Federal Law Gazette

Part I

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Health IT Interoperability Governance Ordinance (IOP Governance Ordinance – GIGV)

of 10 September 2024

Pursuant to Section 385, Paragraph 1, Sentence 1, in conjunction with Sentence 2, Paragraph 2, Sentence 1, as well as Paragraph 3, and Paragraph 4, Sentence 5, of Book Five, of the Social Code, as amended by Article 1, Point 87, of the Act of 22 March 2024 (Federal Law Gazette 2024 I No. 101), also in conjunction with

– Section 355, Paragraph 9, Sentence 2, of Book V, of the Social Code, as amended by Article 1, Point 55, Letter g, of the Act of 22 March 2024 (Federal Law Gazette 2024 I No. 101),
– Section 372, Paragraph 2, Sentence 2, and Section 373, Paragraph 1, Sentence 3, of Book Five, of the Social Code, as amended by Article 1, Point 77, of the Act of 22 March 2024 (Federal Law Gazette 2024 I No. 101), and
– Section 387, Paragraph 7, Sentence 1, of Book V, of the Social Code, as amended by Article 1, Point 87, of the Act of 22 March 2024 (Federal Law Gazette 2024 I No. 101),

the Federal Ministry of Health hereby enacts the following:

Chapter 1

General Provisions

Section 1

Purpose of the Ordinance

The purpose of this ordinance is to create, through the establishment of a Competence Centre, the conditions necessary to promote the interoperability (IOP) of information technology systems, to ensure the mandatory implementation of interoperability requirements, and to enable networked cooperation between service providers.

Chapter 2:

Stakeholders; knowledge platform

Section 2

Competence Centre for Interoperability in Healthcare

(1) The Society for Telematics maintains a Competence Centre for interoperability in the healthcare system (the Competence Centre).

(2) The Competence Centre has the following tasks:

1. identifying requirements for technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, taking into account European requirements and international standards;
2. prioritising the requirements under Point 1;
3. commissioning natural persons or legal entities governed by public or private law to specify technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 7, Paragraph 1;
4. assessing the professional competence of natural or legal persons to draw up specifications in accordance with Section 7, Paragraph 2, as a prerequisite for their appointment;
5. developing technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, taking into account the prioritisation set out in Point 2;
6. recommending technical, semantic and syntactic standards, profiles**,** guidelines, information models, reference architectures and software components for specific areas or the healthcare sector as a whole, and their publication on the knowledge platform in accordance with Section 6;
7. proposing recommendations in accordance with Point 6 for binding adoption by the Federal Ministry of Health;
8. verifying information technology systems for compliance with the requirements set out in Annex 1 in a conformity assessment procedure in accordance with Sections 13 and 14, and the issue of a certificate to that effect,
9. appointing an Expert Panel in accordance with Section 3;
10. appointing experts pursuant to Section 4;
11. establishing IOP Working Groups pursuant to Section 5;
12. annually submitting a report to the Federal Ministry of Health in accordance with Section 17, regular reporting on the measures taken during the reporting period to fulfil the statutory duties and on those planned for the future to achieve the objectives, as well as regular reporting on the measures taken during the reporting period to fulfil the statutory duties and on those planned for the future for the same purpose at the general meeting of the Society for Telematics;
13. obtaining and assessing comments relating to the fulfilment of the task set out in Point 6, particularly those from the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information;
14. operating the knowledge platform in accordance with Section 6;
15. increasing public understanding of issues relating to interoperability in the healthcare sector through measures to build competence and provide communication support for the tasks set out in Points 1 to 13;
16. supporting the Federal Government in projects and committees aimed at promoting interoperability in the healthcare sector at the federal level, within the European Union and through bilateral and multilateral consultations;
17. establishing and updating the Rules of Procedure in accordance with Section 18; and
18. organising and coordinating the tasks set out in Points 1 to 17.

(3) The tasks set out in Paragraph 2, Points 1 to 13, shall be carried out through publicly accessible, documented procedures.

Section 3

Expert Panel

(1) In consultation with the Federal Ministry of Health, the Competence Centre is establishing an Expert Panel to promote interoperability and open standards and interfaces in the healthcare sector (Expert Panel).

(2) The Expert Panel shall have an interdisciplinary composition and consist of seven appointed full members, including the chairperson, and two associate members. To ensure an interdisciplinary approach, one representative from each group as defined in Section 4, Paragraph 4, must be appointed. The Society for Telematics and the Federal Ministry of Health shall each appoint one person as an associate member to the Expert Panel. For this purpose, they can be represented by an expert.

(3) The chairperson acts as the liaison between the Competence Centre and the Expert Panel, coordinates the work of the Expert Panel, including the preparation of the report on the activities of the Competence Centre and the Expert Panel, ensures that the Expert Panel has a quorum and that the Rules of Procedure are observed, and is elected by a majority vote of the Expert Panel's members.

(4) The list of members of the Expert Panel shall be published by the Competence Centre on the knowledge platform in accordance with Section 6 and updated within two weeks of any change in the composition.

(5) Appointments are for a term of three years. The total term of office of each member shall not exceed six years.

The appointment and exclusion procedure is set out in detail in the Rules of Procedure pursuant to Section 18.

(6) The Expert Panel supports the Competence Centre in its tasks in accordance with Section 2, Paragraph 2, Points 1 to 8, 10 to 13, 15 and 16. This support covers the following tasks:

1. providing technical advice;
2. preparing written expert reports;
3. chairing IOP Working Groups in accordance with Section 5;
4. establishing and further developing a catalogue of criteria for the publication of standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 10, to be approved by the Federal Ministry of Health; as well as
5. attending regular and ad hoc meetings; if a member of the Expert Panel is unable to attend a meeting in person, they may, in exceptional cases, be represented by another member, provided that the chairperson has been notified of the representation in advance.

(7) Any further processes and obligations relating to the performance of the Expert Panel's duties are set out in the Rules of Procedure pursuant to Section 18. When drawing up the Rules of Procedure, care must be taken to ensure that the experts on the Expert Panel can exercise their participation in the tasks in accordance with Section 2, Paragraph 2, Points 1 to 8, 10 to 13, 15 and 16, in a manner that is substantively independent of the group referred to in Section 4, Paragraph 4, which they represent.

(8) The Society for Telematics shall reimburse the ordinary members of the Expert Panel for the expenses incurred in connection with their activities. Travel expenses are reimbursed in accordance with the Federal Travel Expenses Act. Furthermore, the amount of the reimbursement is determined in accordance with the relevant provisions in the Rules of Procedure pursuant to Section 18.

Section 4

IOP Expert Group

(1) The IOP Expert Group comprises all appointed experts from whom the specific members of the Expert Panel and the Working Groups are recruited in accordance with Section 5 (IOP Expert Group). In addition, the Competence Centre and the Expert Panel may, as required, call upon members of the IOP Expert Group to assist them in carrying out their respective tasks.

(2) The Expert Panel, referred to in Section 3, shall, in agreement with the Competence Centre, appoint as members of the IOP Expert Group (experts) individuals who possess specialist knowledge in the form of at least three years' full-time professional experience in the fields of healthcare provision, information technology and standardisation in the healthcare sector.

(3) Natural persons who possess the specialist knowledge referred to in Paragraph 2 may apply to the Competence Centre via the knowledge platform for appointment as an expert. The Competence Centre forwards the applications to the Expert Panel.

(4) The IOP Expert Group comprises representatives from the following groups:

1. users of information technology systems, in particular the Society for Telematics and the Federal Associations of Statutory Health Insurance Physicians;
2. federal associations representing the interests of industry in the field of innovative technologies in the healthcare sector;
3. federal states;
4. national and international standardisation organisations with a technical interest in the field;
5. associations, in particular the umbrella organisation, National Association of Statutory Health Insurance Funds (NASHIP);
6. relevant professional associations in the healthcare sector; as well as
7. scientific institutions and patient organisations.

(5) The experts are appointed as members of the IOP Expert Group for a term of six years. If a member no longer wishes to be a member of the IOP Expert Group, they shall declare their resignation in writing to the Competence Centre. Re-admission is possible.

(6) The requirements regarding the evidence to be submitted for the assessment of eligibility for appointment as a member of the IOP Expert Group are set out in the Rules of Procedure pursuant to Section 18.

(7) The Competence Centre publishes a list of the experts nominated for the IOP Expert Group on the knowledge platform.

Section 5

IOP Working Groups

(1) The Competence Centre, in consultation with the Expert Panel, establishes topic-specific IOP Working Groups composed of members of the IOP Expert Group and chaired by a member of the Expert Panel. The composition of the IOP Working Groups is topic-based and interdisciplinary, with care taken to ensure balanced representation of the groups in accordance with Section 4, Paragraph 4. Where justified, expertise from outside the IOP Expert Group may also be drawn upon and integrated. This requires the agreement of the Expert Panel and the Competence Centre.

(2) The IOP Working Groups support the Competence Centre and the Expert Panel in their tasks in accordance with Section 2, Paragraph 2, Points 1, 6, 7, and 13.

(3) The appointment and exclusion procedures, objectives, composition, and working methods of the IOP Working Groups are set out in the Rules of Procedure in accordance with Section 18.

(4) The Society for Telematics reimburses members of the IOP Working Groups for expenses incurred in connection with their activities in accordance with Section 3, Paragraph 8.

(5) The Competence Centre publishes a list of the IOP Working Groups and their membership.

Section 6

Knowledge platform for interoperability in healthcare

(1) The Competence Centre operates and maintains a publicly accessible, barrier-free platform (knowledge platform).

(2) The knowledge platform contains:

1. a list of the members of the Expert Panel, the IOP Expert Group and the IOP Working Groups;
2. technical, semantic and syntactic standards, profiles and guidelines, information models, reference architectures and software components;
3. recommended technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, such that all information necessary for the implementation of applications is available and accessible free of charge;
4. mandatory technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, such that the mandatory specifications are clearly distinguished from mere recommendations and all information necessary for the implementation of applications is available free of charge;
5. an overview of planned or draft standards, profiles, guidelines, information models, reference architectures and software components;
6. recommendations and opinions on technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components pursuant to Section 2, Paragraph 2, Point 6, and Section 2, Paragraph 2, Point 13, together with the associated justifications, as well as the disclosure and presentation of the relevant decision-making processes of the Competence Centre and the Expert Panel;
7. Information on applications submitted, and on the issue, refusal, withdrawal or revocation of a certificate in the context of conformity assessment pursuant to Section 387, of Book Five, of the Social Code, in conjunction with Sections 13 and 14, as well as a summary list of the information technology systems confirmed in accordance with Section 372, Paragraph 3, Sentence 1, of Book V, of the Social Code, and those certified in accordance with Section 387, Paragraph 3, of Book V, of the Social Code;
8. the publication of the Rules of Procedure pursuant to Section 18, as well as the annual reports;
9. the requirements regarding the suitability of staff providing statutory and contract dental care, as necessary for certification under Section 390, Paragraph 7, Sentences 1 and 2, of Book V, of the Social Code;
10. information on the cloud systems and cloud technology certified in accordance with Section 393, Paragraph 3, Point 2, of Book V, of the Social Code, together with a checklist of the corresponding criteria for customers, provided that an application for publication has been made in accordance with Section 393, Paragraph 7, of Book V, of the Social Code;
11. information serving to build expertise and knowledge on matters relating to interoperability in the healthcare sector; and
12. representations by the National Association of Statutory Health Insurance Physicians for the visualisation of information objects in accordance with Section 355, Paragraph 1, Sentence 3, of Book V, of the Social Code.

(3) The Competence Centre may provide further information on technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components on the knowledge platform, in particular those relating to international standards as well as projects and information technology systems

in the healthcare sector, provided that these are not already subject to publication requirements at the federal level. If there are publication obligations at federal level, references to the publications are possible.

(4) The Competence Centre must make available a procedure for applicants within the meaning of Section 387, Paragraph 1, of Book Five, of the Social Code, whereby, after a reasonable period of time, an application may be made for the deletion of the information referred to in Paragraph 2, Point 7, provided that such information is likely to prejudice the applicant's important legal interests significantly. In doing so, due account shall be taken of the particular interest of the public in the publication of the relevant information in order to promote interoperability in the healthcare system.

(5) Further details are to be set out in the Rules of Procedure in accordance with Section 18.

Chapter 3

Procedure for the drafting, recommendation and binding adoption of specifications

Section 7

Commissioning third parties to draw up specifications

(1) The Competence Centre may commission technically qualified natural persons or legally qualified entities under public or private law to develop technical, semantic, and syntactic standards, profiles, guidelines, information models, reference architectures, and software components.

(2) A person is considered professionally qualified if they possess the technical, organisational and economic skills, knowledge and abilities required to specify interoperable technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures or software components. Further details regarding the requirements for professional competence as set out in Sentence 1 shall be laid down in the Rules of Procedure pursuant to Section 18.

(3) When awarding contracts in accordance with Paragraphs 1 and 2, Section 311, Paragraph 7, of Book Five, of the Social Code, must be observed. The Society for Telematics awards the contract; before initiating the procurement process, the Competence Centre must obtain approval from the Federal Ministry of Health.

(4) The costs of the contract are to be borne by the Society for Telematics.

Section 8

Statutory specification contracts for public contracting authorities

The commissioning of a public contracting authority within the meaning of Section 99, Paragraphs 1 to 3, of the Act against Restraints of Competition to draw up specifications for technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components shall be carried out by including the contracting authority, the title of the specification to be drawn up by it and the relevant deadline for this in Annex 2.

Section 9

Standardised commenting and consultation procedure

(1) The Competence Centre shall establish a standardised consultation and comment procedure for the processes underlying the development, recommendation and adoption of specifications under this ordinance.

(2) In its Rules of Procedure pursuant to Section 18, the Competence Centre shall lay down framework conditions that enable uniform, user-centred commenting, irrespective of the specifying body.

Section 10

Inclusion in the knowledge platform

(1) Providers of information technology systems or third parties with a legitimate interest may submit a written or electronic application to the Competence Centre requesting the publication of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components on the knowledge platform. The application must be accompanied by all information necessary for implementation and application, as described in more detail in the Rules of Procedure pursuant to Section 18. In particular, the application shall be accompanied by proposals for a reasonable deadline for the implementation of the specification submitted and its scope of application. The Competence Centre shall assess the applications within four weeks in terms of completeness and quality and, in the event of a positive result, forward them to the Expert Panel. In the event of a

negative assessment result, the Competence Centre shall formulate requests to the applicant, the implementation of which shall be necessary to obtain a positive assessment result.

(2) The Expert Panel shall decide on the publication of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for information technology systems on the knowledge platform, based on a catalogue of criteria, no later than three months after the Expert Panel has received the complete application. The publication shall take place no later than four weeks after the decision of the Expert Panel.

(3) Where there is a statutory obligation to include information on the knowledge platform, the Competence Centre shall, notwithstanding Paragraphs 1 and 2, publish this information no later than four weeks after it has been submitted to the Competence Centre.

(4) Upon written or electronic request from the manufacturers of information technology systems, the Competence Centre shall publish the information referred to in Section 6, Paragraph 2, Point 10, on the platform in accordance with Section 6. The Rules of Procedure in accordance with Section 18 shall regulate the details of a procedure for the inclusion and deletion of content in accordance with Sentence 1. The content shall be published free of charge.

(5) The Federal Associations of Statutory Health Insurance Physicians must submit to the Competence Centre, in writing, the requirements regarding the suitability of staff in statutory health insurance and statutory dental care necessary for certification under Section 390, Paragraph 7, Sentences 1 and 2, of Book V, of the Social Code, as specified by each association. The Competence Centre shall publish the requirements referred to in Sentence 1 on the platform referred to in Section 6 without delay following their submission by the Federal Associations of Statutory Health Insurance Physicians.

Section 11

Recommendations for information technology systems in the healthcare sector

(1) The Competence Centre, in collaboration with the Expert Panel, recommends technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for information technology systems in the healthcare sector. These are published on the knowledge platform.

(2) In the run-up to the recommendations referred to in Paragraph 1, the Competence Centre is supported by the Expert Panel. In addition, prior to the recommendation, the Competence Centre shall conduct a comment and opinion process in accordance with Section 9.

(3) The Competence Centre publishes the statements and recommendations, together with the accompanying justifications, on the knowledge platform without delay.

Section 12

Proposal to the Federal Ministry of Health for the binding adoption of recommendations

(1) The Competence Centre submits its proposal to the Federal Ministry of Health for the binding adoption of a recommendation pursuant to Section 11, including the deadlines for implementing the recommendation and the intended scope of its application.

(2) The Competence Centre shall take the Expert Panel’s opinion into account when deciding whether to recommend binding adoption.

Chapter 4

Conformity assessment procedures

Section 13

Application for conformity assessment

(1) Manufacturers of information technology systems used in the healthcare sector for processing personal patient data must undergo the conformity assessment procedure at the Competence Centre. They must also obtain certification confirming that their system complies with the mandatory requirements set out in Annex 1. In the case of interfaces between information technology systems within the meaning of Section 371, Paragraphs 1 and 2, of Book V, of the Social Code, the provisions of Section 372, of Book V, of the Social Code, or Section 373, of Book V, of the Social Code, shall apply in addition to the requirements set out in Sentence 1.

(2) Conformity assessment is carried out following a written or electronic application submitted to the Competence Centre by a manufacturer of an information technology system. Only the application forms published by the

Competence Centre may be used for such an application. The application shall contain the following, as a minimum:

1. name and address of the applicant;
2. date of the application;
3. name and address of an authorised representative of the applicant in a Member State of the European Union or in another State party to the Agreement on the European Economic Area;
4. name and address of a contact person for the applicant who possesses the necessary expertise to provide technical information on the information technology system to be assessed;
5. precise description of the information technology system to be assessed, in particular
   a) software name as per the manufacturer's product designation;
   b) software version number; and
   c) scope of application of the software;
6. indication of whether this is an initial conformity assessment or a repeat assessment following a notifiable substantial change to the system in accordance with Section 15;
7. declaration by the applicant that the application does not infringe the rights of any third party;
8. test reports and other evidence of compliance with the requirements set out in Annex 1;
9. details of the identification numbers of the mandatory requirements set out in Annex 1, on which the test reports and other evidence referred to in Point 8 are based;
10. in the case of a repeat assessment within the meaning of Point 6, the previous certificate of compliance with the mandatory requirements set out in Annex 1 and the identification number of the mandatory requirements set out in Annex 1 on which it is based;
11. declaration of consent to the publication of the rejection, issue, failure or withdrawal of the certificate.

The Rules of Procedure pursuant to Section 18 set out further details regarding the content of applications as referred to in Sentence 3.

(3) The Competence Centre shall process applications in the order received.

(4) A federal association representing the interests of industry in the field of innovative healthcare technologies may, as the authorised representative of its member companies, submit the applications referred to in Paragraph 2 on behalf of manufacturers of information technology systems. At the request of the Competence Centre, the authorised representative must provide written proof of their authorisation and submit the documents referred to in Paragraph 2, Sentence 3.

(5) The Competence Centre shall issue a request for supplementary information if any details or documents are missing. The supplementary application must be submitted within three months of receipt of the request for further information; otherwise, the Competence Centre will reject the application.

Section 14

Certificate

(1) An information technology system is certified if it meets the requirements set out in Annex 1.

(2) The certificate contains the following information:

1. software name as per the manufacturer's product designation;
2. software version number;
3. name and address of the manufacturer of the information technology system;
4. validity period of the certificate, which shall not exceed 18 months from the date of issue;
5. identification number of the mandatory requirements checked for conformity in accordance with Annex 1;
6. version of the requirements set out in Annex 1 on which the conformity assessment is based;
7. statement that the Competence Centre issued the certificate;
8. further details, insofar as these have been specified by the Competence Centre in the Rules of Procedure pursuant to Section 18.

(3) The applicant will be notified of the issuance of the certificate electronically.

(4) Information regarding submitted applications and the issue, refusal, withdrawal, or revocation of a certificate must be published by the Competence Centre on the platform in accordance with Section 6.

(5) Sections 48 and 49 of the Administrative Procedure Act shall apply to the withdrawal or revocation of a certificate.

(6) Persons employed by or commissioned by the Competence Centre must not disclose or use, without authorisation, any confidential information obtained in the course of their duties, even if they are no longer in service

or their employment has ended. This shall also apply to other persons who, through official reporting become aware of the information referred to in Sentence 1.

(7) Conformity assessment procedures under this ordinance, which were formally initiated before the entry into force of an amendment to the ordinance, shall be completed in accordance with the legal provisions in force until the entry into force of the amendment to the ordinance, unless otherwise specified below. If individual steps of the procedure required by law have not yet been commenced, these may also be carried out in accordance with the provisions of the amended ordinance. Certificates and decisions issued by the Competence Centre in accordance with previous versions of this ordinance remain valid.

Chapter 5

Obligation to notify in the event of significant changes; appeals procedure

Section 15

Obligation to report significant changes to information technology systems

(1) If an information technology system certified in accordance with Sections 13 and 14 is to undergo a significant change, the manufacturer of the system must notify the Competence Centre of this before implementing the change in the production systems. For this provision, ‘significant’ refers to any changes that may affect compliance with the mandatory requirements set out in Annex 1 for information technology systems that have been certified in accordance with Section 14. For the notification referred to in Sentence 1, only the electronic forms published by the Competence Centre are to be used. The notification must contain at least basic technical details of the planned change, as well as information on which of the binding specifications set out in Annex 1 may be affected by the change.

(2) Should the certificate holder be unable to demonstrate that the change will not compromise compliance with the mandatory requirements, the Competence Centre shall subsequently make the granting of the certificate subject to conditions ensuring compliance with the mandatory provisions set out in Annex 1, or suspend or revoke the certificate to the extent of the non-conformity.

Section 16

Complaints procedure

The Competence Centre shall lay down, in its Rules of Procedure pursuant to Section 18, a procedure for dealing with reports of a certified system deviating adversely from the binding requirements set out in Annex 1.

Chapter 6

Rules of Procedure, reporting and evaluation

Section 17

Report on the activities of the Competence Centre and the Expert Panel

(1) The Competence Centre shall submit a report on the previous calendar year to the Federal Ministry of Health by 31 March each year. The report shall include at least the following:

1. information on the current status of the planning and implementation of the strategic direction and tasks of the Competence Centre and the Expert Panel, including activities relating to the publication and recommendation of standards, profiles, guidelines, information models, reference architectures and software components;
2. information on the current status of planning and implementation of the operation of the knowledge platform, including key performance indicators relating to the use of the knowledge platform;
3. information on the composition and work of the Expert Panel and the IOP Working Groups; as well as
4. an overview of the costs incurred in fulfilling the tasks set out in Section 385, Paragraph 3, Point 10, of Book V, of the Social Code.

(2) The Competence Centre publishes the report on the knowledge platform following approval by the Federal Ministry of Health.

Section 18

Rules of Procedure

(1) The Competence Centre shall adopt Rules of Procedure. The Rules of Procedure shall supplement and operationalise the provisions laid down in this ordinance on:

1. the structure and organisation of the Competence Centre;
2. the definition of the Competence Centre's tasks;
3. the composition of the Competence Centre;
4. the procedure to be followed in carrying out its tasks;
5. the rules governing a quorum, whereby the non-voting member seconded by the Federal Ministry of Health shall be granted a right of veto and resolutions shall be adopted by a two-thirds majority, with at least five members required to cast a vote; in this context, proxies shall cast both their own vote and that of the member they represent; resolutions by circular resolution shall be permitted and abstentions shall not be allowed;
6. the time limits for individual actions; and
7. the reimbursement of expenses.

Furthermore, the Rules of Procedure set out further details regarding the Expert Panel's participation in decision-making, in particular about the tasks under Section 2, Paragraph 2, Points 6 and 10, the adoption and recommendation of standards, and the operation of the knowledge platform.

(2) The Rules of Procedure shall establish the processes, procedures and decision-making mechanisms for the fulfilment of the tasks in accordance with Section 2, Paragraph 2, in addition to the provisions laid down in this ordinance. Key procedural steps include:

1. establishing the Expert Panel and definition of its specific tasks, working processes, duties and deadlines in accordance with Section 3, as well as ensuring that the Expert Panel defines evaluation criteria based on which decisions are made regarding the publication or rejection of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 10;
2. appointing experts and definition of their specific tasks, work processes, duties and deadlines in accordance with Section 4;
3. establishing IOP Working Groups and defining specific tasks, work processes, duties and deadlines in accordance with Section 5;
4. regulations governing the application, appointment and dismissal procedures for members of the Expert Panel, the IOP expert group and the IOP Working Groups;
5. defining the fundamental technical, structural and semantic framework conditions, as well as data security requirements relating to standards, profiles, guidelines, information models, reference architectures and software components;
6. taking into account requirements and technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, as well as the involvement of international experts;
7. commissioning of third parties to draw up specifications in accordance with Section 7;
8. and establishing and operating on an ongoing basis a standardised consultation and feedback procedure in accordance with Section 9, which allows for consistent and user-centred feedback regardless of the specific body responsible for the specifications;
9. regulations governing the conduct of a complaints procedure in accordance with Section 16;
10. requirements regarding content pursuant to Section 13, Paragraph 2, Sentence 3;
11. details of a procedure for adding content to the knowledge platform in accordance with Section 6 and for its deletion; and
12. defining the documentation and disclosure of all work and decision-making processes.

(3) The Rules of Procedure shall set out all-time limits for the tasks not provided for in this ordinance in accordance with Section 2, Paragraph 2.

(4) The Rules of Procedure shall be reviewed by the Competence Centre at least every three years to assess the need for updates and, where necessary, amended in consultation with the Expert Panel.

(5) The Federal Ministry of Health shall approve the Rules of Procedure.

(6) The Competence Centre shall publish the Rules of Procedure on the knowledge platform within four weeks upon approval by the Federal Ministry of Health.

Section 19

Evaluation

The Federal Ministry of Health shall commission an external research institution to evaluate the Competence Centre and the fulfilment of its tasks in accordance with Section 2, Paragraph 2. The evaluation report shall be available every three years, for the first time on 30 September 2026.

Section 20

Entry into force, abrogation

This ordinance shall enter into force on the day following its promulgation. At the same time, the IOP Governance Ordinance of 7 October 2021 (Federal Law Gazette I, p. 4634) ceases to have effect.

Bonn, 10 September 2024

The Federal Minister for Health Karl Lauterbach

Publisher: Federal Ministry of Justice

Annex 1
(Re Section 13, Paragraph 1, Sentence 1)

Mandatory requirements

The technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components mandated by the Federal Ministry of Health are listed in the table below. The publication shall be made on the website of the Federal Ministry of Health and the knowledge platform pursuant to Section 6 of this ordinance.

Date (entry into force of this ordinance): 14/09/2024

ID	Title	Brief description	Version	Chapter	Date of admission (in the annex)	Date of binding implementation by	Legal basis	Scope of application
001	Implementation guide for primary systems – electronic patient records (ePA)	Guidance on the implementation of the relevant requirements concerning interoperability between ePA record systems and primary systems with regard to the implementation of the electronic medication list (eML)	3.1.0	3.10.2	14/09/2024	15/01/2025	Section 355, Paragraph 3, Sentence 2, Point 1, Book Five, of the Social Code	1. Practice Management Systems (PMS), 2. Dental Practice Management Systems (DPMS), 3. Hospital Information Systems (HIS), and 4. Pharmacy Management Systems (PMS)

Note: Several versions of a profile/standard/guideline/information model/reference architecture/software component may be included in the annex.

Note:

ID: Identification number of the interface recorded on both the knowledge platform and the annex to ensure a clear assignment.

Title: The designation of the standard/profile/guideline/information model/reference architecture/software component as recorded on the knowledge platform.

Brief description: Description of the standard/profile/guideline/information model/reference architecture/software component.

Version: Version number as recorded on the knowledge platform.

Date of inclusion (in the annex): The effective date when the relevant version of the standard/profile/guideline/information model/reference architecture/software component was included in the annex.

Mandatory implementation date: Date by which the standard/profile/guideline/information model/reference architecture/software component must be implemented in a binding manner.

Legal basis: Legal provision from which the authorisation to make binding determinations derives; unless otherwise specified, these are provisions of Book V of the Social Code (SGB V).

Scope of application: The name of the IT system for which a specification must be implemented in accordance with the implementation deadline.

Annex 2
(regarding Section 8)

List of statutory specification contracts for public contracting authorities

Date (entry into force of this ordinance): 14/09/2024

ID	Legal basis	Body	Title	Short description	Date of creation of the specification up to
110	Section 355, Paragraph 1	Federal Association of Statutory Health Insurance Physicians	Example interface	The example interface is used here for illustrative purposes	

Note:

ID: Identification number of the interface recorded on both the knowledge platform and the annex to ensure a clear assignment.

Legal basis: Legal provision from which the statutory specification requirement arises; unless otherwise specified, these are provisions of Book V of the Social Code (SGB V).

Body: Name of the body or organisation entrusted with a statutory specification mandate.

Title: The designation of the standard/profile/guideline/information model/reference architecture/software component as recorded on the knowledge platform.

Brief description: Description of the standard/profile/guideline/information model/reference architecture/software component.

Date by which the specification must be drawn up: Date by which the specification of the standard/profile/guideline/information model/reference architecture/software component must be drawn up.