details on age, gender and municipality key, the phenotyping data as well as the data regarding treatment history. For case identification as referred to in subsection (9c) sentence 7 no. 1,

1. the requesting healthcare provider submits to the Trust Centre the genomic dataset or clinical dataset pseudonym provided by a data service,

2. the requested healthcare provider submits to the Trust Centre the random transaction number generated in accordance with subsection (9c) sentence 3 no. 4 and provided to it by the requesting healthcare provider.

For case identification as referred to in subsection (9c) sentence 7 no. 2, the treating healthcare provider submits to the Trust Centre the relevant pseudonyms submitted by the platform operator in accordance with subsection (9c) sentence 11.
(10a) Qualified scientific research institutions can set up genomic data centres. In order for the centres to be part of the model project, the platform operator must give authorisation to the operator of the genomic data centre.
Subsection (9) sentence 3 applies accordingly. The genomic data centres must in particular

1. check the data quality in line with the requirements pursuant to subsection (9) sentence 4 no. 1 of the data submitted to them in accordance with subsection (10) sentence 1 no. 2, store these data and submit the respective transaction numbers to the Trust Centre,

2. link the stored genomic data with the genomic dataset pseudonyms submitted in accordance with subsection (9c) sentence 3 no. 2 and store them.

The genomic data centres must erase the individual datasets related to insured persons after no more than 100 years. Access to the data stored in the genomic data centres is subject exclusively to the rules in subsections (11) to (11b). If the genomic data centre fails to meet its obligations pursuant to sentence 4, the platform operator can instruct the genomic data centre to take measures to ensure the tasks are performed. If the genomic data centre repeatedly fails to follow the instructions, the platform operator can have the genomic data centre excluded from the model project.
(10b) The healthcare providers set up clinical data nodes and operate the data nodes or link in with the clinical data node of a different healthcare provider. In order for them to be used in the model project, the platform operator must give authorisation to the operator of the clinical data node. Subsection (9) sentence 3 applies accordingly. The clinical data nodes must in particular

1. check the data quality in line with the requirements pursuant to subsection (9) sentence 4 no. 1 of the data submitted to them in accordance with subsection (10) sentence 1 no. 3, store these data and submit the respective transaction numbers to the Trust Centre,

2. link the stored clinical data and consent data with the clinical dataset pseudonyms submitted in accordance with subsection (9c) sentence 3 no. 3 and store them.

The clinical data nodes must erase the individual datasets related to insured persons after no more than 100 years. Access to the data stored in the clinical data nodes is subject exclusively to the rules in subsections (11) to (11b). If the clinical data node fails to meet its obligations pursuant to sentence 4, the platform operator can instruct the clinical data node to take measures to ensure the tasks are performed. If the clinical data node repeatedly fails to follow the instructions, the platform operator can have the clinical data node excluded from the model project.

(10c) Data are made accessible pursuant to subsection (11) and provided pursuant to subsection (11a) via automated IT solutions (data services). Subsection (9) sentence 3 applies accordingly. In order for the data services to be part of the model project, the platform operator must give authorisation to the operator of the data services.

(11) The platform operator will make the data stored in the clinical data nodes and genomic data centres accessible to the authorised users in accordance with sentences 4 and 5 as well as subsections (11a) and (11b). Authorised users are natural and legal persons within the scope of Regulation (EU) 2016/679 to the extent they are authorised to process the data in accordance with sentence 3. It is permissible for the data made accessible by the platform operator to be processed by the authorised users to the extent necessary for the following purposes:

1. Improvement of care through comprehensive diagnostics and therapy identification through genome sequencing,

2. Quality assurance,

3. Evaluation of the model project,

4. Scientific research.

If the prerequisites pursuant to sentences 3 and 5 are met, the platform operator will provide the authorised user, on application, with the anonymised and aggregated data selected in accordance with the requirements of the authorised user by means of one-off or repeated access to a data service. In the application, the authorised user must conclusively demonstrate that the scope and structure of the data requested are appropriate and necessary in order to resolve a question the user needs to address.

(11a) The platform operator can provide an authorised user with pseudonymised individual datasets if the authorised user submitting the application can conclusively demonstrate that an intended purpose referred to in subsection (11) sentence 3 requires this. For the purpose referred to in subsection (11) sentence 3 no. 1, the platform operator can provide the authorised user, on application, with pseudonymised individual datasets via a data service for repeated use. The platform operator provides an authorised user with the pseudonymised individual datasets for processing subject to monitoring by the platform operator in so far as

1. it is ensured that these data are provided only to persons who are bound by secrecy, and

2. appropriate technical and organisational measures are taken to ensure that processing by the authorised user is restricted to the necessary amount and in particular that it is not possible to copy the data.

The platform operator can provide persons not bound by secrecy with pseudonymised individual datasets in accordance with sentences 1 and 2 if they agreed to be bound by secrecy prior to obtaining access. Section 1 subsections (2), (3) and (4) no. 2 of the Obligations Act (Verpflichtungsgesetz) applies accordingly.
(11b) In respect of the data made accessible or provided in accordance with subsections (11) and (11a), the authorised users

1. may use them only for the purposes for which they were made accessible or provided, and

2. may not pass them onto third parties unless the platform operator gives approval for the data to be passed on to a third party within the scope of an intended purpose referred to in subsection (11) sentence 3. More details on the prerequisites for approval as referred to in sentence 1 no. 2 must be set out in the terms of business and use pursuant to subsection (9) sentence 6.

The authorised users will inform the platform operator of the projects for which the data were applied for as well as their results. The authorised users must ensure that the data made accessible or provided in accordance with subsections (11) and (11a) are processed in a manner that does not allow the data to be linked to individual persons or healthcare providers. If data have been unintentionally linked to individual persons or healthcare providers, the platform operator must be notified of this immediately. The intentional processing of the data provided for the purpose of tracing data back to individuals, for the purpose of identifying healthcare providers and for the purpose of deliberately gaining knowledge of third-party trade and commercial secrets is prohibited. This does not apply in the event of a case identification by the Trust Centre as referred to in subsection (9c) sentence 7 no. 1. If there is sufficient reason to suspect that authorised users have processed data made accessible or provided by the platform operator in accordance with subsections (11) and (11a) in a manner that does not comply with the applicable data protection regulations or the rules of the platform operator, the platform operator can exclude the authorised users from access to the data. The exclusion can be temporary. The platform operator will inform the competent data protection supervisory authorities of every incidence of sufficient reason to suspect unlawful processing as referred to in sentence 8 and of every exclusion of an authorised user from data access.
(12) The Federal Ministry of Health will determine in agreement with the Federal Ministry of Education and Research by means of an ordinance subject to the approval of the Bundesrat details regarding

1. the type of data and scope of data to be submitted in accordance with subsections (9) to (11b) as well as the deadlines for submission of data,

2. data processing by the healthcare providers,

3. the pseudonymisation procedure and

4. the technical method used for data submission in accordance with subsections (9) to (11b).

(13) Section 65 applies subject to the proviso that the report on the results of the evaluations must contain a proposal as to whether or not to adopt the services from the model project in standard care and that the scientific research support and evaluation must take place in agreement with the Federal Ministry of Health. After the term in accordance with subsection (1) sentence 2 has expired and pending submission of the report on the results of the evaluations or until a statutory provision is passed to adopt the services in standard care, the health insurance funds can continue the model project based on a contract in accordance with section 140a. Furthermore, for the term of the model project the National Association of Statutory Health Insurance Funds must present to the Federal Ministry of Health an annual

interim report of the evaluation, which contains in particular the scientific evaluation of the results available to date.
(14) The National Association of Statutory Health Insurance Funds must present the contract pursuant to subsection (1) sentence 1 to the Federal Ministry of Health for approval. Approval is deemed granted unless the Federal Ministry of Health denies approval in part or in full within two months of being presented with the contract. As part of the review, the Federal Ministry of Health can request from the National Association of Statutory Health Insurance Funds additional information underlying the conclusion of the contract as well as supplementary opinions; the deadline pursuant to sentence 2 is interrupted until the information is received. Already during the ongoing contractual negotiations, the Federal Ministry of Health is entitled to request information regarding the status of the negotiations and have the relevant documents presented to it. It is entitled to take part in the negotiations between the contractual parties in accordance with subsection (1) sentence 1. The National Association of Statutory Health Insurance Funds must inform the Federal Ministry of Health at an early stage of the respective negotiation dates.
(15) The provisions in the Genetic Diagnostics Act, in particular on information, consent and notification of the results of genetic testing and analyses remain unaffected.