INTERNATIONAL STANDARD

ISO 17523

First edition
2016-06-01

Health informatics — Requirements for electronic prescriptions

Informatique de santé — Exigences applicables aux prescriptions électroniques

Reference number
ISO 17523:2016(E)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

Modern healthcare is rapidly advancing and relying on electronic communications. Many countries already have or are in the process of developing electronic systems to contain and distribute personal data regarding healthcare, among which is exchange of electronic prescriptions. Therefore, it becomes increasingly important to set up International Standards that in the end will facilitate safe and reliable dispensing and administration of the prescribed product to the patient. Also, since international travelling has become integrated into daily life, it is important that electronic communications regarding prescriptions can somehow be synchronized between prescribers and dispensers in different jurisdictions.

The most important question regarding electronic prescriptions is which information is required to accompany the electronic prescription in order to have exactly the intended medicine dispensed to the patient, including all relevant information with regard to its correct and safe use. This International Standard provides the basic set of information requirements to support electronic prescription.

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. The market authorization is strictly legislated in jurisdictional specific directives and laws. Part of this legislation regulates prescribing and dispensing of medicinal products. Information systems in healthcare must be designed so that end-users comply with this legislation (preferably without needing to pay too much attention). An International Standard on electronic prescriptions may support the implementation of (international) legislation on medicinal products in health informatics. For instance, the definition of the term “electronic prescription” has to comply with that of national legislations and multinational directives.

The prescription written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an electronic prescription instead of paper is a change that must be guided to ensure society’s trust in healthcare professionals. Requirements for the processing of electronic prescriptions can fulfil this need. An example of use in practice of this specification is the following: a general practitioner prescribes a medicinal product for a patient with the aid of an information system and sends the electronic prescription to the local pharmacy where the patient picks up the medication a short while thereafter.

The benefit of an International Standard on the requirements of an electronic prescription is that it can serve as a starting point and reference for all kinds of records and messages related to electronic prescriptions, facilitating the communication between stakeholders and information systems.

The intended audience for this International Standard is made up of the developers of standards and information systems, so that in using their products, end-users (healthcare professionals) comply with legislation, regulations and expectations of society relating to the prescribing and dispensing of medicinal products. Specifically, this International Standard provides a basis for a common understanding of the data elements contained in an electronic prescription across legislations.

Health informatics — Requirements for electronic prescriptions

1 Scope

This International Standard specifies the requirements that apply to electronic prescriptions. It describes generic principles that are considered important for all electronic prescriptions.

The scope of this International Standard is constrained to the content of the electronic prescription itself, the digital document which is issued by a prescribing healthcare professional and received by a dispensing healthcare professional. The prescribed medicinal product is to be dispensed through an authorized healthcare professional with the aim of being administered to a human patient. Other messages, roles and scenarios (e.g. validation of a prescription, administration, medication charts, EHR of the patient, reimbursement of care and dispensed products) are out of scope of this International Standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare. However, requirements and content of electronic prescriptions within the context of jurisdictions have a relationship with these scenarios. The way in which electronic prescriptions are made available or exchanged also fall outside the scope of this International Standard.

This International Standard is applicable to electronic prescriptions of medicinal products. Although other kinds of products (e.g. medical devices, wound care products) can be ordered by means of an electronic prescription, the requirements in this International Standard are aimed at medicinal products that have a market authorization and at pharmaceutical preparations which are compounded in a pharmacy. An electronic prescription is an information object that authorizes a healthcare professional to legally dispense a medicinal product.

This International Standard specifies a list of data elements that can be considered as essential for electronic prescriptions, depending on jurisdiction or clinical setting (primary healthcare, hospital, etc.).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO 17090-1, *Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services*

ISO/TS 16791, *Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers*

ISO/TS 22220, *Health informatics — Identification of subjects of health care*

ISO/TS 27527, *Health informatics — Provider identification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
dispenser
healthcare professional authorized to dispense medicinal products

3.2
dispensing
process of validation of the electronic prescription, preparation of the medicinal product, labelling, informing and handing the medication to the patient or administering healthcare professional

3.3
electronic prescription
e-prescription
prescription (issued by electronic means) that complies with this International Standard

3.4
digital signature
signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified

Note 1 to entry: Digital signatures employ a type of asymmetric cryptography. For messages sent through an insecure channel, a properly implemented digital signature gives the receiver reason to believe the message was sent by the claimed sender.

3.5
prescriber
healthcare professional authorized to issue electronic prescriptions

3.6
prescribing
process in which an authorized healthcare professional, the prescriber, issues a prescription information object

Note 1 to entry: Typically, the healthcare professional is a medical specialist or a general practitioner but this differs across legislations. In some countries, pharmacists or nurse practitioners are also authorized to prescribe.

3.7
prescription
set of values of attributes that is produced as the output of a prescription act

Note 1 to entry: A prescription is a set of instructions written by a prescriber that authorizes a medicinal product or treatment to be given to a patient. It is a) an instruction by an authorized healthcare professional, b) a request to dispense by an authorized healthcare professional and c) advice to a patient on his/her medication treatment or d) an instruction to administer by an authorized healthcare professional.

Note 2 to entry: The word “prescription” is sometimes used when referring to the act of prescribing, “prescription process”. To avoid confusion with the term “prescription” as an information object, throughout this International Standard, the word “prescription” is reserved for the information object. For the act of prescribing, the term “prescribing” is used.

3.8
medicinal product
substance or combination of substances, which can be administered to human beings for treating or preventing disease, making a medical diagnosis or to restore, correct or modify physiological functions

3.9
authentication
formalized process of verification that, if successful, results in an authenticated identity for an entity

Note 1 to entry: The authentication process involves tests by a verifier of one or more identity attributes provided by an entity to determine, with the required level of assurance, their correctness.

Note 2 to entry: Authentication typically involves the use of a policy to specify a required level of assurance for the result of a successful completion.

Note 3 to entry: Identification is usually done as authentication to obtain a specific level of assurance in the result.

[SOURCE: ISO/IEC 24760-1:2011, 3.3.1, modified]

3.10
authorization
granting of rights, which includes the granting of access based on access rights

[SOURCE: ISO 7498-2:1989, 3.3.10]

3.11
identification
process of recognizing an entity in a particular domain as distinct from other entities

Note 1 to entry: The process of identification applies verification to claimed or observed attributes.

Note 2 to entry: Identification typically is part of the interactions between an entity and the services in a domain and to access resources. Identification can occur multiple times while the entity is known in the domain.

[SOURCE: ISO/IEC 24760-1:2011, 3.2.1, modified]

3.12
identity information
set of values of attributes that differentiate one entity from others

Note 1 to entry: In an information and communication technology system, an identity is present as identity information.

[SOURCE: ISO/IEC 24760-1:2011, 3.2.4, modified]

4 Conformance

4.1 Generic conformance

An electronic prescription is conformant to this International Standard when it fulfils all detailed requirements in Clause 6.

4.2 Data element conformance

An electronic prescription is conformant to Annex A when it fulfils the requirements described in Clause 6 by using data elements from Annex A.

NOTE Data element conformance implies generic conformance.

5 General information

5.1 Structure of this International Standard

This International Standard provides the requirements for electronic prescriptions. Clause 6 describes the generic requirements considered important for any electronic prescription, regardless of the data elements presented in the electronic prescription. Annex A lists a selection of data elements and their definition that should be used to fulfil the requirements as specified in Clause 6. Annex B has three parts: B.1 lists examples of electronic prescription implementations in other countries; B.2 provides an overview of data structures and standards; B.3 lists examples and code snippets belonging to either the core or optional elements.

5.2 Usage of this International Standard

This International Standard provides a basis for a common understanding of the data elements contained in an electronic prescription within and across jurisdictions to achieve interoperability. This International Standard is therefore intended to be used in the process of development of standards and information systems handling electronic prescription information. Healthcare system designers should specify which data elements are supported by their implementation. The chosen subset may vary based on their intended use, regulatory background, and other aspects that condition the local requirements. However, data elements used have to fulfil the requirements of Annex A.

5.3 Use cases, actors, processes

This International Standard intends to specify the requirements for the information object that is to be created when a system issues a prescription. While an electronic prescription can appear in a wide range of processes, the intended scope of this International Standard is for a simple use case:

A physician enters prescription information for medication. The prescription information may then be reviewed by another professional before dispensing and the medication is then dispensed. After the dispense, the medication is expected to be administered.

NOTE 1 In a cross-border setting, the use case can be described as follows: A physician enters prescription information for medication in country A. The prescription information may then be reviewed by another professional before dispensing, and the medication is then dispensed in country B. After the dispense, the medication is expected to be administered. Extended information on cross-border requirements of electronic prescriptions can, e.g. be found in the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.[7] Article 11 (2-b) of the Directive defines the need for supporting the Member States in developing the interoperability of electronic prescriptions. The "Guidelines on eprescriptions dataset for electronic exchange under cross-border directive 2011/24/EU" [8] is aiming to facilitate this.

NOTE 2 Review, dispense, and administration processes use the prescription information. These processes might lead to the creation of new additional information possibly including parts of the prescription information or referring to it. The review, dispense and administration processes are considered only in so far as they impose additional requirements on the prescription information. The information created by those processes is not subject of this International Standard.

This International Standard only addresses the requirements that are necessary for the electronic prescription. However, this use case may trigger the following acts.

Prescribing: the intellectual process of deciding on a medication, related to medication treatment plans, decision support, etc. All considerations that lead to defining the information to be entered are considered to be prior to the prescription entry.

Prescription review: to check prescription information against pharmaceutical knowledge and regulations, e.g. drug interaction checking.

In order to fulfil this task, the reviewer should have access to information concerning the current treatment of the patient and medication already dispensed. For a prescription to be validated, a prescription review (or several) may be needed. The conditions for this are not relevant for this International Standard.

During the review process, there can arise a need to contact the prescriber.

NOTE 3 Prescription review is also known as medication order review or pharmaceutical review.

Dispense of medication: to dispense the physical medication, based on the (previously validated) prescription information assigning (giving) the medication to a particular patient, including the necessary actions that lead to that dispensing. The dispenser may be entitled to diverge from the initial prescription (e.g. change the brand of the medication) or to reject the prescription and inform the prescriber on this rejection.

One prescription may lead to more than one dispense action, such as repeat prescriptions for chronic diseases. Differences may exist between healthcare settings. In some settings, repeat dispenses require repeat prescriptions, yielding a 1:1 relationship between prescriptions and dispenses; in other settings multiple dispenses per prescription are allowed.

Administration: the prescribed medication is intended to be administered to the patient by a person who may be the patient or another person.

Additional acts can be triggered by the prescription, like those related to reimbursement (eligibility, reimbursement requests) or secondary uses (adding to the patient history).

The use case leads to the following requirements:

a) the patient shall be unambiguously identifiable by all the healthcare professionals (see 6.1);

b) the healthcare professional that enters the prescription shall be identifiable for legal and auditing reasons and in order to be contacted by the other participants (see 6.2);

c) the prescription information entry is a professional activity of the responsible prescribing person, potentially causing patient safety issues and also liability issues in subsequent process steps (see 6.7). Therefore there shall be an appropriate level of assurance that the prescription information entry accurately and unambiguously captures the intention of the prescriber (see 6.3);

d) the medicinal product(s) that is the object of the prescription shall be clearly and unambiguously identifiable by all actors (see 6.3 and 6.4);

e) the contextual information of the prescription that is relevant for the dispensing or administration shall also be available. This may include access to specific patient information or instructions (see 6.5);

f) the content shall convey the legal authorization to dispense a medicinal product (see 6.6);

g) since the prescription is a trigger for a process, the data for these processes (validity, identification, conditions for dispense or others like reimbursement) should be available (see 6.7);

h) the data that are available (or are permitted) may differ across clinical cases, across regulatory frameworks, or across different products. Therefore, the standard mechanisms should not limit or enforce any specific set of data (see 6.7).