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Health informatics — Requirements for electronic prescriptions

Informatique de santé — Exigences applicables aux prescriptions électroniques

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17523:2016), of which it constitutes a minor revision. The changes are as follows:

— introduction of a data model;

— reshuffling of requirements into clauses in line with the data model;

— rephrasing the requirements in well-defined capability statements;

— updating the relationship between other ISO standards and this document such as IDMP.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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, including the exchange of electronic prescriptions (ePrescriptions). Therefore, it becomes increasingly important to set up a document that can 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 ePrescriptions is which information is required to be included in the ePrescriptions 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 document provides the basic set of information requirements for ePrescriptions.

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. For the identification of medicinal products (IDentification of Medicinal Products, IDMP), five ISO standards are available. This document on ePrescriptions is based on these standards. In addition, 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 ePrescriptions can support the implementation of (international) legislation on medicinal products in health informatics.

The prescription written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an ePrescription instead of paper is a change that should be guided to ensure society's trust in healthcare professionals. Requirements for the processing of ePrescriptions 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 ePrescription 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 ePrescription is that it can serve as a starting point and reference for all kinds of records and messages related to ePrescriptions, facilitating the communication between stakeholders and information systems.

The intended audience for this document 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 document provides a basis for a common understanding of the data elements contained in an ePrescription across legislations.

Health informatics — Requirements for electronic prescriptions

1 Scope

The scope of this document is constrained to the content of the electronic prescription (ePrescription) 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. The ePrescription in the administrative workflow of reimbursement is not covered in this document.

This document specifies the requirements that apply to ePrescriptions. It describes generic principles that are considered important for all ePrescriptions.

This document is applicable to ePrescriptions of medicinal products for human use. Although other kinds of products (e.g. medical devices, wound care products) can be ordered by means of an ePrescription, the requirements in this document are aimed at medicinal products that have a market authorization and at pharmaceutical preparations which are compounded in a pharmacy.

This document does not limit the scope to any setting (community, institutional) and leaves it to the National bodies to decide on this matter.

This document specifies a list of data elements that can be considered as essential for ePrescriptions, depending on jurisdiction or clinical setting (primary healthcare, hospital, etc.). Ensuring the authenticity of these data elements is in scope and will have impact on the requirements of information systems.

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 not covered in this document, because they are country-specific or region-specific, due to differences in culture and in legislation of healthcare. However, requirements and content of ePrescriptions within the context of jurisdictions have a relationship with these scenarios. This document also does not cover the way in which ePrescriptions are made available or exchanged, and the process of prescribing itself.

The logistic process of prescribing itself is not part of the scope. A prescription can either be sent (pushed) to a dispenser or either be retrieved (pulled) at the dispenser. However, the requirement for the prescription is described, that it will be able to function in both environments.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
dispenser
healthcare professional authorized to dispense medicinal products

3.2
dispensing
process of validation of the *electronic prescription* (3.3), preparation of the *medicinal product* (3.8), labelling, informing and handing the medication to the patient or administering healthcare professional

3.3
electronic prescription
ePrescription
prescription (3.7) (issued by electronic means) that conforms with this document

3.4
digital signature
signature based upon cryptographic methods of originator *authentication* (3.10), 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* (3.3)

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.

3.6
prescribing
the intellectual process of deciding on a medication, related to medication treatment plans, decision support, etc. including all considerations that lead to defining the information to be entered prior to the *prescription* (3.7) entry

3.7
prescription
a set of instructions issued by a *prescriber* (3.5) that authorizes a *medicinal product* (3.8) to be dispensed or administered to a patient.

Note 1 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 document, the word “prescription” is reserved for the information object. For the act of prescribing, the term “prescribing” is used.

Note 2 to entry: The word prescription is used in different contexts depending on the language and country. In certain languages it only refers to a community setting, while the *prescribing* (3.6) in institutional setting is called differently, such as medication order. In other languages the same word is used for the community as well as the institutional setting. In general, the content should still abide to (International) Medicinal acts, that do not distinguish any setting.

3.8
medicinal product
substance or combination of substances that may be administered to human beings to treat or prevent disease

[SOURCE: ISO 11615:2012, 3.1.49, modified — "with the view to making a medical diagnosis or to restore, correct or modify physiological functions" was removed from the definition; the Notes to entry were removed.]

3.9
medicinal product dictionary
system that is specifically designed to support the *prescription* (3.7), *dispensing* (3.2) and administration of medications in healthcare based on an accurate listing, description and *identification* (3.12) of medicinal products

3.10
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]

3.11
authorization
granting of rights, which includes the granting of access based on access rights

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

3.12
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]

3.13
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 — "optionally with any associated metadata in an identity" was changed to "that differentiate one entity from others".]

4 Conformance

4.1 Generic conformance

An ePrescription is conformant to this document when it fulfils all detailed requirements in Clause 6.

4.2 Data element conformance

An ePrescription 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 document

Clause 6 describes the generic requirements considered important for any ePrescription, regardless of the data elements presented in the ePrescription. 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: Clause B.1 lists examples of ePrescription implementations in other countries; Clause B.2 provides an overview of data structures and standards; Clause B.3 lists examples and code snippets belonging to either the core or optional elements.

5.2 Usage of this document

This document is intended to be used in the process of development of standards and information systems handling ePrescription information. It can also be used as the baseline for compliance, validation and certification of information systems. 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 shall fulfil the requirements of Annex A.

5.3 Use cases, actors, processes

This document specifies the requirements for the information object that is created when a system issues a prescription. While an ePrescription can appear in a wide range of processes, the intended scope of this document is for a simple use case:

A prescriber 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 The confirmation of the ordering process of a prescription is often a dispense. The requirements for a dispense is defined in ISO/TS 19293.

NOTE 2 In the cross-border setting in the EU, the use case is described in the “Guidelines on e-prescriptions dataset for electronic exchange under cross-border directive 2011/24/EU”.[17]

NOTE 3 Review, dispense, and administration processes use the prescription information. These processes can 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 document.

NOTE 4 Beside the primary process of ordering prescriptions, the data of prescriptions can also be subject for secondary purposes, i.e. as the subject of a query. Examples are input for medication lists or research purposes.

This document only addresses the requirements that are necessary for the ePrescription. However, this use case can trigger the following acts.

— Prescribing: the activities involved with prescribing as defined in Clause 3.

— 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) can be needed. The conditions for this are not relevant for this document.

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

    NOTE 5 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.

  NOTE 6 One prescription can lead to more than one dispense action, such as repeat prescriptions for chronic diseases. Differences can exist between healthcare settings. In some settings, repeated dispenses require separate individual 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 the patient itself or by another person.

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

5.4 Information objects

5.4.1 Prescription

The prescription shall describe the medication that the prescriber wants to be administered to or used by the patient. It may serve as input to the prescription review and dispense process. Variations in the content of the prescription can occur, varying from country to country, depending upon regulations, responsibilities, and standards.

5.4.2 Related information objects

The following information related to a prescription is necessary to support the chain from prescription to administration.

a) The dispensed medication information contains what medication has actually been dispensed. The prescription that resulted in a dispense is traceable from the dispense. There can be, in general, multiple dispenses originating from one prescription.

b) The prescription review documentation object contains the observations and actions of the pharmacist in the prescription review process. The possible states, represented in the status of a prescription, are dependent on the protocols of the environment (community, institutional, country). The review documentation is traceable to the prescription.

c) The administration documentation object describes the administration event (primarily in hospitals). These events are traceable to the prescription, they may be sent along with the prescription information or managed in some other way, independently from the prescription information.