Draft Ordinance

of the Federal Ministry of Health

Second Ordinance amending the Health IT Interoperability Governance Ordinance

A. Problem and objective

Medical care in Germany depends to a considerable extent on the ability of healthcare providers to exchange patient health data in a safe, complete and timely manner. Although the legal framework established by the digital laws already opens up considerable potential for improving patient care through digitalisation, a lack of interoperability between the information technology systems used in hospitals continues to hinder the consistent, cross-sectoral and standardised use of health data, especially in the inpatient sector. Different data formats, incompatible software systems and inadequate interface standards can, therefore, lead to loss of information, avoidable duplication of tests and an increased administrative burden for clinics in day-to-day care. In addition, hospitals are thus highly dependent on IT providers for information technology systems that are already integrated into day-to-day clinical practice.

The aim of this ordinance is therefore to lay down, in particular, mandatory requirements for the interoperability of information technology systems in hospitals. By means of clear technical and organisational specifications, uniform standards are to be created that enable secure, structured and automated communication between information technology systems within hospitals, but also with other actors in the healthcare sector. It aims to lay the foundations for a cost-effective, future-proof and digital supply infrastructure that enhances patient safety, optimises healthcare processes and sustainably improves data sharing in the healthcare sector.

B. Solution

The interoperability process in the healthcare sector is largely dependent on the binding definition of specifications and standards for the information technology systems used in healthcare. Pursuant to Section 385, Paragraph 2, Sentence 1, Point 1, of Book V of the Social Code (SGB V), the Federal Ministry of Health is, pursuant to Section 385, Paragraph 1, Sentence 1, SGB V, authorised to establish binding technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for specific areas or the entire health sector in the annex to the ordinance.

This ordinance, therefore, lays down mandatory requirements for the implementation of the Information Technology Systems in Hospitals (ISiK) standard in Annex 1 to the Health IT Interoperability Governance Ordinance (IOP Governance Ordinance). ISIK is a uniform interface for the exchange of data between information technology systems in hospitals, which enables communication between different systems. The interoperability standard creates a binding framework for the rapid and seamless exchange of health data both within a hospital and with other service providers, funding agencies and digital health applications. By imposing uniform requirements, data should be collected, processed and transferred in a structured and standard-compliant manner. In this way, administrative and clinical processes can be optimised and the quality of care in the treatment of patients can be significantly improved. In addition, this ordinance includes minor adjustments for the

purpose of further optimising the interoperability process in the context of the updating of specifications, certification and evaluation.

C. Alternatives

None. The binding definition of ISiK is necessary for structured and standardised communication within a hospital and with external partners in the healthcare sector. Due to the heterogeneous system landscape and the existing incentives in the healthcare sector, it is not expected that the required degree of interoperability will be achieved without a binding requirement. If ISiK is not implemented in hospital information systems in a timely manner, this will hamper digital collaboration between hospitals and compromise the quality and efficiency of patient care.

D. Budgetary expenditure exclusive of compliance costs

a) Federal Government

None.

b) Federal state government

None.

c) Social security

None.

E. Compliance costs

E.1 Compliance costs for citizens

None.

E.2 Compliance costs for businesses

For the manufacturers and providers of information technology systems in the healthcare sector as well as providers and manufacturers of digital health and care applications, the preparation and implementation of the conformity assessment procedure within the meaning of Section 387, SGB V, creates a non-quantifiable but minor additional effort, since manufacturers and providers already have to undergo certification or confirmation procedures.

In addition, there may be an unquantifiable effort for the economy to adapt products to the required interoperability requirements.

Administrative costs as a result of information obligations

None.

E.3 Compliance costs for the authorities

There are no compliance costs for the federal government and the federal states. The compliance burden for the administration has already been recorded by defining the power to issue statutory instruments within the framework of the Digital Act (DigiG). There are no other costs arising from the use of the power to issue statutory instruments.

F. Other costs

None.

Second Ordinance amending the Health IT Interoperability Governance Ordinance [1])

of ...

The Federal Ministry of Health decrees, pursuant to Section 385, Paragraph 1, Sentence 1, Paragraph 2, Sentence 1, Points 1 and 3, Paragraph 3, Points 11 and 14, Section 373, Paragraph 1, Sentence 3, as well as Section 387, Paragraph 7, Sentence 1 of Book V of the Social Code in the version published on 20 December 1988 (Federal Law Gazette I p 2477, 2482), as last amended by Article 9 of the Act of 30 September 2025 (Federal Law Gazette 2025 I No 231):

Artikel 1

Amendment of the Health IT Interoperability Governance Ordinance

The Health IOP Governance Ordinance of 10 September 2024 (Federal Law Gazette 2024 I No. 279), which was amended by Article 1 of the Ordinance of 17 December 2024 (Federal Law Gazette 2024 I No.419) is amended as follows:

1. Section 7, Paragraph 1, is replaced by the following Paragraph 1:

   "(1) The Competence Centre may commission professionally qualified natural persons or professionally qualified legal persons under public or private law to draw up and update specifications in accordance with Section 384, Sentence 1, Point 7, of Book V of the Social Code."

2. Section 14 is amended as follows:

   a) Paragraph 4 is replaced by the following Paragraph 4:

      "(4) The information about applications submitted and the issue, renewal, refusal, withdrawal or revocation of a certificate shall be published by the Competence Centre on the platform in accordance with Section 6."

   b) Paragraph 5 is replaced by the following Paragraph 5:

      "(5) The period of validity of the certificate referred to in Paragraph 2, Point 4 may be extended by the Competence Centre within the framework of Section 387, Paragraph 42, Sentence 1, of Book V of the Social Code, insofar as and for as long as an already certified information technology system complies with the applicable interoperability requirements. Sections 48 and 49 of the Administrative Procedure Act shall apply to the withdrawal or revocation of a certificate."

3. In Section 19, Sentence 2, the words "30 September 2026" are replaced by the words "31 March 2028".

4. In Annex 1 (to Section 13, Paragraph 1, Sentence 1), the table is worded as follows:

[1] Notified in accordance with 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).

“ID	Title	Short description	Version	Chapter	Date of acceptance (in annex)	Date of binding implementation 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 Electronic Medicines List (eML)	3.1.0.	3.10.2	14/09/2024	15/01/2025	Section 355, Paragraph 3, Sentence 2, Point 1, of the Book V of the Social Code	1 Practice Management Systems (PVS), 2 Dental Practice Management Systems (ZPVS), 3 Hospital Information Systems (KIS), and 4 Pharmacy Management Systems (AVS)
002	IOP requirements in accordance with Section 385, SGB V, within the framework of interfaces for information technology systems in hospitals		1.0.0		01/06/2026	31/05/2027	Section 373, Paragraph 1, Sentence 3, of Book V of the Social Code	Hospital Information Systems (KIS)”.

Artikel 2

Entry into force

This ordinance enters into force on 1 July 2026.

Justification

A. General part

I. Objective and necessity of the regulations

Medical care in Germany depends to a considerable extent on the ability of healthcare providers to exchange patient health data in a safe, complete and timely manner. Although the legal framework established by the digital laws already opens up considerable potential for improving patient care through digitalisation, a lack of interoperability between the information technology systems used in hospitals continues to impede the consistent, cross-sectoral and standardised use of health data and thus the permeability of innovative software, especially in the inpatient sector. Different data formats, incompatible software systems and inadequate interface standards can, therefore, lead to losses of information, avoidable duplication of tests and an increased administrative burden for clinics.

Thus, the aim of this ordinance is to lay down, in particular, mandatory requirements for the interoperability of information technology systems in hospitals. Through clear technical and organisational specifications, uniform standards are to be created that enable secure, structured and automated communication between information technology systems within hospitals, but also with other actors in the healthcare sector. It aims to lay the foundations for a cost-effective, future-proof and digital supply infrastructure that enhances patient safety, optimises healthcare processes and sustainably improves data sharing in the healthcare sector.

II. Main content of the draft

This ordinance lays down binding requirements for the implementation of the ISiK standard in Annex 1 to the Health IOP Governance Ordinance. ISIK is a uniform interface for the exchange of data between information technology systems in hospitals, which enables communication between different systems. The interoperability standard creates a binding framework for the rapid and seamless exchange of health data both within a hospital and with other service providers, funding agencies and digital health applications. By imposing binding uniform requirements, data should be collected, processed and transferred in a structured and standard-compliant manner. In this way, administrative and clinical processes can be optimised and the quality of care in the treatment of patients can be significantly improved. In addition, this ordinance includes minor adjustments for the purpose of further optimising the interoperability process in the context of the updating of specifications, certification and evaluation.

III. Executive footprint

The binding definition of ISiK is in accordance with Section 385, Paragraph 1, Sentence 2, Point 4, SGB V, and follows the proposal of the Competence Centre for Interoperability in Healthcare and the recommendations of the IOP expert group in accordance with Section 4 of the Health IOP Governance Ordinance. The relevant stakeholders in the healthcare interoperability process pursuant to Sections 385 et seq., SGB V, have therefore been involved.

IV. Alternatives

None. The binding definition of ISiK is necessary for structured and standardised communication within a hospital and with external partners in the healthcare sector. Due to the heterogeneous system landscape and the existing incentives in the healthcare sector, it is not expected that the required degree of interoperability will be achieved without a binding requirement. If ISiK is not implemented in hospital information systems in a timely manner, this will hamper digital collaboration between hospitals and compromise the quality and efficiency of patient care.

V. Regulatory competence

The authorisation to issue this ordinance follows from Section 385, Paragraph 1, Sentence 1, Paragraph 2, Sentence 1, Points 1 and 3, Paragraph 3, Points 11 and 14, Section 373, Paragraph 1, Sentence 3, as well as Section 387, Paragraph 7, Sentence 1, SGB V.

VI. Compatibility with European Union law and international treaties

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

VII. Consequences of the legislation

The introduction of standardised, interoperable interfaces in hospitals leads to a higher quality of care and contributes to the modernisation and safety of hospital care.

By standardising the digital exchange of data between clinical information systems, specialist applications and cross-sector healthcare partners, medical information is made complete, structured and available in real time. This reduces transmission errors, avoids redundant diagnostics and enables faster, more precise decision-making in the treatment process.

1. Legal and administrative simplification

Not applicable.

2. Sustainability aspects

The draft ordinance 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 within the meaning of the German sustainability strategy. With the draft ordinance, further necessary measures to digitalise the healthcare system are pursued. The improved interoperability of health-related data should, in particular, further improve and ensure the continuity of medical care in the inpatient sector. This eases the burden of everyday care and allows existing resources to be used more effectively.

The draft ordinance 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 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 promoting 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 state government

None.

c) Social security

None.

4. Compliance costs

a) Compliance costs for citizens

None.

b) Compliance costs for businesses

None.

Of which administrative costs as a result of information obligations

None.

c) Compliance costs for the authorities

Administrative compliance costs have already been recorded under the Patient Data Protection Act (PDSG), the Digital Health and Care Modernisation Act (DVPMG) and the Digital Act (DigiG). There are no other costs arising from the use of the power to issue statutory instruments.

d) Compliance costs for social security

None.

5. Other costs

None.

6. Further regulatory consequences

No impact on issues relating to equality policy is anticipated. In a context of increasing ageing and multi-morbidity in society, the measures provided for in the draft ordinance, through facilitated data exchange for cross-sectoral, interprofessional forms of care, contribute to ensuring the performance of the healthcare system in the future and improving the quality of the healthcare.

VIII. Time limit; evaluation

None. A time limit cannot be considered insofar as technical progress requires constant adaptation of the framework conditions for interoperability in order to ensure seamless communication between the information technology systems used in the healthcare sector. An accompanying evaluation is ensured both by the annual report on the activities

of the Competence Centre in accordance with Section 17 of the Health IOP Governance Ordinance, as well as by the evaluation of the Competence Centre and the fulfilment of its tasks in accordance with Section 19 of the Health IOP Governance Ordinance.

B. Specific part

Re: Article 1 (Amendment to the Health IT Interoperability Governance Ordinance)

Re: Point 1

Pursuant to Section 385, Paragraph 1, Sentence 1, Point 2, in conjunction with Section 385, Paragraph 4, of Book V of the Social Code, the Competence Centre may instruct natural or legal persons to draw up specifications. 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.

In order to avoid differing interpretations regarding the task profile of the commissioned third parties, Section 7 is amended to the effect that the commissioning includes both the definition and the updating of a specification. This ensures that the specifications comply with the current, applicable technical requirements for information technology systems.

Re: Point 2

Pursuant to Section 14, Paragraph 1, of the Health IOP Governance Ordinance, an information technology system shall be certified if it meets the mandatory requirements set out in Annex 1. The period of validity of the certificate pursuant to Section 14, Paragraph 2, Point 4, of the Health IOP Governance Ordinance shall not exceed 18 months from the date of issue. This time limit for a certificate is fundamentally necessary in order to take account of technical progress and to ensure that information technology systems comply with the currently applicable mandatory requirements laid down in Annex 1 to the Health IOP Governance Ordinance. However, to the extent that no further mandatory interoperability requirements have been established within the validity period of a certificate in the scope concerned, an information technology system shall continue to comply with the mandatory requirements set out in Annex 1 even after the expiry of the validity period. Under these conditions, the Competence Centre is, therefore, entitled to extend the validity period of a certificate for an information technology system to the extent and for as long as these requirements continue to be met.

If new binding interoperability requirements arise within the period of validity of the certificate, a new application for certification shall be submitted to the Competence Centre after the expiry of the period of validity of the certificate, provided that the new interoperability requirements are met by the information technology system.

Re: Point 3

The deadline of 30 September 2026 for the evaluation of the Competence Centre and the fulfilment of its tasks has been extended to 31 March 2028. The data and experience required for a robust assessment are currently not available in sufficient quantity. In particular, the significant effects of the interoperability regulations and the performance of tasks by the Competence Centre can be measured only after a lengthy start-up and implementation phase. An evaluation at the originally planned time would therefore lead to incomplete or distorted results and significantly impair the validity of the study. The postponement thus serves to ensure a methodologically sound, representative and usable evaluation.

Re: Point 4

Under the first sentence of Section 373, Paragraph 1, of Book V of the Social Code, the Competence Centre for interoperability in the health sector must draw up the necessary specifications for the information technology systems used in approved hospitals for the open and standardised interfaces referred to in Section 371, in consultation with the German Hospital Society and the federal associations relevant to information technology in the health sector. The specifications for the ISiK interoperability standard developed within this framework were proposed to the Federal Ministry of Health in accordance with Section 385, Paragraph 1, Sentence 2, Point 4, SGB V, for binding adoption within the framework of Annex 1 of the Health IOP Governance Ordinance.

The ISiK specifications are structured in stages, with additional modules being specified or updated for each stage with a respective use case.

For the ISiK interface level 5, the following use cases are represented as individual modules:

– Basic profile

– Document exchange

– Vital signs and body measurements

– Scheduling

– Medicines

– ICU - General ward

– Lab

– Connect

– Form

– Subscription.

The specifications are authoritative for manufacturers of hospital information systems and subsystems that implement the interfaces in accordance with Sections 371 and 373, SGB V, and undergo an ISiK confirmation procedure at gematik. By incorporating the requirements in Annex 1 of the IOP Governance Ordinance, these specifications are considered binding for implementation in hospital information systems and must be checked for compliance as part of the conformity assessment procedure in accordance with Section 387, SGB V. The binding implementation date is set for 31 May 2027. Since the specification of ISiK Level 5 was already published on 1 July 2025 and ISiK Levels 1-3 were already to be mandatorily integrated into hospital information systems by means of previous legislation, this implementation period is considered sufficient.

Re: Article 2 (Entry into force)

The ordinance shall enter into force on 1 June 2026.