Draft bill

of the Federal Ministry of Health

Health IT Interoperability Governance Regulation*)

(IOP Governance Regulation – GIGV)

A. Problem and objective

Digital processes, applications and systems are becoming increasingly important in healthcare. In particular, with a view to further increasing interprofessional and cross-sectoral realities of care, a smooth exchange of information between the parties involved is imperative. Interoperability (IOP) is a key prerequisite for this.

Important digitalisation measures to improve the care of insured persons and to promote interoperability have therefore already been initiated and implemented in the context of previous legislative procedures.

With the adoption of the Health IT Interoperability Governance Regulation (GIGV) in 2021 under the Digital Healthcare and Nursing Care Modernisation Act (DVPMG), new structures and processes were established as a first step to further promote interoperability in the healthcare system within the framework of statutory health insurance, to advance the definition of interfaces and standards, to establish transparency on interoperability standards and to create the necessary organisational framework for this.

To this end, the Coordinating Body for Interoperability (KOS) was set up within the Telematics Company (Gesellschaft für Telematik). The key tasks of the KOS include identifying and prioritising needs for requirements, directives and guidelines as a basis for setting priorities, deriving areas of action, developing proposals, and ultimately establishing binding regulations. The aim is to adopt a holistic approach involving the technical, syntactic and semantic interoperability of information technology systems in the healthcare system. The Coordinating Body is supported in this regard by technical experts from different groups, who act as a decision-making body in an Expert Panel or as an IOP working group. To this end, a pool of experts from the respective areas of the healthcare system has been created (IOP Expert Group).

In the course of the statutory evaluation by the KOS, the Expert Panel and the working groups, it was assessed that the establishment of the above-mentioned structures was perceived positively by the specialist community and that the activities of the Coordinating Body in particular have significantly improved the transparency and visibility of the issue of interoperability. It became clear that the activities carried out so far are fundamentally expedient to strengthen the promotion of interoperability, but that the mission of the KOS has so far been too limited to achieve the best possible impact.

Despite the new structures and processes already in place, it was not possible, for example, to sufficiently prevent, for example, the continued emergence of partially contradictory or duplicated specifications. This requires holistic and cross-sectoral coordination and orchestrating of the interoperability process.

B. Solution

The Digital Act, which entered into force on 26 March 2024, further develops the already existing structures and processes to address the identified and persisting challenges and

*) Notified under 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).

ensure holistic and cross-sectoral coordination and orchestrating of interoperability activities.

On the one hand, the scope and competence of the Competence Centre will be expanded, and relevant new tasks defined. These include in particular the central prioritisation of needs, the commissioning of third parties to develop specifications, and the provision of a uniform quality-assured commentary and standardisation procedure, as well as conformity assessment procedures. In this way, the Competence Centre will become the key actor in creating interoperability in the healthcare system, while continuing the community-based approach as an integral part of the process. Only by creating such a central actor can it be ensured in a sustainable manner that the existing challenges in promoting interoperability can be addressed effectively.

This regulation makes use of the power to issue regulations conferred by Section 385(1) sentence 1 of Book V of the Social Code and further develops the existing regulation based on the previous Section 394a of Book V of the Social Code and expands it to include the additional tasks and responsibilities of the Competence Centre.

C. Alternatives

None

D. Budgetary expenditure exclusive of compliance costs

a) Federal government

None.

b) Federal states

None.

c) Social insurance system

None.

E. Compliance costs

None.

E.1 Compliance costs for citizens

None.

E.2 Compliance costs for businesses

The minor but non-quantifiable compliance costs for the economy in connection with the preparation and implementation of the conformity assessment procedure under Section 387 of Book V of the Social Code were already recognised under the Digital Act. There are no other costs arising from the use of the power to issue regulations: The provisions of this Regulation serve to establish uniform standards, profiles, guidelines on data exchange in the health sector and to establish uniform information models, reference architectures and software components in accordance with Section 384(1)(4), (7) and (13) of Book V of the Social Code. The further development of the new governance structure under this Regulation does not give rise to any compliance costs for the economy.

Of which administrative costs arising from obligations to provide information

None.

E.3 Compliance costs for the authorities

a) Federal government:

None.

b) Federal states:

None.

c) Social insurance system

Administrative compliance costs were already recognised under the Digital Act. There are no further costs arising from the exercise of the power to issue regulations.

F. Other costs

None.

Health IT Interoperability Governance Regulation

(IOP Governance Regulation – GIGV)

[...Date]

Pursuant to Section 385(1) sentence 1, (2) sentence 1 and section 373(8) of Book V of the Social Code, as amended by Article 1 no. 77 and 87 of the Law of 22 March 2024 (Federal Law Gazette 2024 I No. 101), the Federal Ministry of Health hereby decrees:

Section 1.

Purpose of the Regulation

The purpose of this Regulation is to create, through the establishment of a Competence Centre, the conditions for promoting the interoperability of information technology systems, the mandatory implementation of interoperability requirements and the networking of service providers. In order to increase cybersecurity, service providers are given access to information to improve the implementation of cybersecurity requirements for information technology systems.

Section 2.

Competence Centre for interoperability in the healthcare system

(1) The Telematics Company maintains a Competence Centre for interoperability in the healthcare system (the Competence Centre). The Competence Centre emerged from the Coordinating Body for Interoperability in the healthcare system.

(2) The Competence Centre shall have the following tasks:

1. Identification of the needs for requirements, directives and guidelines for technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, taking into account European requirements and international standards,
2. prioritisation of the needs under point 1,
3. commissioning of natural persons or legal entities governed by public or private law with the specification of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 7,
4. verification of the professional qualification of natural or legal persons to develop specifications in accordance with Section 7(2) as a condition for their commissioning,
5. development of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, taking into account the prioritisation in accordance with point 2,
6. recommendation of technical, semantic and syntactic standards, profiles**,** guidelines, information models, reference architectures and software components for specific domains or the entire health care system and their publication on the knowledge platform in accordance with Section 6,
7. proposal of recommendations in accordance with point 6 for binding specifications to the Federal Ministry of Health,
8. verification of information technology systems for their compliance with the mandatory requirements specified in Annex 1 in a conformity assessment procedure in accordance with Section 13 and issuance of a certificate thereof,

9. examination of the professional and organisational capacity of the applicants to carry out a conformity assessment procedure in accordance with point 8 in conjunction with Section 13 by means of an accreditation procedure in accordance with Section 12 and continuous monitoring of compliance with the relevant requirements,
10. appointment of an Expert Panel in accordance with Section 3,
11. appointment of Experts in accordance with Section 4,
12. establishment of IOP working groups in accordance with Section 5,
13. annual reporting to the Federal Ministry of Health in accordance with Section 16, monthly reporting on the progress of the work and planned developments, as well as regular reporting on the progress of the work and planned developments at the general meeting of the telematics company,
14. obtaining and evaluating opinions on the fulfilment of the task in accordance with point 6, in particular the opinions of the Federal Office for Information Security and the Federal Commissioner for Data Protection and Freedom of Information,
15. Operation of the knowledge platform in accordance with Section 6,
16. Improving the public understanding of issues relating to interoperability in the healthcare system through measures to build skills and communicate the tasks in accordance with points 1 to 14,
17. Supporting the Federal Government in the context of projects and panels promoting interoperability in the healthcare system at federal level, in the European Union and in the context of bilateral and multilateral agreements,
18. specification and maintenance o the Rules of Procedure in accordance with Section 17,
19. Organisation and coordination of the tasks in accordance with points 1 to 18.

(3) The tasks under paragraph 2, points 1 to 14 shall be fulfilled by means of publicly accessible and transparently documented procedures.

Section 3.

Expert Panel

(4) The Competence Centre, in consultation with the Federal Ministry of Health, shall set up an Expert Panel to promote interoperability and open standards and interfaces in the healthcare system (the Expert Panel). The Expert Panel shall have an interdisciplinary composition and shall consist of seven appointed full members, including the chairperson. The chairperson shall act as an interface between the Competence Centre and the Expert Panel, coordinate the work of the Expert Panel, including contributing to the report on the activities of the Competence Centre and the Expert Panel, ensure the quorum of the Expert Panel as well as compliance with Rules of Procedure of the Expert Panel and shall be elected by majority decision of the members of the Expert Panel. The Telematics Company and the Federal Ministry of Health may act as extraordinary members of the Expert Panel and may be represented for this purpose by an expert. In order to ensure interdisciplinarity, there shall be one representative for each group in accordance with Section 4(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 shall be made for a period of three years. The total term of office of each member shall not exceed six years. The procedure for appointment and exclusion shall be specified in the Rules of Procedure.

(6) The Expert Panel shall support the Competence Centre in its tasks in accordance with Section 2(2) points 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 16 and 17. The support includes technical advice, drafting of written expert reports, management of IOP working groups in accordance with Section 5, the definition and further development of a set of criteria for the publication of standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 9which shall be released by the Federal Ministry of Health, as well as participation in regular and unscheduled meetings. Exceptionally, if a member cannot personally attend meetings, another member of the Expert Panel appointed by the member may fulfil the tasks on behalf of the relevant member. The additional processes and duties in the performance of tasks by the Expert Panel shall be laid down in the Rules of Procedure in accordance with Section 17. When drawing up the rules of the Rules of Procedure, it must be ensured that the experts of the Expert Panel are able to participate as regards content independently of the group they represent in accordance with Section 4(4).

(7) The consent to the publication of the member's name and institution is a prerequisite for appointment.

(8) The Telematics Company shall reimburse the full members of the Expert Panel for the expenditure incurred in connection with their work in accordance with the current guideline on the identification and presentation of the compliance costs in regulatory projects of the Federal Government. Travel expenses are reimbursed in accordance with the Federal Travel Expenses Act. The amount of the reimbursement shall be determined by the Telematics Company upon approval of the Federal Ministry of Health in the Rules of Procedure in accordance with Section 17.

Section 4.

IOP Expert Group

(9) The IOP Expert Group is a list of appointed experts, from which members are recruited for the Expert Panel and the working groups in accordance with Section 5 (Expert Group). In addition, the Competence Centre and the Expert Panel may call on members of the Expert Group as required to carry out their respective tasks.

(10) The Expert Panel appoints, in agreement with the Competence Centre, persons with expertise in the form of at least 3 years full-time professional experience in the fields of healthcare as well as information technology and standardisation in healthcare (Experts) to the IOP Expert Group.

(11) The Experts may apply to the Competence Centre for appointment and admission to the IOP Expert Group through the knowledge platform, which will forward the application to the Expert Panel.

(12) The IOP Expert Group is composed of representatives of the following groups:

1. Users of information technology systems, in particular the Telematics Company and the Federal Associations of Statutory Health Insurance Physicians,
2. federal associations from the field of innovative technologies in the health sector that are key to representing the interests of the industry,
3. the federal states,
4. professionally concerned national and international standardisation organisations,
5. associations, in particular the Central Association of Health Insurance Funds and the associations responsible for accident insurance institutions,
6. professionally concerned specialist associations in the healthcare system, and

7. scientific institutions and patient organisations.

(13) The experts are appointed to the IOP Expert Group for a period 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.

(14) The Rules of Procedure shall specify the evidence to be submitted in order to verify the requirement for admission to the IOP Expert Group.

(15) The Competence Centre shall publish a list of the experts appointed to the IOP Expert Group on the knowledge platform. Consent to the publication of the candidate's name and institution is a prerequisite for submitting the evidence to be submitted in accordance with paragraph 6.

Section 5.

IOP working groups

(16) The Competence Centre shall, in agreement with the Expert Panel, set up issue-specific IOP working groups composed of the IOP Expert Group and chaired by a member of the Expert Panel. The composition of the IOP working groups shall be issue-related and interdisciplinary, with a view to ensuring equal representation of groups. In principle, the IOP working groups are composed of the members of the Expert Group. In justified cases, expertise outside the Expert Group may also be consulted and integrated. This requires the agreement of the Expert Panel and the Competence Centre.

(17) The IOP working groups shall assist the Competence Centre and the Expert Panel in their tasks in accordance with Section 2(2) points 1, 6, 7 and 14.

(18) The appointment and exclusion procedures, objectives, composition and working methods of the IOP working groups shall be laid down in the Rules of Procedure in accordance with Section 17.

(19) The Telematics Company shall reimburse the members of the IOP working groups for the expenses incurred in connection with their activities in accordance with Section 3(5).

(20) The Competence Centre shall publish a list of the IOP working groups and their composition.

Section 6.

Knowledge platform for interoperability and cybersecurity in the healthcare system

(21) The Competence Centre shall operate and maintain a publicly accessible platform (knowledge platform). The knowledge platform shall promote interoperability between information systems and create transparency on interoperability and cybersecurity in the healthcare system.

(22) The knowledge platform shall contain:

1. a list of the Expert Panel, the appointed experts in the Expert Group and the IOP working groups, respectively,
2. accepted, published 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, in such a way that all information necessary to implement applications is available and accessible free of charge,

4. binding technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, in such a way that the binding specifications are shown separately from mere recommendations,
5. an overview of standards, profiles, guidelines, information models, reference architectures and software components that are planned or currently being developed,
6. Opinions and recommendations on technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 2(2) point 6 and Section 2. (2) point 14 and the related justifications as well as the disclosure and presentation of the related decision-making processes of the Competence Centre and the Expert Panel,
7. a publication of the accredited bodies in accordance with Section 385(8) of Book V of the Social Code, in conjunction with Section 12, including an identification number,
8. information on applications submitted, the issue, refusal, withdrawal, or cancellation of a certificate in the context of the conformity assessment pursuant to Section 387 of Book V of the Social Code, in conjunction with Section 13 and an overview list of the information technology systems certified in accordance with Section 372(3) sentence 1 and Section 387(3) of Book V of the Social Code,
9. the publication of the Rules of Procedure and the annual reports,
10. the requirements for the qualification of staff in contractual medical and dental care for the certification in accordance with Section 390(7) sentence 2 of Book V of the Social Code,
11. information on the cloud systems and cloud technology tested in accordance with Section 393(3) point 2 of Book V of the Social Code, including a checklist of the corresponding criteria for customers, provided that an application for publication in accordance with Section 393(7) of Book V of the Social Code was submitted,
12. information designed to develop competences and knowledge on interoperability issues in the healthcare system,
13. presentations of the Federal Association of Statutory Health Insurance Physicians for the visualisation of the items of information pursuant to Section 355(1) sentence 3 of Book V of the Social Code.

(23) The Competence Centre may, in consultation with the Expert Panel, provide further information on technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components on the knowledge platform, in particular information on international standards, projects and information technology systems in the healthcare system, provided that they are not already subject to publication obligations at federal level. If there are publication obligations at federal level, references to the publications are possible.

(24) The Competence Centre shall provide a procedure for authorised persons in accordance with Section 387(1) of Book V of the Social Code in which, after a reasonable period of time, the deletion of the information in accordance with paragraph 2, point 8 may be applied for, provided that such information is likely to substantially affect the significant legal interests of the authorised person. 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.

(25) Further details should be laid down in the Rules of Procedure.

Section 7.

Commissioning of third parties with the development of specifications

(26) The Competence Centre may commission professionally qualified natural persons or legal persons under public or private law to specify technical, semantic

and syntactic standards, profiles, guidelines, information models, reference architectures and software components.

(27) A person is professionally qualified if they have the technical, organisational and business abilities, the knowledge and skills necessary to specify interoperable technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures or software components. Further information on the requirements for professional qualification in accordance with sentence 1 shall be laid down in the Rules of Procedure. The professional qualification of legal persons in accordance with Section 385(4) sentence 3 of Book V of the Social Code shall be presumed.

(28) When awarding contracts in accordance with paragraphs 1 and 2 Section 311(7) of Book V of the Social Code shall be complied with.

(29) The commissioning shall be carried out by the Telematics Company with the approval of the Federal Ministry of Health.

(30) The costs of commissioning shall be borne by the Telematics Company.

Section 8.

Standardised comment and opinion procedure

(31) The Competence Centre shall establish a standardised comment and opinion procedure for the processes underlying the development, recommendation, and definition of specifications under this Regulation.

(32) The Competence Centre shall establish, in its Rules of Procedure, framework conditions allowing consistent and user-centred commentary, irrespective of the specifying body.

Section 9.

Inclusion in the knowledge platform

(33) Providers of information technology systems or third parties with a legitimate interest may apply to the Competence Centre for the publication of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components on the knowledge platform in text form. The application shall be accompanied by all the information necessary for implementation and application, as further described in the Rules of Procedure. 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.

(34) 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 shall be decided by the Expert Panel on the basis of a set of criteria no later than three months after the submission of the complete application to the Expert Panel. The publication shall take place no later than four weeks after the decision of the Expert Panel.

(35) The Competence Centre shall, at the request of manufacturers of information technology systems, the information referred to in Section 6(2) point 11 in text form on the platform in accordance with Section 6. The Rules of Procedure in accordance with Section 17 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.

(36) The Federal Associations of Statutory Health Insurance Physicians shall submit the qualification requirements of staff in contractual medical and dental care for certification in accordance with Section 390(7) sentence 2 of Book V of the Social Code to the Competence Centre in text form in accordance with the respective specification. The Competence Centre shall publish the information in accordance with sentence 1 immediately upon submission by the Federal Associations of Statutory Health Insurance Physicians on the platform according to Section 6.

(37) Providers of an electronic application pursuant to Section 306(1), sentence 2, point 2, of Book V of the Social Code must apply for inclusion in accordance with paragraph 1 via the standards, profiles, guidelines and information models used, unless recommended standards, profiles, guidelines and information models are already used. The form of provision shall be set out in the Rules of Procedure and in accordance with Section 17.

Section 10.

Recommendation of standards, profiles, guidelines, information models, reference architectures and software components for information technology systems in the healthcare system

(38) The Competence Centre shall recommend, in cooperation with the Expert Panel, technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for information technology systems in the healthcare system published on the knowledge platform. The recommendations of the Competence Centre shall not depart from specifications made on the basis of tasks assigned by law.

(39) In the run-up to the recommendation in accordance with paragraph 1, the Competence Centre shall be assisted by the Expert Panel. In addition, prior to the recommendation, the Competence Centre shall conduct a comment and opinion process in accordance with Section 8.

(40) The opinions and recommendations and their justifications shall be published on the knowledge platform without delay. The Expert Panel shall be consulted on the publication of recommendations on the knowledge platform in accordance with Section 10.

Section 11.

Proposal to the Federal Ministry of Health for binding specifications

(41) The Competence Centre shall submit its proposal for the binding specification of a recommendation in accordance with Section 10, including deadlines for its implementation and intended scope of application to the Federal Ministry of Health.

(42) The Competence Centre shall include the opinion of the Expert Panel in its decision whether or not to propose a recommendation for binding specification.

Section 12.

Accreditation procedures

(43) Upon application in text form, the Competence Centre shall verify the professional qualification of the applicant to carry out procedures for assessing the conformity of information technology systems in accordance with Section 13.

(44) To this end the Competence Centre may require the applicant and their staff responsible for the management and performance of specialist tasks to provide the information and other assistance necessary for the assessment and monitoring of professional qualification, in particular to submit the relevant documents.

(45) In the Rules of Procedure, the Competence Centre shall define the professional and organisational requirements to be verified in accordance with paragraphs 1 and 2 and define the verification method to be applied.

(46) If evidence of professional qualification is provided, the Competence Centre shall provide the conformity assessment body with a corresponding accreditation certificate (accredited body). The Competence Centre shall publish the accredited bodies with an identification number on the platform in accordance with Section 6. The accreditation shall be granted for an appropriate period of time and subject to conditions.

(47) The Competence Centre shall monitor the accredited bodies. If the Competence Centre determines that an accredited body no longer has the necessary qualifications in accordance with paragraphs 1 und 3, has seriously violated an obligation pursuant to parapraph 4, sentence 3 or its other obligations, the Competence Centre shall, within a reasonable period of time, take all appropriate measure to restrict, suspend or withdraw the accreditation; the Competence Centre may also revoke accreditations.

(48) In the Rules of Procedure, the Competence Centre shall establish a procedure in accordance with Section 17 for how to deal with appeals against decisions of the Competence Centre in accordance with paragraphs 4 und 5.

(49) A conformity assessment body may not carry out a conformity assessment in accordance with Section 13 in conjunction with Section 387 of Book V of the Social Code, without accreditation in accordance with this provision.

Section 13.

Conformity assessment procedures

(50) Manufacturers of information technology systems used in the healthcare system for the processing of personal patient data shall be subject to the conformity assessment procedure at the Competence Centre or by a body accredited by the Competence Centre in accordance with Section 385(7) of Book V of the Social Code, in conjunction with Section 12 the accredited body and have it certified that the respective information technology system complies with the mandatory requirements set out in Annex 1. In the case of interfaces between the information technology systems in accordance with Section 371(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 under sentence 1.

(51) The conformity assessment shall be carried out at the request of a manufacturer of an information technology system in text form. Only the application forms published by the Competence Centre for Interoperability shall be used for such an application. The application shall contain at least the following elements:

1. Name and address of the applicant,
2. date of application,
3. name and address of an authorised representative of the applicant or 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 of the applicant who has the necessary expertise to provide technical information about the information technology system to be assessed,
5. precise designation of the information technology system to be assessed, in particular:
   a) name of the software according to the manufacturer's product designation,
   b) version number of the software, and
   c) scope of application of the software,
6. Indication of whether it is an initial conformity assessment or a repeat assessment following a notifiable substantial change to the system in accordance with Section 14,
7. declaration by the applicant that the application does not conflict with the rights of third parties,
8. test reports and other evidence of compliance with the mandatory requirements laid down in Annex 1,
9. details of the relevant identification number of the test reports and other evidence provided in accordance with point 8 identifying the mandatory requirements laid down in Annex 1,
10. in case of a repeat assessment in accordance with point 6, the previous certificate of compliance with the mandatory requirements laid down in Annex 1 and indication of the relevant identification number of the mandatory requirements laid down in Annex 1,
11. declaration of consent to the publication of the rejection, issue, refusal or withdrawal of the certificate.

The Rules of Procedure shall provide further details on the content of the application in accordance with sentence 3.

(52) The Competence Centre or the accredited body should process the applications in the order in which they are received.

(53) A federal association from the field of innovative technologies in the healthcare system as the authorised representative of its member companies may submit applications for the manufacturers of information technology systems in accordance with paragraph 2. The authorised representative shall, at the request of the Competence Centre or the accredited body, provide written evidence of its power of attorney and the documentation provided for in paragraph 2 sentence 3.

(54) Missing information or documents shall be requested by the Competence Centre or the accredited body as a request for supplement. The request shall be submitted within three months of receipt of the request for supplement, otherwise the Competence Centre or the accredited body shall reject the application.

(55) An information technology system shall be certified if it complies with the mandatory requirements set out in Annex 1.

(56) The certificate shall contain the following final information:

1. Name of the software according to the manufacturer's product designation,
2. version number of the software,
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 according to Annex 1 on which the conformity assessment is based,
7. identification number of the issuing accredited body or the information that the certificate was issued by the Competence Centre,
8. further information, in so far as it was additionally provided for by the Competence Centre in the Rules of Procedure in accordance with Section 17.

(57) The issue of the certificate shall be notified to the applicant in electronic form.

(58) The information about applications submitted and the issue, refusal, withdrawal, or revocation of a certificate shall be published by the Competence Centre on the platform in accordance with Section 6. To this end, an accredited body shall transmit the information specified in sentence 1 to the Competence Centre without undue delay upon becoming aware of it.

(59) For the withdrawal or the revocation of a certificate, Sections 48 and 49 of the Administrative Procedure Act shall apply.

(60) The persons employed by or commissioned by the Competence Centre and the accredited bodies shall not disclose or use confidential information obtained in the course of their work without authorisation, even if they are no longer in service or their work has ended (duty of confidentiality). This shall also apply to other persons who, through official reporting become aware of the information referred to in sentence 1.

(61) Conformity assessment procedures in accordance with this Regulation, which were formally initiated before the entry into force of an amendment to the Regulation, shall be completed in accordance with the previously applicable legal provisions, unless otherwise specified below. Where individual steps of the procedure prescribed by legal provisions have not yet started, they may also be carried out in accordance with the provisions of this Regulation. Certificates and decisions of the Competence Centre effectively issued on the basis of previous versions of this Regulation shall continue to apply.

(62) The Competence Centre shall perform the tasks assigned to it under this Regulation only in the public interest.

Section 14.

Obligation to report significant changes to information technology systems

(63) If an information technology system certified in accordance with Section 13 is to be significantly changed, the manufacturer of the system must notify the Competence Centre in text form before implementing the change in the production systems. For the purposes of this provision, a significant change is a change which may affect compliance with the mandatory requirements for information technology system laid down in Annex 1 on which the certificate in accordance with Section 13 is based. For the notification in accordance with sentence 1 only the electronic forms published by the Competence Centre shall be used. The notification shall include, as a minimum, basic technical information on the proposed change and information on which of the mandatory requirements laid down in Annex 1 may be affected by the change.

(64) If the manufacturer fails to demonstrate that the change does not adversely affect compliance with the mandatory requirements, the Competence Centre shall, within a reasonable period of time, impose obligations on the manufacturer to comply with the mandatory requirements in accordance with Annex 1, suspend the certificate in accordance with Section 13(6) and (7) or withdraw the certificate to the extent of non-compliance. The Competence Centre may also revoke certificates.

Section 15.

Complaints office

(65) The Competence Centre shall define a procedure in the Rules of Procedure in accordance with Section 17 for dealing with evidence of negative deviation of a certified system from the mandatory interoperability requirements.

(66) The Competence Centre shall define a procedure in the Rules of Procedure in accordance with Section 17 for dealing with evidence of a lack of professional qualification of an accredited body in accordance with Section 12(1) to (3) in conjunction with Section 17(2) point 9 and with evidence of violations of the rules of the conformity assessment procedure in Section 13. The procedure shall adequately protect the confidentiality of the identity of the person providing the information.

Section 16.

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

(67) The Competence Centre shall submit an annual report on the previous calendar year to the Federal Ministry of Health by 31 March. The report shall include at least information:

1. on the current status of the planning and implementation of the strategic orientation and tasks of the Competence Centre and the Expert Panel, including the activities to publish and recommend standards, profiles, guidelines, information models, reference architectures and software components,
2. on the current status of the planning and implementation of the operation of the knowledge platform, including key figures for the use of the knowledge platform,
3. on the composition and work of the Expert Panel and the IOP working groups, and
4. an overview of the expenditure incurred in the performance of the tasks referred to in Section 385(3) point 10 of Book V of the Social Code.

(68) The Competence Centre shall publish the report on the knowledge platform upon approved by the Federal Ministry of Health.

Section 17.

Rules of Procedure

(69) The Competence Centre shall establish its own Rules of Procedure. The Rules of Procedure shall supplement and operationalise the provisions laid down in this Regulation on:

1. the structure and organisation of the Competence Centre,
2. the organisation of the tasks of the Competence Centre,
3. the composition of the Competence Centre,
4. the procedures to be followed for the performance of the tasks,
5. the quorum requirements, whereby the extraordinary member delegated by the Federal Ministry of Health must be granted a right of veto and decisions must be taken by a two-thirds majority, whereby at least five members must cast a vote, representatives must cast their own vote and the vote of the represented member uniformly, circular resolutions are permitted and abstentions are excluded,
6. the deadlines for individual actions, and
7. the reimbursement of expenses.

In addition, the Rules of Procedure shall lay down detailed rules on the participation of the Expert Panel, in particular as regards its tasks in accordance with Section 2(2) points 6 and 11 to adopt and recommend standards and to operate the knowledge platform.

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

1. Establishment of the Expert Panel and defining the specific tasks, working processes, obligations, and deadlines in accordance with Section 3 as well as ensuring that the Expert Panel defines assessment criteria on the basis of which a decision can be taken on the publication or rejection of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components in accordance with Section 9,
2. appointment of experts and definition of specific tasks, working processes, duties, and deadlines in accordance with Section 4,
3. establishment of IOP working groups and definition of specific tasks, working processes, duties, and deadlines in accordance with Section 5,
4. provisions for the application, admission and dismissal procedures for members of the Expert Panel, Expert Group and working groups,
5. specification of the basic technical, structural and semantic framework conditions and data security requirements regarding standards, profiles, guidelines, information models, reference architectures and software components,
6. consideration of 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 with the development of specifications in accordance with Section 7,
8. establishment and permanent operation of a standardised comment and opinion procedure in accordance with Section 8 which shall allow for a consistent and user-centred commenting independent of the respective specifying body,
9. provisions in accordance with Section 12 (3) concerning the professional and organisational requirements to be demonstrated in accordance with Section 12(1) and (2) and the applicable verification procedures,
10. provisions for the implementation of a complaints procedure pursuant to Section 15,
11. content requirements in accordance with Section 13(2) sentence 3 and
12. details of a procedure for recording and deleting content in accordance with Section 6(2) point 11 on the platform in accordance with Section 6.
13. Specification of the documentation and disclosing all work and decision-making processes.

(71) The Rules of Procedure shall specify all the deadlines for tasks not provided for in this Regulation in accordance with Section 2(2).

(72) The Rules of Procedure shall be reviewed for the need of updates and, if necessary, updated in consultation with the Expert Panel least every three years.

(73) The Federal Ministry of Health shall approve the Rules of Procedure in accordance with paragraph 1.

(74) 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 18.

Evaluation

The Federal Ministry of Health shall commission an external research institution with the task of evaluating the Competence Centre and the performance of its tasks in accordance with Section 2(2). The evaluation report shall be available every three years, for the first time on 30 September 2025.

Section 19.

Entry into force, expiry

This Ordinance shall enter into force on the day following its promulgation. At the same time, the Health IT Interoperability Governance Regulation of 7 October 2021 (Federal Law Gazette I p. 4634) will expire.

Annex 1

Mandatory requirements

(Reference: Federal Law Gazette I 2021, 4639)

The technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components laid down by the Federal Ministry of Health shall be published 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 7 of this Regulation.

Date (publication of the annex): dd.mm.yyyy

ID	Title	Short description	Version	Chapter	Date of admission (in the annex)	Mandatory implementation date: by	Legal basis	Scope of application
001	Implementation guideline for Primary Systems – electronic patient record (ePA)	Guidance on the implementation of the relevant requirements for interoperability between ePA filing systems and primary systems with regard to the implementation of the eML	3.1.0	3.10.2	[Insert: Date of entry into force...]	15.1.2025	Section 355 paragraph 3, sentence 2, point 1	1. Practice Management Systems (PVS), 2. Dental Practice Management Systems (ZPVS), 3. Hospital Information Systems (KIS), and 4. Pharmacy Management Systems (AVS)

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

Comments:
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: A legal standard conferring the power to make binding specifications; unless otherwise specified, the standards of Book V of the Social Code (SGB V).

Annex 2

List of the statutory specification orders to legal persons governed by public law pursuant to Section 7 in conjunction with Section 385(4) sentence 4 of Book V of the Social Code

Date (publication of the annex): [...Date]

ID	Legal basis	Authorised body	Title	Short description
110	Section 355 . paragraph 1	Federal Association of Statutory Health Insurance Physicians	Example interface	The example interface is used here for illustrative purposes

Comments:

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

Legal basis: The legal standard from which the statutory specification mandate arises; unless otherwise specified, the standards of Book V of the Social Code (SGB V).

Authorised body: Name of the body/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.

Explanatory statement

A. General part

I. Objective of and need for the provisions

The purpose of the further development of the Regulation is to ensure that interoperability efforts in the healthcare system in the context of statutory health insurance are accelerated, become more transparent and binding than hitherto, on the basis of the further developed interoperability process and its expanded scope of application and competence.

Technical requirements for healthcare providers under Book V of the Social Code (SGB V) are the basic prerequisite for interoperable data exchange between healthcare providers and in relation to insured persons. They are therefore a key element of the SGB V as an essential requirement for the functionality of service provision in the statutory health insurance (SHI). As digitalisation progresses, the importance of uniform exchange formats for healthcare is becoming even more important.

II. Main content of the draft

Interoperable communication and collaboration between information technology systems is essential for the successful digital transformation of the healthcare system. This requires uniform specifications in the form of standards, profiles, guidelines, information models, reference architectures and software components. In order to ensure that these uniform requirements are coordinated and developed across sectors, taking into account the necessary expertise from a wide range of disciplines, it is necessary to have a central actor who not only coordinates and orchestrates this process, but also sets the direction, i.e. prioritises which specifications are developed and in which order. The aim is to ensure that multiple and double specifications, as well as conflicting developments, become a thing of the past. At the same time, the creation of a uniform conformity assessment procedure is intended to ensure that the requirements laid down in the process by the Federal Ministry as binding are implemented by the manufacturers and that the relevant requirements are put into practice and thus have concrete effects on the provision of healthcare services for the population.

The Competence Centre thus makes a significant contribution to a more stringent and cross-sectoral interoperability governance in the healthcare system. The Competence Centre is a key actor responsible for promoting interoperability.

The essential content of the underlying Regulation is derived from Section 385(3) points 1 to 17 of Book V of the Social Code.

III. Alternatives

None

IV. Legislative competence

The authorisation to decree this Regulation follows from Section 385(1) sentence 1 of Book V of the Social Code.

V. Compatibility with European Union law and international treaties

The draft Act is compatible with European Union legislation and treaties under international law concluded by the Federal Republic of Germany.

VI. Impact of the Act

1. Legal and administrative simplification

Not applicable.

2. Sustainability aspects

In line with the version of 7 October 2021, the draft Regulation follows the Federal Government's guiding principles on taking account of sustainability by contributing to the strengthening of the quality of life and health of citizens as well as to social cohesion and equal participation in the economic development in the sense of the German sustainability strategy. The draft Regulation pursues further necessary measures to digitalise the healthcare system. In particular, improving the interoperability of health-related data and the establishment of uniform standards, profiles, guidelines, information models and reference architectures will further improve and permanently ensure medical and nursing care for people.

The draft Regulation was examined with regard to sustainability in the light of the principles of sustainable development. In terms of its effects, it is in line with the goals 3 (health and well-being) and 9 (industry, innovation and infrastructure) of the German sustainability strategy by ensuring a healthy life for all at all ages and promoting their well-being as well as innovation. This will further support the implementation of the German sustainability strategy.

3. Budgetary expenditure exclusive of compliance costs

a) Federal government

None.

b) Federal states

None.

c) Social insurance system

None.

4. Compliance costs

a) Compliance costs for citizens

None.

b) Compliance costs for businesses

The compliance costs for the economy were already recognised under the Digital Act. The underlying Regulation shall not give rise to any additional compliance costs.

c) Administrative compliance costs

None.

d) Social security

The compliance costs for the social security were already recognised under the Digital Act. The underlying Regulation shall not give rise to any additional compliance costs.

5. Additional costs

None.

6. Other consequences of the legislation

No impact on issues relating to gender equality policy is to be expected. In a context of increasing ageing and multi-morbidity in society, the measures provided for in the draft Regulation contribute to cross-sectoral, interprofessional forms of healthcare by facilitating the exchange of data, to ensure the performance of the healthcare system in the future and to improve the quality of the healthcare.

VII. Time limits; evaluation

None. A time limit is out of the question insofar as fundamental technical progress requires constant adaptation of the framework conditions for interoperability in order to ensure a smooth interaction between different information technology systems.

An accompanying evaluation is ensured by the annual report of the activities of the Competence Centre, as well as by the evaluation of the Competence Centre and the performance of its tasks pursuant to Section 2(2) of this Regulation in accordance with Section 18 (evaluation). The evaluation report is to be submitted every three years, for the first time on 30 September 2025, by a commissioned external research organisation.

B. Specific part

Re Section 1 (Purpose of the Regulation)

The adaptations result from the renaming of the Coordinating Body for Interoperability in Healthcare into a Competence Centre for Interoperability in Healthcare in accordance with Section 385 of Book V of the Social Code and the expansion of the tasks of the Competence Centre. In Section 385(1), sentence 2, point 7, the Competence Centre is given the task of carrying out a conformity assessment procedure in accordance with Section 13 in conjunction with Section 387 of Book V of the Social Code.

The aim of the conformity assessment procedure is to implement, through a centralised and standardised certification procedure, the conformity assessment of information technology systems in the healthcare system in a more comprehensive and uniform manner in future. The certificate as a result of the conformity assessment is essential for the implementation of the binding mechanism under Section 388 of Book V of the Social Code.

The publication of C5 certificates in accordance with Section 393(3) point 2, (4) and (7) of Book V of the Social Code and the end-user controls in accordance with Section 393(3) point 3, creates transparency about the security-tested systems that can be used by service providers and how these systems must be configured for safe use. The aim is to increase the overall cybersecurity of the systems.

Re Section 2 (Competence Centre for interoperability in the healthcare system)

Re paragraph 1

With the adoption of the Health IT Interoperability Governance Regulation (GIGV) in 2021 under the Digital Healthcare and Nursing Care Modernisation Act (DVPMG), new structures and processes were established as a first step to further promote interoperability in the healthcare system, to advance the definition of interfaces and standards, to establish transparency on interoperability standards and to create the necessary organisational framework for this.

In accordance with Section 311(1) point 8 of Book V of the Social Code, the tasks of the Telematics Company "gematik" include the establishment of a Competence Centre for interoperability in the health system in order to implement the interoperability process pursuant to Section 385 of Book V of the Social Code. To this end, the Coordinating Body for Interoperability (KOS) was set up within the Telematics Company (Gesellschaft für Telematik). This will be transformed into a Competence Centre for interoperability in the

healthcare system. The Competence Centre shall be part of the generally applicable thematic decision-making processes as far as they are materially affected. The practical knowledge gained so far by the Coordinating Body and the Expert Panel appointed by it have been taken into account directly in the redesign of the underlying Regulation.

Re paragraph 2

Paragraph 2 describes the tasks of the Competence Centre, which arise in particular from Sections 385, 387 and 371 to 373 of Book V of the Social Code upon the entry into force of the Digital Act, and the structures which must necessarily be established for that purpose. The main task of the Competence Centre is therefore to identify and prioritise future standardisation requirements with regard to the specification of technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, develop or have standards developed, and to ensure, through a conformity assessment procedure, that the IT systems comply with the established standards. The Competence Centre will thus form a central body to promote interoperability in the healthcare system in a coordinated, cross-sectoral and orchestrated manner. The aim is to better coordinate actors and their activities in the field of standardisation in future and to eliminate duplicate structures. Missing or multiple, even conflicting, standards are to be reduced. In doing so, the Competence Centre takes into account both gematik's internal communications and the published strategic guidelines and the list of priorities of the Federal Ministry of Health, such as the planning of measures for the ePA roll-out and the digitalisation strategy for healthcare and nursing. The Competence Centre thus has a much more important role than the previous Coordinating Body. The Competence Centre continues to be responsible for recommending technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for use in the healthcare system and for binding specification to the Federal Ministry of Health. The specifications are further developed or updated on an ad hoc or regular basis.

In order to include the necessary professional expertise, experts will continue to be involved in a community-based approach and provide advice and support to the Competence Centre in its tasks. Existing structures, i.e. the Expert Group, the Expert Panel and the IOP working groups, should be used for this purpose. The Competence Centre is responsible for the nomination or appointment and establishment of the thematic IOP working groups.

The Competence Centre shall also operate and maintain a knowledge platform that serves both to map existing, recommended and declared mandatory standards, profiles and guidelines, and to plan and develop them, as well as to communicate with the specialist community and to share knowledge. With the interoperability navigator for digital medicine (INA), a corresponding platform has already been set up. The Competence Centre shall continue and further develop the Platform as such.

In addition, Rules of Procedure corresponding to the tasks will be drawn up and an annual activity report published.

A detailed statement of reasons for the general expansion of the Competence Centre’s tasks can be found in the explanatory memorandum concerning the amendments to Section 385 of Book V of the Social Code of the Digital Act (Federal Law Gazette 2024 I No. 101).

Re point 1

The Competence Centre shall be responsible for identifying needs for requirements, directives and guidelines for technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components, taking into account European requirements and international standards. The aim is to also ensure the identification of such needs that are not addressed to the Competence Centre by commercial ac-

tors on the market. This is motivated, for example, by the fact that the perspectives of the healthcare users are often not adequately represented. However, this is without prejudice to the possibility of continuing to report needs by third parties through the INA platform and to transmit them to the Competence Centre. Centralising these needs is the task of the Competence Centre.

Re point 2

By focusing the collection of needs and identifying them in accordance with point 1 and by prioritising in accordance with point 2 it is to be ensured that a coordinated governance of the interoperability process in the healthcare system as a whole is possible. Only centrally coordinated prioritisation can ensure that standards, profiles, guidelines, information models, reference architectures and software components are specified for the areas of application that meet the needs of insured persons and effectively allocate resources to the main challenges.

Re point 3

Another task of the Competence Centre is to act as a central body and commission natural or legal persons under private and public law with the specification of prioritised needs in accordance with Section 7. In particular, the aim is to avoid multiple specifications, to ensure scalability of resources and to develop specifications on the basis of uniform prioritisation in appropriate time contexts.

Re point 4

In order to ensure that the actors are professionally qualified to implement a specification of the respective requirement, the Competence Centre is given the task of checking their qualification. The professional qualification of those natural or legal persons who were previously appointed by way of a statutory mandate to develop specifications may be directly commissioned by the Competence Centre to develop a specific specification (e.g. the National Association of Statutory Health Insurance Physicians (KBV)).

Re point 5

In addition to commissioning third parties to develop specifications, the Competence Centre has the possibility to prepare/develop specifications itself (in-house development). This is without prejudice to the process of involving the community through the standardised commenting procedure; in doing so, the Competence Centre shall take into account the prioritisation in accordance with point 2.

Given that requirements for processes and systems are subject to constant change and progress, and in order to adequately address this situation, the recommended and binding specifications must be regularly reviewed to ensure that they are up to date and consistent. This revision and updating is traditionally reflected in the implied powers of the Competence Centre. The Competence Centre can perform this task itself or, in addition, make use of professionally qualified third parties and commission them in accordance with point 3. The Competence Centre may be assisted by a working group in accordance with Section 5(2) of the Regulation.

Re point 6

Once a specification has been submitted or a specification order has been fulfilled and the corresponding quality checks have been successfully completed, the specification is sent to the recommendation process. This process serves to assess the extent to which the specification should be recommended and, if necessary, subsequently made binding, taking into account technical and formal criteria.

Re point 7

The Federal Ministry of Health must be informed in writing of recommendations for binding specifications. The transmission must be accompanied by a justification for the decision and access to the relevant specification, e.g. in PDF format. Together with the recommen-

dation, a unique identification number of the specification for the Knowledge Platform in accordance with Section 6 is to be transmitted.

In accordance with the professional content update of the specifications in accordance with point 5, the recommendations must also be updated; this applies both to those that are defined as binding by the Federal Ministry of Health and those that are not binding. The accompanying documentation of the recommendation should show which version of a specification is concerned, what impact the adaptations have in practice and what the potential update burden is.

Re point 8

The Competence Centre or a professionally qualified third party commissioned by the Competence Centre shall carry out a conformity assessment procedure in which manufacturers of information technology systems may participate on a voluntary basis. The Competence Centre shall issue a certificate to demonstrate compliance with the mandatory requirements. The certificate forms the basis for placing and keeping information technology systems on the market in accordance with Section 388 of Book V of the Social Code.

Re point 9

In order to make the conformity assessment process scalable and thus take account of a future increase in the number of binding specifications and, where appropriate, an increase in the number of relevant IT systems, the Competence Centre may commission third parties with appropriate professional and organisational qualifications to carry out the conformity assessment. To this end, these qualifications must be proven by means of an accreditation process and be regularly verified by the Competence Centre.

Re point 10

No substantive changes to the version of 7 October 2021. This is essentially an editorial shift due to the new tasks of the Competence Centre from point 5 in the version of 7 October 2021 to this point 10. Following the initial appointment of an Expert Panel, a corresponding linguistic adjustment has been made.

Re point 11

No substantive changes to the version of 7 October 2021. This is merely an editorial shift due to the new tasks of the Competence Centre from point 6 in the version of 7 October 2021 to this point 11.

Re point 12

No substantive changes to the version of 7 October 2021. This is merely an editorial shift due to the new tasks of the Competence Centre from point 7 in the version of 7 October 2021 to this point 12.

Re point 13

In order to evaluate the work of the Competence Centre, it must submit an annual report in accordance with Section 15 of the underlying Regulation, as well as a monthly report on the progress of the work, e.g. on the progress of the respective working groups, as well as on planned further developments, e.g. with regard to the knowledge platform management, planned working meetings or working groups. Point 13 of this Regulation corresponds to point 8 of the version of 7 October 2021.

Re point 14

Specifications should only be developed and evaluated as part of an interprofessional voting process. Therefore, in order to fulfil its tasks, the Competence Centre shall obtain evaluations and opinions in accordance with point 6. If necessary, for example, the advisory mandate of the Federal Office for Information Security under Section 3(1) point 12a of the Act on the Federal Office for Information Security or the advisory mandate of the Federal Commissioner for Data Protection and Freedom of Information under Section 14(1) point 3 of the Federal Data Protection Act may be used.

Re point 15

No substantive changes to the version of 7 October 2021. This is merely an editorial shift due to the new tasks of the Competence Centre from point 10 in the version of 7 October 2021 to this point 15.

Re point 16

Interprofessional coordination processes are essential for the targeted development of specifications. In line with this requirement, the Expert Panel represents opinions from different groups of actors in the healthcare system. At the same time, the issue of interoperability does not yet have the necessary importance in public discourse. Therefore, one of the tasks of the Competence Centre is, for example, to report within specialist circles on current developments within the Competence Centre's activities, but at the same time to raise awareness of the importance of the topic and to create low-threshold information offers outside the specialist circles. In particular, these activities should also aim to attract interest in participating in the existing bodies and to increase public understanding of the need for interoperability.

Re point 17

Increasing interconnectivity in the healthcare system will make interoperability increasingly important in national but also cross-border data exchange in the coming years. Last but not least, the European Health Data Space will require bi- and multilateral standardisation processes. In this context, the Competence Centre is intended to assist, provide technical advice and representation to the Federal Government in negotiating processes, but also project-related plans.

Re point 18

No substantive changes to the version of 7 October 2021. This is merely an editorial shift due to the new tasks of the Competence Centre from point 11 in the version of 7 October 2021 to this point 18.

Re point 19

The operational organisation of the tasks under points 1 to 18 shall be the responsibility of the Competence Centre.

Re paragraph 3

With regard to its tasks in accordance with paragraph 2, the Competence Centre shall be required to implement transparent and publicly available documentation. The development and maintenance of specifications of technical, semantic and syntactic standards, profiles, information models, reference architectures and software components shall be based on a transparent (public) and consensus-based (consistency of opinions by majority decision) procedure. The aim is to further increase procedural and decision-making transparency.

Re Section 3 (Expert Panel)

Re paragraph 1

In accordance with Section 2(2) point 10, the Competence Centre shall appoint an Expert Panel to monitor and support its performance in order to promote interoperability. The initial appointment took place after the entry into force of the HIGR on 7 October 2021, so that the corresponding wording is deleted.

In order to ensure interdisciplinarity, different interest groups shall be taken into account in the recruitment process; the Expert Panel will thus be appointed in an interdisciplinary manner. The Expert Panel shall consist of seven full members (including the chairperson); in addition, an extraordinary member may be appointed by the Telematics Company and by the Federal Ministry of Health. When making the appointments, care must be taken to

ensure that each Expert Group in accordance with Section 4 is represented by one person. The deployment of the Expert Panel will ensure that different expertise and perspectives are brought into the process of promoting interoperability.

Re paragraph 2

In order to ensure greater permeability, the term of office of the Expert Panel shall continue to be limited to a total of two regular terms (of three years each). The term of office should therefore not exceed 6 years; a new appointment, including the election of the chairperson, shall be required between two terms of office. The specific procedure shall be governed by the Rules of Procedure of the Competence Centre.

Re paragraph 3

Paragraph 3 lays down the tasks of the Expert Panel. These shall consist in particular in providing assistance and professional support to the Competence Centre in its tasks in accordance with Section 2(2), points 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 16 and 17.

No permanent representation is planned. A quorum is to be ensured by members of the Expert Panel representing each other. Working groups may also be chaired, if necessary, by other experts from the Expert Group. The decision on this shall be taken by the Competence Centre.

Re paragraph 4

Corresponds to Section 4(6) of the HIGR of 7 October 2021. This is merely a shift due to the merging or repeal of previous paragraphs.

Re paragraph 5

Paragraph 5 corresponds in terms of content to paragraph 6 of the HIGR of 7 October 2021. Only the reference to the Rules of Procedure has been adapted.

Re Section 4 (IOP Expert Group)

Re paragraph 1

The experts support and advise the Coordinating Body and the Expert Panel as required and thus form the necessary working structure and basis in the Expert Panel and in the IOP working groups. Paragraph 1 corresponds in terms of content to paragraph 1 of the HIGR of 7 October 2021. No changes have been made to the role of the Expert Group. Only the reference to the working groups has been adapted in accordance with the changes made in this version.

Re paragraph 2

Paragraph 2 regulates the necessary professional qualifications of IOP experts and is essentially in line with the version of 7 October 2021. Only the formal requirement for minimum professional experience has been reduced from 5 years to 3 years on the basis of previous experience. This will in future ensure that start-ups are also given greater consideration in the Expert Group.

Re paragraph 3

Paragraph 3 describes the process of applying for appointment as an expert. This corresponds in substance to the procedure set out in the version of 7 October 2021. Only the deadline for the first application, which was in the past, was deleted as part of the adaptation.

Re paragraph 4

In order to ensure different perspectives, experts from a total of 7 fields of expertise are to be appointed. These mainly correspond to the fields of expertise of the version of 7 October 2021. The selection shall take into account expertise in the fields of healthcare and nursing as well as in the fields of information technology and standardisation; in particular, the availability of medical expertise is also of great importance for future Expert Groups.

The number of experts that can be admitted is not limited.

Re point 1

This is merely an editorial shift from Section 5(4) point 1 of the version of 7 October 2021 to Section 4(4) point 1 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re point 2

This is merely an editorial shift from Section 5(4) point 2 of the version of 7 October 2021 to Section 4 point 2 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re point 3

This is merely an editorial shift from Section 5(4) point 3 of the version of 7 October 2021 to Section 4(4) point 3 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re point 4

This is merely an editorial shift from Section 5(4) point 4 of the version of 7 October 2021 to Section 4(4) point 4 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re point 5

Point 5 is essentially based on Section 4(4) point 5 of the version of 7 October 2021.

Only the specialist fields of the associations, in particular the Central Federal Association of Health Insurance Funds, were expanded to include the associations relevant to accident insurance institutions.

Re point 6

This is merely an editorial shift from Section 5(4) point 6 of the version of 7 October 2021 to Section 4(4) point 6 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re point 7

This is merely an editorial shift from Section 5(4) point 7 of the version of 7 October 2021 to Section 4(4) point 7 in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re paragraph 5

No substantive changes to the version of 7 October 2021. This is merely an editorial shift from Section 5(5) of the version of 7 October 2021 to Section 4(5) in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re paragraph 6

Due to the outdated legal basis, a corresponding adjustment has taken place. In terms of content, there were no changes compared to the version of 7 October 2021. Editorially, there has been a shift from Section 5(6) of the version of 7 October 2021 to Section 4(6) in the current version, as a result of the repeal of Section 2 of the version of 7 October 2021.

Re paragraph 7

This is merely a follow-up adjustment due to the change of name of the previous Coordination Body for interoperability to the Competence Centre in accordance with Section 385(1) sentence 1 of Book V of the Social Code and an editorial shift. The shift from Section 5(7) of the version of 7 October 2021 to Section 4(7) in the current version is due to the repeal of Section 2 of the version of 7 October 2021.

Re Section 5 (IOP working groups)

Re paragraph 1

Paragraph 1 regulates the establishment of IOP working groups by the Competence Centre. These are only follow-up adjustments due to the change of name of the previous Coordinating Body for Interoperability to the Competence Centre in accordance with of Section 385(1) sentence 1 of Book V of the Social Code. There are no substantive changes to the version of 7 October 2021 pursuant to Section 6(1).

In order to continue to ensure the necessary expertise for the performance of the tasks, care must be taken to ensure an interdisciplinary specifically topic-related composition. The working groups continue to be composed primarily of experts from the Expert Group. The addition of experts from outside the Expert Group to working groups is, in exceptional cases, possible, must be justified individually and requires the agreement of both the Competence Centre and the Expert Panel. The availability of medical expertise is highly relevant, and it should be ensured, when forming working groups, that it is consistently available.

Re paragraph 2

The IOP working groups shall support the Competence Centre and the Expert Panel in the identification of needs, the development, revision and assessment of standards, profiles, guidelines, information models, reference architectures and software components and shall be appointed by the Competence Centre for this purpose. The IOP working groups may assist the Competence Centre in the assessment of opinions where necessary. The IOP working groups are composed of an appropriate number of experts in order to be able to handle a task or issue with reasonable effort, while involving all relevant groups of actors.

Re paragraph 3

Paragraph 3 refers to the Rules of Procedure regulating the specific organisation of the IOP working groups.

Re paragraph 4

Paragraph 4 regulates the procedure for determining the reimbursement of expenses incurred by the members of the IOP working groups, which is based on the reimbursement of costs incurred by the Expert Panel.

Re paragraph 5

Paragraph 5 regulates the Coordinating Body’s publication obligations with regard to the IOP working groups. The IOP working groups and their composition must be published on the knowledge platform in accordance with Section 6.

Re Section 6 (Knowledge platform for interoperability and cybersecurity in the healthcare system)

Re paragraph 1

The knowledge platform acts as a central port of call for knowledge about interoperability in the German healthcare system as well as other relevant requirements in the indirect scope of application, thereby creating transparency and providing guidance for healthcare actors. It serves as an overview of existing and recommended standards, profiles, guidelines, information models, reference architectures and software components, as well as a platform for planning and developing them, as well as for communication and knowledge

sharing. In line with the expansion of the regulatory scope of the Regulations, the knowledge platform will also inform about topics related to cybersecurity in the healthcare system in future.

Re paragraph 2

Paragraph 2 regulates the contents of the platform.

Re point 1

No substantive changes to the version of 7 October 2021 pursuant to Section 7(2) point 1; it is merely a shift due to the repeal or merging of previous paragraphs.

Re point 2

This is a follow-up content adaptation due to the expanded scope of the Competence Centre and an editorial shift from Section 7(2) point 2 of the version of 7 October 2021 to Section 6(2) point 2 in the current version.

Re point 3

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre and an editorial shift from Section 7(2) point 3 of the version of 7 October 2021 to Section 6(2) point 3 in the current version.

Re point 4

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre and an editorial shift from Section 7(2) point 4 of the version of 7 October 2021 to Section 6(2) point 4 in the current version.

Re point 5

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre and an editorial shift from Section 7(2) point 5 of the version of 7 October 2021 to Section 6(2) point 5 in the current version.

Re point 6

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre and an editorial shift from Section 7(2) point 5 of the version of 7 October 2021 to Section 6(2) point 5 in the current version.

Re point 7

The publication of the accredited body shall be based on Section 12 of the present Regulation and Section 385(9) of Book V of the Social Code.

Re point 8

The publication of information relating to the applications submitted, the issue, refusal, withdrawal, or revocation of a certificate shall result from Section 13 this Regulation and Section 387(5) of Book V of the Social Code.

Re point 9

This is a shift of point 6 of the version of 7 October 2021 to: point 9 due to the expanded content for publication on the platform in accordance with points 7 and 8 of the present version.

Re point 10

The publication of the information in accordance with point 10 this follows from Section 390(7) sentence 2 of Book V of the Social Code on the creation of transparency with regard to the necessary qualification of employees of providers of information technology systems to support the implementation of the Directive pursuant to Section 390(1) in contractual medical and dental care. . .

Re point 11

The publication of the information in accordance with point 11 follows from Section 393(7) of Book V of the Social Code.

Re point 12

In accordance with the task under Section 2(2), point 17, the Competence Centre's task is to increase public understanding of interoperability in the healthcare system and to make the relevant knowledge easily accessible. The knowledge platform acts as a key tool to fulfil this task.

Re point 13

[…]

Re paragraph 3

In addition to the contents in accordance with paragraph 2, the Competence Centre may continue to provide further information in consultation with the Expert Panel. This should avoid duplication of content with existing information offers and reporting obligations. Where appropriate, reference should be made to relevant information offers.

Re paragraph 4

The aim of the provision is to strike a fair balance between the interests of the producers of information technology systems in protecting their economic interests and the interest of the providers of services and, indirectly, the insured persons in the transparent publication and communication of the information to be published here in a transparent manner, by creating a deletion procedure. In accordance with sentence 2, the public's interest in transparency in order to improve interoperability should always prevail.

Re paragraph 5

Contents and processes shall be described more in detail in the Rules of Procedure in accordance with Section 17.

Re Section 7 (Commissioning of third parties with the development of specifications)

Re paragraph 1

Pursuant to Section 385(1), sentence 2, point 2, in conjunction with paragraph 4 of Book V of the Social Code, the Competence Centre may, upon verification of their professional qualification, commission natural or legal persons with the development of specifications for standards, profiles, guidelines, information models, reference architectures and software components. This makes it possible to distribute and synchronise workload in the development of specifications, increase the quality of specifications and avoid duplicate or multiple specifications.

Re paragraph 2

Paragraph 2 regulates who is considered to be professionally qualified for developing specifications. Further details on the requirements for professional qualification shall be laid down in the Rules of Procedure. The professional qualification of such legal persons in accordance with Section 385(4) sentence 3 of Book V of the Social Code who previously had a statutory mandate for the specification is presumed on the basis of this.

Re paragraph 3

Paragraph 3 clarifies by referring to Section 311(7) of Book V of the Social Code that the procurement rules referred to therein also apply to the commissions in this context.

Re paragraph 4

Paragraph 4 lays down the obligation of the Federal Ministry of Health to authorise the commissioning of third parties by the Telematics Company.

Re paragraph 5

Paragraph 5 provides for the coverage of costs for commissions, if any.

Re Section 8 (Standardised comment and opinion procedure)

Re paragraph 1

One of the objectives of creating the new interoperability process is to improve the quality of the developed specifications. In order to ensure a uniform approach to the process of developing specifications, various quality assurance measures are therefore integrated into the interoperability process in accordance with Section 385(1) sentence 2 of Book V of the Social Code. This includes, in addition to the development of guidelines for the preparation of specifications, the establishment of a standardised comment procedure for exchanges with the professional public in accordance with Section 385(3) point 13 of Book V of the Social Code, so as to ensure that the greatest possible expertise is taken into account in the development of a standard and various groups of actors can assess a specification from the relevant perspective. The aim is to ensure that the specifications are applicable and usable in practice and fulfil their original purpose.

Re paragraph 2

Further information on the procedure for comments and opinions is laid down in the Rules of Procedure of the Competence Centre. It should be borne in mind here that comments are made on the basis of uniform considerations independently of the body providing the specification. By providing a standardised comment and opinion procedure for all specification assignments, the specialist community can be relieved in terms of time and content, redundancies can be avoided and work processes can be optimised. It is the task of the Competence Centre to establish such a procedure.

Re Section 9 (Inclusion in the knowledge platform)

Re paragraph 1

One task of the Competence Centre and the knowledge platform is to provide transparency on standards, profiles, guidelines, information models, reference architectures and software components in the healthcare system, as well as to accompany related coordination processes. Paragraph 1 regulates the process of recording and publishing them on the knowledge platform. Applications may be made by providers of an information technology system or by third parties with a legitimate interest, e.g. associations, operators of information technology systems or users. Paragraph 1 regulates the information and evidence to be provided by an applicant for inclusion of a specification so that it can be assessed by the Competence Centre. These are further specified in the Rules of Procedure of the Competence Centre. In particular, the clear definition of the scope of the application in the context of the submission of an application should be emphasised. No recommendation can be made unless it is transparently clear to which information technology systems the recommendation applies. It is also a proposal for a reasonable implementation period. This proposal is not binding for the further recommendation process. The Competence Centre shall assess the applications in terms of completeness and quality within four weeks. Quality must be understood in terms of the completeness and maturity of the documents. In the event of poor quality, the Competence Centre may submit additional requests. These will be formulated until the documents reach a decision-making stage for the Expert Panel.

The Telematics Company and the Competence Centre itself can also contribute content by submitting applications.

Re paragraph 2

Paragraph 2 lays down the main deadlines for the processes described in paragraph 1 and relevant principles on the basis of which the result of the Competence Centre was derived. The Expert Panel shall decide on the publication.

Re paragraph 3

The regulation implements the provisions of Section 393(7) of Book V of the Social Code, newly introduced by the Digital Act, according to which information on tested cloud systems or cloud technology following a previous application is also to be included on the platform in accordance with Section 6.

Re paragraph 4

The regulation operationalises the obligation to publish the certification requirements for employees under Section 390(7) sentence 2 of Book V of the Social Code on the platform in accordance with Section 6 by requiring that the Federal Associations of Statutory Health Insurance Physicians must immediately transmit the requirements electronically to the Competence Centre once they have been laid down.

Re paragraph 5

No changes to the version of 7 October 2021 (see Section 8(4) HIGR).

Re Section 10 (Recommendation of standards, profiles, guidelines, information models, reference architectures and software components for information technology systems in the healthcare system)

Re paragraph 1

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre. Furthermore, Section 10(1) of the underlying version corresponds to Section 9(1) of the version of 7 October 2021.

Re paragraph 2

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre. In addition, follow-up adaptations are made as a result of the above adaptations to the opinion procedure.

Re paragraph 3

This is merely a follow-up content adaptation due to the expanded scope of the Competence Centre. An additional adaptation was made to the effect that the Competence Centre shall publish relevant opinions and recommendations, together with justifications, without delay in the future. Where a publication constitutes a recommendation, the Expert Panel shall be consulted only in accordance with sentence 2.

Re Section 11 (Proposal to the Federal Ministry of Health for binding specifications)

Re paragraph 1

If a recommendation is to be made binding in accordance with Section 10 and is therefore also considered as a relevant specification in accordance with Sections 387 and 388 of Book V of the Social Code, the relevant recommendation shall first be proposed to the Federal Ministry of Health. The proposal shall include both a reasonable period of time for the implementation and the proposed scope of application. Further details regarding the process for proposing a specification for assessment and subsequent determination by the Federal Ministry is to be laid down in the Rules of Procedure of the Competence Centre.

Re paragraph 2

In the process referred to in paragraph 1, the Competence Centre shall take due account of the Expert Panel’s opinion on the binding specification.

Re Section 12 (Accreditation procedure)

Re paragraph 1

In accordance with Section 385(7) and (8) of Book V of the Social Code, the Competence Centre may also partially delegate the performance of the conformity assessment and the certification of the outcome of the audit to other actors. To this end, an application for ac-

creditation in electronic form shall be submitted to the Competence Centre in advance. The purpose of the accreditation is to ensure the competence to carry out the tasks within the conformity assessment procedure set out in Section 13 while at the same time preventing the creation of a bottleneck, if only one or a few bodies are available for verifying the conformity. The applicant shall demonstrate that it has the necessary professional, structural and staff capacity and is able to verify the conformity in accordance with the requirements set out in Annex 1 in general and in particular. In general, accredited bodies may verify and certify all the requirements set out in Annex 1 or limit themselves e.g. to specifications for a specific scope of application. Relevant information on this shall be published both on the website of the accredited body and on the knowledge platform in accordance with Section 6.

Re paragraph 2

In order to ensure that the applicant and its staff responsible for carrying out the conformity assessment procedure comply with the requirements, the Competence Centre shall have the possibility to request further documentation and information to be provided without delay by the applicant. This serves the purpose of quality assurance in the selection of potential accredited bodies and thus quality assurance concerning the subsequent result of the conformity assessment procedure.

Re paragraph 3

The specific procedure for identifying the professional and organisational requirements, including structural and staffing requirements in accordance with the paragraphs 1 and 2, including the verification procedure, shall be regulated by the Competence Centre in its Rules of Procedure.

Re paragraph 4

Upon successful proof of professional qualification, the Competence Centre shall issue an accreditation certificate to the applicant, which shall then be deemed to be an accredited body. For the purposes of transparency and quick retrieval of information on the available accredited bodies, that information shall be made available on the platform in accordance with Section 6. Accreditation may also be granted subject to conditions to be complied with within a reasonable period of time. This period of time shall not exceed the maximum period of time defined in the Rules of Procedure. The respective conditions shall be established by the Competence Centre. When the information is published on the platform, each accredited body shall receive an identification number in accordance with Section 6 for unique identification. Accreditation shall be limited in time by the Competence Centre, so that compliance with all quality assurance requirements and conditions shall be re-verified at an appropriate time.

Re paragraph 5

The Competence Centre shall, following accreditation, monitor the relevant body in order to ensure continued compliance with the accreditation criteria as well as the performance of the tasks and the observance of the deadlines set out in Section 12(2) and the Rules of Procedure of the Competence Centre. In the event of serious breaches of these obligations, the Competence Centre shall have the possibility to limit, suspend or completely withdraw the accreditation, or to impose conditions where the breaches are of a minor nature. This may be the case, for example, in the case of regular failure to comply with the applicable deadlines for the feedback to the applicants. The different ways of responding to breaches serve not least to ensure a high level of professional quality of the certification process itself and its results.

Re paragraph 6

Applicants for accreditation under Section 12(1) can in the event of a refusal of accreditation under Section 12(4) sentence 1a time limit or condition in accordance with Section 12(4) sentence 3 and in the case of an measure in accordance with Section 12(5),

sentence 2 submit a complaint to the Competence Centre. The procedure for dealing with these complaints shall be specified in the Rules of Procedure of the Competence Centre.

Re paragraph 7

Accreditation as a conformity assessment body in accordance with Section 12 and the Rules of Procedure of the Competence Centre is a prerequisite for carrying out conformity assessment procedures in accordance with Section 13 in conjunction with Section 387 of Book V of the Social Code. Otherwise, the performance of such procedures shall be prohibited and certificates issued by such bodies shall not be valid.

Re Section 13 (Conformity assessment procedure)

Re paragraph 1

For further quality assurance of the developed information technology systems developed, the tasks of the Competence Centre include the development, establishment and coordination
of a conformity assessment procedure. By means of a centrally controlled and standardised certification procedure, the conformity assessment of information technology systems in the healthcare system is to be carried out in the future in a more comprehensive and qualitatively uniform manner. To date, different certification or confirmation procedures exist by law for verifying compliance, in particular with interoperability requirements, of information technology systems. These procedures are assigned to different actors in the healthcare system and follow different standards, requirements and procedural steps, so that uniform quality cannot be guaranteed.
Manufacturers of information technology systems used in the healthcare system for the processing of personal patient data must therefore in future undergo the conformity assessment procedure at the Competence Centre or one by a body accredited by the Competence Centre in accordance with Section 385(7) of Book V of the Social Code in conjunction with Section 12 and have their systems certified. Successful certification shall demonstrate that the relevant information technology system complies with the mandatory requirements laid down in Annex 1 from the date indicated therein.
The Competence Centre shall publish the mandatory requirements and the corresponding deadlines for mandatory implementation on the knowledge platform in accordance with Section 6 of this Regulation.
The conformity assessment shall meet all the requirements laid down at the time of application, where applicable to a system. In order to increase legal certainty for applicants, the mandatory requirements – which are therefore to be checked in the conformity assessment procedure – are also presented separately on the knowledge platform pursuant to Section 6. The corresponding scope of application is also indicated here.
For the interfaces of the information technology systems in accordance with Section 371(1) and (2), the provisions of Section 372 or Section 373 shall also apply as requirements to be checked for compliance.

Re paragraph 2

Paragraph 2 lays down the procedure for applying to carry out a conformity assessment and the content of that application. Manufacturers shall apply electronically using the forms provided by the Competence Centre. Forms other than those of the Competence Centre are not allowed.

Re point 1

In order to clearly identify the applicant responsible for the information technology system and the correct issue of the certificate and, where appropriate, delivery of the certificate in the event of successful conformity assessment procedures, the name and address of the applicant must be provided.

Re point 2

The date of the application must be stated in order to precisely allocate the time of an application and thus to take into account the requirements profile of the conformity assessment procedure that is to be examined and applicable at that time, as well as to take into account other deadlines.

Re point 3

The indication of the name and address of a receiving agent in a Member State of the European Union or another State party to the Agreement on the European Economic Area shall ensure clarity about the contact persons and speed up proceedings.

Re point 4

In order to be able to make and clarify queries during the conformity assessment procedure, it is necessary to provide the name and address of a contact person of the applicant who has the necessary expertise to provide technical information about the information technology system to be assessed.

Re point 5

Paragraph 5 regulates which information concerning the information technology system is to be taken into account in the application. The precise designation of the system is important to ensure that the correct system – or the correct module of a system – is covered by the verification, that non-compliance due to the incorrect application of the conformity assessment procedure can be ruled out, or to provide clear documentation and traceability throughout the conformity assessment process, in particular where different systems of a manufacturer are certified within a shorter period of time. This is also relevant for the legality and validity of the result of the conformity assessment procedure.

Re letter a

The relevant information includes the software name according to the manufacturer's product designation. The manufacturer's product designation makes it possible to clearly assign and identify a product and to distinguish it from other systems of a manufacturer.

Re letter b

As a manufacturer of information technology systems can offer the same product with the same name but in different versions, the respective version number is required in addition to ensure unambiguous identification. This is important to enable customers or service providers, as well as competitors on the market, to check closely whether a version of a software on the market holds a certificate or is, for example, only a successor model. This may be the case, for example, after the release of substantial changes. Substantial changes are those that affect compliance with the specified requirements for a system.

Re letter c

In order to ensure that both users and the Competence Centre understand the uses for which information technology systems are intended by the manufacturer, the application purpose shall be specified in accordance with the application purpose of the specification to be certified in each case. This should also make it easier to identify which specifications are to be taken into account by the relevant information technology systems on the basis of the purpose of the application. It is the task of the Competence Centre to ensure, in an appropriate manner, that the indication thereof shall not allow for deviations from the specified fields of application in the respective specifications.

Re point 6

In addition, for the purposes of traceability and documentation, it must be indicated whether it is an initial conformity assessment or a repeat assessment following a significant change in the system in accordance with Section 14.

Re point 7

By means of the declaration, the applicant confirms that he has the right to make the application and that no other parties, in particular third parties, have any rights to the good or service in question that would conflict with the application. The declaration is also intended to ensure that the applicant has all the necessary rights and authorisations to submit the application. By declaring that there are no conflicting rights of third parties, the applicant assumes responsibility and liability for the accuracy of that declaration.

Re point 8

For proof of compliance of the information technology systems to be certified with the mandatory requirements laid down in Annex 1 the applicant must provide appropriate supporting documents.

Re point 9

The test reports and supporting documents to be submitted by the applicant shall, in each case, bear the identification numbers (ID) of the mandatory requirements set out in Annex 1 for which they are intended to serve as evidence. This serves to speed up the processing.

Re point 10

In the case of repeated or renewed certification as part of the conformity assessment procedure, the currently valid certificates must be submitted when the application is submitted. This serves to speed up the processing of the certification and to identify any necessary certifications.

Re paragraph 2 sentence 4

In accordance with sentence 4, the supporting documents and test reports to be submitted in accordance with sentence 3, point 8 must be specified in the Rules of Procedure in accordance with Section 17.

Re point 11

Corresponding to Section 6(2) point 8 the declaration of consent is an integral part of the application. In accordance with Section 387(5) of Book V of the Social Code, by submitting an application the applicant consents to publication.

Re paragraph 3

Paragraph 3 regulates the sequence of the processing of applications.

Re paragraph 4

Federal associations serve to represent the interests and concerns of their members and in some cases to provide them with services and support in return for their membership. In accordance with this role, such associations in the field of innovative healthcare technologies, which are relevant for the protection of the interests of the industry, may, as authorised representatives of their member companies, submit applications to manufacturers of information technology systems in accordance with paragraph 2. This reduces the burden on manufacturers and individual applicants. Applications may then be bundled and submitted together. In this case, too, the procedure laid down in paragraph 3 applies. The authorised representative shall, at the request of the Competence Centre or the accredited body, provide written evidence of his power of attorney and the documentation in accordance with paragraph 2 sentence 4. This provision is intended to take account of the role of the federal associations.

Re paragraph 5

Paragraph 5 regulates how to deal with missing documents or signatures during the application process. The examining body requests missing signatures or documents electronically in the form of additional requirements. The applicant shall then have 3 months to provide this information to the Competence Centre or the accredited body; if this deadline is

not met, the conformity assessment procedure shall be rejected. The 3-month period referred to in sentence 2 is a limitation period.

Re paragraph 6

The requirements to be checked in the conformity assessment procedure are based on the mandatory requirements laid down by the Federal Ministry of Health following the recommendation of the Competence Centre and included in Annex 1 of the present Regulation. All requirements relevant to the system shall be checked at the time of submission of the application. Where a valid certificate already exists for one or more requirements, they shall be excluded from certification. Proof of this must be provided by the applicant during the application process.

Re paragraph 7

Section 13. Section 7 lays down the minimum information to be included in the certificate. This ensures that both the certificate of an accredited body and the Competence Centre itself contains all relevant information and that comparability is guaranteed. A certificate may also contain further information, which shall then be determined by the Competence Centre. Accredited bodies shall not be allowed to include in a certificate any information other than that mentioned here or specified further by the Competence Centre. The aim is to ensure comparability between certificates issued by different actors.

Re paragraph 8

Upon completion of the conformity assessment procedure, the applicant shall be notified of the result by electronic means. The certificate shall also be provided electronically. If the applicant so requests, it can also be delivered by post.

Re paragraph 9

In order to create transparency, to implement the binding mechanism under Section 387 of Book V of the Social Code in a barrier-free manner and to ensure assistance, in particular with regard to the choice of a suitable information technology system by service providers, the information on applications submitted, the issue, refusal, withdrawal, or revocation of a certificate shall be published by the Competence Centre on the platform in accordance with Section 6. Any rejection, issue, refusal, or withdrawal of a certificate shall always be justified by the Competence Centre or the accredited body. A certificate may be withdrawn by the Competence Centre, for example, when it becomes known that the relevant requirements are no longer met or were not met from the outset. The granting of a certificate constitutes an administrative act in accordance with Section 35 of the Administrative Procedure Act (VwVfG). Before the withdrawal or revocation of a certificate, the manufacturer or supplier must therefore be consulted and given an appropriate period of to submit an opinion. With the application, the applicant agrees to the corresponding publication.

Re paragraph 10

Paragraph 10 regulates the procedure for withdrawing and revoking a certificate. Sections 48 and 49 of the Administrative Procedure Act apply to the withdrawal or revocation of a certificate.

Re paragraph 11

Paragraph 11 regulates the circle of persons concerned by the duty of confidentiality within the Competence Centre or the accredited body during the conformity assessment procedure.

The duty of confidentiality is crucial for persons employed or commissioned by the Competence Centre and the accredited bodies, as well as for others who become aware of confidential information through official reporting. Such persons shall not disclose or use confidential information obtained in the course of their work without authorisation, even after their work has ended (duty of confidentiality). The duty of confidentiality protects sensi-

tive and confidential information, ensures the integrity and credibility of the Competence Centre and the accredited body, and prevents potential future conflicts of interest.

Re paragraph 12

In order to reduce ambiguity, paragraph 12 regulates how to deal with procedures already started which are not covered by the conformity assessment procedure in accordance with Section 13. If they have already started, they may be concluded on the basis of the procedure initiated. Provided that the procedure already started is continued, the certificates and decisions issued by the Competence Centre shall remain valid. The aim is to ensure that possible adjustments to the procedure do not require a new conformity assessment procedure in the short term.

Re paragraph 13

In the context of the conformity assessment procedure, the Competence Centre shall operate solely with the objective of promoting interoperability and without the intention of making a profit.

Re Section 14 (Obligation to report significant changes to information technology systems)

Re paragraph 1

The objective of the conformity assessment procedure under Section 387 of Book V of the Social Code is to ensure that only such systems are demonstrably kept or placed on the market that comply with the requirements laid down in Annex 1 of the present Regulation. Therefore, substantial changes, i.e. those affecting the implementation of the mandatory requirements under Annex 1, must be notified to the Competence Centre in electronic form. The Competence Centre shall be notified of at least the basic technical details of the proposed changes and whether and which requirements of Annex 1 are affected by the changes in order to be able to assess possible re-certification measures. The electronic forms published by the Competence Centre shall be used for this purpose.

Re paragraph 2

If it cannot be demonstrated, on the basis of the documents submitted, that a change will not interfere with the implementation of the mandatory requirements laid down in Annex 1 or the relevant requirements to be certified, the Competence Centre may first request further documentation or verifications. If the risk of non-compliance cannot be addressed by imposing conditions, the Competence Centre may suspend or even withdraw the certificate. The Competence Centre shall duly exercise its discretion on the basis of the seriousness of the imminent deviation and the legal interests involved.

Re Section 15 (Complaints office)

Re paragraph 1

Applicants for conformity assessment under Section 13(1) and (2) may report any evidence of a negative deviation of a certified system of another manufacturer or supplier from the mandatory interoperability requirements via the complaints office of the Competence Centre pursuant to Section 385(2) point 17 of Book V of the Social Code. The Competence Centre shall examine the information and, where appropriate, initiate measures in accordance with Section 13(10). The procedure for dealing with these complaints shall be specified in the Rules of Procedure of the Competence Centre.

Re paragraph 2

Manufacturers who undergo a conformity assessment procedure at a body accredited in accordance with Section 12 and become aware in the course of the procedure that the accredited body does not meet the professional qualification referred to in Section 12 or infringes violates the conformity assessment procedure and its framework conditions pursuant to Section 13 may forward this information to the Competence Centre via the complaints office. The Competence Centre shall examine the information and, where appropri-

ate, initiate measures to address those deficiencies. The aim is to ensure the highest possible quality of the processes and structures of the accredited bodies. The procedure for dealing with these complaints shall be specified in the Rules of Procedure of the Competence Centre.

Re Section 16 (Report on the activities of the Competence Centre and the Expert Panel)

Re paragraph 1

The Competence Centre must submit a report on the previous calendar year to the Federal Ministry of Health by 31 March of each year. Paragraph 1 regulates the content of the report. The purpose of the report is to evaluate and promote transparency.

Re paragraph 2

The report will be published on the knowledge platform after approval by the Federal Ministry of Health.

Re Section 17 (Rules of Procedure)

Re paragraph 1

The Rules of Procedure shall in particular regulate the work processes of the Competence Centre, thus creating transparency for outsiders in relation to decision-making processes.

Re point 1

Among other things, the internal relationship of the Competence Centre within gematik and the corresponding organisational anchoring must be presented. The organisational structure within the Competence Centre in terms of interaction between Expert Group, Expert Panel and working groups shall also be presented.

Re point 2

The Competence Centre, Expert Group, Expert Panel and IOP working groups have various tasks in the interoperability process. In order to achieve high-quality work results as efficiently as possible, the necessary steps will be specified.

Re point 3

When filling the various roles of the Competence Centre, emphasis should be placed on interdisciplinarity. Corresponding principles shall be taken into account in the Rules of Procedure.

Re point 4

The procedures should be designed in such a way that in particular recommendation processes can be completed within a short period of time, depending on the urgency and availability.

Re point 5

The Rules of Procedure shall set out, in addition to the provisions laid down in the Regulation, how the quorum is established and how decisions are to be prepared and followed up. In the event of representation, the vote of the member represented shall be cast by the representative. In this case, the representative shall therefore have two votes, the member’s own vote and the vote of the member represented. These shall be submitted in a uniform manner.

Re point 6

Deadlines shall be set for success-critical process steps in order to ensure high-quality results and to have sufficient time for decision-making processes.

Re point 7

In principle, compensation may be paid for the reimbursement of the expenses incurred. The underlying procedure for this purpose should be described in more detail.

Re paragraph 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(2) in addition to the provisions laid down in this Regulation. This includes, for example, the set-up and work of the panels, the necessary steps in the interoperability process, the recommendation of the specifications and their certification, as well as the necessary preceding accreditation.

Re paragraph 3

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

Re paragraph 4

In order to take account of technical and regulatory progress, the Rules of Procedure shall be reviewed at least every three years for any need of further development and, if necessary, updated.

Re paragraph 5

The Federal Ministry of Health must approve updates to the Rules of Procedure.

Re paragraph 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.

Re Section 18 (Evaluation)

The re-evaluation allows for a systematic analysis of the performance and further development of the Competence Centre in relation to the promotion of interoperability in Germany as well as the implementation of other defined tasks and requirements. The first evaluation of the Coordinating Body in 2023 provided valuable indications of the future work of the Competence Centre, which were afterwards taken into account. In the interests of quality assurance and targeted development, the Competence Centre will also be evaluated by an independent research organisation in the same way.

Re Section 19 (Entry into force, expiry)

Section 19 regulates the entry into force of the Regulation.

Re Annex 1

In order to create transparency on the mandatory requirements, these shall be published both in Annex 1 and on the knowledge platform in accordance with Section 6 of this Regulation. Each requirement shall be assigned a unique ID, title, brief description, version number, date of inclusion in the annex, mandatory date of implementation and reference to the underlying legal basis. When requirements are included in the Annex 1 they are considered binding for implementation in information technology systems.

The mandatory date of implementation indicates when a manufacturer must have implemented the requirement in his systems and undergone the conformity assessment procedure under Section 387 of Book V of the Social Code.

Re Annex 2 (List of statutory specification contracts for legal persons governed by public law pursuant to Section 7 in conjunction with Section 385(4) sentence 4 of Book V of the Social Code)

In order to create transparency with regard to the award of specification contracts to public-law actors, these are set out in Annex 2 of the underlying Regulation. This excludes actors in accordance with Section 7.