Draft Ordinance

of the Federal Ministry of Health

Third Ordinance amending the Health IT Interoperability Governance Ordinance

A. Problem and objective

The safe and effective use of medicinal products requires treating doctors, pharmacists and other healthcare professionals to have a complete and up-to-date overview of the medications a patient is taking at all times. Medications are prescribed or adjusted by different healthcare providers, especially in the case of patients with multiple illnesses and complex treatments. This poses an increased risk of interactions, medication errors, and information gaps at the boundaries between sectors.

With the introduction of the electronic patient record, the Electronic Medication List has already been established, thereby enabling the automated and structured collation of information on prescribed medicinal products. However, the Electronic Medication List is merely a static compilation of prescription medicinal products that as of yet does not enable ongoing maintenance or cross-institutional updating of medication data. Against this background, risks remain regarding the completeness, timeliness and reliability of medication data, which can have a detrimental effect on patient safety.

The aim of this Ordinance is to establish mandatory requirements for the interoperability of information technology systems in the healthcare sector by introducing an interoperability standard for a digitally supported medication plan. Clear technical and organizational guidelines are intended to establish uniform standards that will enhance medication safety, improve cross-sector care, and ensure the long-term quality of medication data.

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 § 385(2)(1)(1) SGB V, the Federal Ministry of Health is, pursuant to § 385(1)(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 lays down mandatory requirements for the implementation of the interoperability standards in Annex 1 to the Health IT Interoperability Governance Ordinance (IOP Governance Ordinance).

To improve medication safety and ensure continuous, quality-assured medication documentation, the digitally supported medication process (dgMP) is being introduced as a mandatory use case. To this end, we propose to establish the legal foundations necessary to make the dgMP an integral part of healthcare in the electronic plan as regards medicines (ePA). The eMP builds on the already existing Electronic Medication List (eML) in the ePA and provides a structured overview of patients' current medication use. In addition to the information provided by the eML, it contains information on the dosage and indication of use for the respective medicines and can be supplemented with instructions for the co-treater.

C. Alternatives

None. Not implementing the eMP in the dgMP and relying solely on the existing electronic medication list in the ePA is not a suitable alternative and does not meet statutory requirements. The eML essentially only plays a documentary role and does not guarantee either consistently accountable care or a quality-assured, continuous updating of medication data. Without further binding regulations on integration into care processes and guidelines on data structuring, it is unlikely that the existing shortcomings regarding the completeness, timeliness, and reliability of information on medicinal products will be addressed, nor that cross-sectoral collaboration within the dgMP can be ensured.

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 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 § 387 SGB V, due to the changed interoperability requirements 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 businesses 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.

Draft Ordinance of the German Federal Ministry of Health

Third Ordinance amending the Health IT Interoperability Governance Ordinance[1]

of ...

The Federal Ministry of Health hereby issues the following ordinance pursuant to § 385(1), first sentence; (2), first sentence, points 1 and 2; § 355(1), first sentence; (3), first and second sentences, point 1; (9), second sentence; and § 341(8) of Social Code Book V – Statutory Health Insurance – (Article 1 of the Act of 20 December 1988, Federal Law Gazette I p 2477, 2482), as last amended by Article 2 (9) of the Act of 12 May 2026 (Federal Law Gazette 2026 I Point 143):

Artikel 1

Amendment of the Health IT Interoperability Governance Ordinance

The Health IT Interoperability Governance Ordinance of 10 September 2024 (Federal Law Gazette 2024 I Point 279), as last amended by […], is amended as follows:

In Annex 1 (re: § 13(1)(1)), the following Points 003 and 004 are inserted after Point 002:

ID	Title	Short description	Version	Chapter	Date of acceptance (in annex)	Date of binding implementation by	Legal basis	Scope
„003	IOP requirements according to § 385 SGB V within the framework of the ePA for all – Medication Service (ePA 3.1.3)	Guidance on the implementation of the relevant requirements for interoperability between ePA filing systems and primary systems with regard to the implementation of the digitally supported medication	2.0.1		1 September 2026	31 December 2026	§ 355(3) (2)(1) of Social Code Book V	1.Practice Management Systems (PVS), 2.Dental Practice Management Systems (ZPVS), 3.Hospital Information Systems (KIS), and 4.Pharmacy Management Systems (AVS)

[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).

		process (dgMP)						
004	IOP requirements according to § 385 SGB V within the framework of the ePA for all – Medication Service (ePA 3.1.3)	Guidance on the implementation of the relevant requirements for interoperability between ePA filing systems and primary systems with regard to the implementation of the digitally supported medication process (dgMP)	2.0.1		1 September 2026	30 September 2027	§ 341(8) Social Code Book V	1. Primary Systems in Care.

Artikel 2

Entry into force

This Ordinance shall enter into force on 1 September 2026.

Justification

A. General part

I. Objective and necessity of the regulations

The safe and effective use of medicinal products requires treating doctors, pharmacists and other healthcare professionals to have a complete and up-to-date overview of the medications a patient is taking at all times. Medications are prescribed or adjusted by different healthcare providers, especially in the case of patients with multiple illnesses and complex treatments. This poses an increased risk of interactions, medication errors, and information gaps at the boundaries between sectors.

With the introduction of the ePA, the eML has already been established, thereby enabling the automated and structured consolidation of information on prescribed medicines. However, the eML is a purely static compilation of medicinal products subject to prescription, which so far does not enable continuous maintenance and updating of medication data across institutions. Against this background, risks remain regarding the completeness, timeliness and reliability of medication data, which can have a detrimental effect on patient safety.

II. Main content of the draft

This Ordinance lays down binding requirements for the implementation of the standards for dgMP in Annex 1 to the Health IOP Governance Ordinance.

In order to improve the safety of medicine-based treatment and to ensure ongoing, quality-assured documentation on medicines, a dgMP is introduced as a standalone mandatory application. To this end, the legal foundations necessary to make the dgMP an integral part of care in the ePA are established. The dgMP builds on the already existing eMP in the ePA, provides a structured overview of the patient's currently prescribed medications, and includes information such as structured dosage information and instructions for use for the respective medicines.

The aim of this Ordinance is to establish mandatory requirements for the interoperability of information technology systems in the healthcare sector by introducing an interoperability standard for a digitally supported medication plan. Clear technical and organizational guidelines are intended to establish uniform standards that will enhance medication safety, improve cross-sector care, and ensure the long-term quality of medication data.

III. Executive footprint

The mandatory establishment of the dgMP is in accordance with § 385(1)(2)(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 § 4 of the Health IOP Governance Ordinance. The key stakeholders of the healthcare interoperability process in accordance with §§ 385 et seq. SGB V have therefore been involved.

IV. Alternatives

None. A renunciation of the introduction of a dgMP and the exclusive use of the existing eML in the ePA are not an appropriate alternative. The eML essentially only plays a documentary role and does not guarantee either consistently accountable care or a quality-assured, continuous updating of medication data. Without further mandatory regulations for integration into care processes, it is not expected that the existing deficiencies in terms of completeness, timeliness and reliability of information on regards medicinal products will be remedied.

V. Regulatory competence

The authorisation to issue the statutory ordinance follows from § 385(1) sentence 1, (2) sentence 1, Points 1 and 2 and § 355(1) sentence 1, (3) sentence 1 and 2 Point 1, (9) sentence 2 and § 341(8) 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 the dgMP improves the quality, safety and efficiency of care. More comprehensive, up-to-date and reliable medication information, combined with the integration of digital decision-support tools, will improve medication safety and strengthen cross-sector coordination.

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

4.1. Compliance cost for citizens

None.

4.2. Compliance costs for businesses

None.

4.3. 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.

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 care.

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 § 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 § 19 of the Health IOP Governance Ordinance.

B. Special part

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

Re: Column 1, ID 003 and ID 004

Pursuant to § 385(1)(2)(6) SGB V, the Competence Centre for Interoperability in Healthcare is tasked with developing technical, semantic and syntactic standards, profiles, guidelines, information models, reference architectures and software components for information technology systems used in the healthcare sector. The specifications for the interoperability standard dgMP developed within this framework were proposed to the Federal Ministry of Health in accordance with § 385(1)(2)(4) SGB V, for mandatory adoption within the framework of Annex 1 of the IOP Governance Ordinance.

The electronic patient record for all (ePA for all) supports various care processes through dedicated FHIR-based services. A central component of the dgMP is the provision of:

– the eMP for the structured documentation of prescribed medicines,

– the eML for the documentation of medicinal products actually delivered.

These are provided via the ePA Medication Service (FHIR Data Service) and enable a cross-sectoral and interprofessional exchange of information.

The dgMP thus addresses the following patient-relevant challenges:

– Polymedication: avoiding hazardous interactions in the case of multiple ordinances,

– Sector boundaries: Consistent information concerning medicines when changing healthcare providers,

– medicines safety: Reducing errors as regards medicines through a comprehensive overview,

– Patient autonomy: transparency as regards own medicinal product therapy,

– Emergency care: Quick access to current medicines in critical situations.

The dgMP requirements apply to manufacturers of information technology systems that implement the ePA Medication Service and undergo a conformity assessment procedure in accordance with § 387 SGB V.

The scope of application covers IT systems (product variants/modules) provided by service providers as defined in § 352(1) SGB V, which are used in the context of patient care for medicines and process medication information (eMP and eML) via the ePA Medication Service. Confirmation-relevant systems are therefore:

– Practice Management Systems (PVS)

– Dental Practice Management Systems (ZPVS)

– Hospital Information Systems (KIS)

– Pharmacy management systems (AVS) and

– Primary systems in care.

Depending on the confirmation-relevant system, the table in Annex 1, column 7, gives different implementation deadlines.

Systems that do not perform a care function within the medicinal products process (purely billing, administrative, warehousing or statistical systems), as well as systems in specialist fields that do not involve patient-related medication decisions (laboratory medicine, pathology, microbiology), are not subject to verification under the conformity assessment procedure set out in § 387 SGB V.

Re: Article 2 (Entry into force)

The Ordinance shall enter into force on 1 September 2026.