SLOVENSKI STANDARD
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Zdravstvena informatika - Zahteve za elektronske recepte (ISO/DIS 17523:2024)

Health informatics - Requirements for electronic prescriptions (ISO/DIS 17523:2024)

Medizinische Informatik - Anforderungen an elektronische Verschreibungen

Informatique de santé - Exigences applicables aux prescriptions électroniques (ISO/DIS 17523:2024)

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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 two (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 a document that in the end will facilitate safe and reliable *dispensing* (3.2) 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 be included in the electronic *prescription* (3.7) 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 electronic *prescription* (3.7).

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. For the *identification* (3.12) of medicinal products, a suit of five ISO Standards (IDentification of Medicinal Products, IDMP) is available. This document on e-Prescription is based on these standards. In addition, the market *authorization* (3.11) is strictly legislated in jurisdictional specific directives and laws. Part of this legislation regulates *prescribing* (3.6) and *dispensing* (3.2) 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* (3.7)” has to comply with that of national legislations and multinational directives.

The *prescription* (3.7) written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an electronic *prescription* (3.7) 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* (3.8) for a patient with the aid of an information system and sends the electronic *prescription* (3.7) 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* (3.7) 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 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* (3.6) and *dispensing* (3.2) of medicinal products. Specifically, this document provides a basis for a common understanding of the data elements contained in an electronic *prescription* (3.7) across legislations.

Health informatics — Requirements for electronic prescriptions

1 Scope

1.1 In scope

The scope of this document is constrained to the content of the electronic *prescription* (3.7) itself, the digital document which is issued by a *prescribing* (3.6) healthcare professional and received by a *dispensing* (3.2) healthcare professional. The prescribed *medicinal product* (3.8) is to be dispensed through an authorized healthcare professional with the aim of being administered to a human patient.

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

This document is applicable to electronic prescriptions 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 electronic *prescription* (3.7), the requirements in this document are aimed at medicinal products that have a market *authorization* (3.11) and at pharmaceutical preparations which are compounded in a pharmacy. An electronic *prescription* (3.7) is an information object that authorizes a healthcare professional to legally dispense a *medicinal product* (3.8) as specified in the *prescription* (3.7).

The word *prescription* (3.7) is used in different context 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 still should abide to (International) Medicinal acts, that do not distinguish any setting. This document does not limit the scope to any setting 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 electronic prescriptions, 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.

1.2 Out of scope

Other messages, roles and scenarios (e.g. validation of a *prescription* (3.7), administration, medication charts, EHR of the patient, reimbursement of care and dispensed products) are out of scope of this document, 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.

The process of *prescribing* (3.6) itself is not part of the scope. The logistic flow depends very much on local customs and infrastructure. A *prescription* (3.7) could either be sent (pushed) to a *dispenser* (3.1) or either be retrieved (pulled) at the *dispenser* (3.1). The requirements for the *prescription* (3.7) however must take into account, that it should 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 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

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

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

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.

3.1
dispenser
healthcare professional authorized to dispense medicinal products

3.2
dispensing
process of validation of the electronic *prescription* (3.7), preparation of the *medicinal product* (3.8), labelling, informing and handing the medication to the patient or administering healthcare professional

3.3
electronic prescription
e-prescription
prescription (3.7) (issued by electronic means) that complies with this International Standard

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* (3.4) 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* (3.5), issues a *prescription* (3.7) 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* (3.7) act

Note 1 to entry: A *prescription* (3.7) is a set of instructions written by a *prescriber* (3.5) that authorizes a *medicinal product* (3.8) 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 (usually in a community setting) or d) an instruction to administer by an authorized healthcare professional (usually in an institutional setting).

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 that may be administered to human beings to treat or prevent disease

[SOURCE: [1], 3.1.49 — modified]

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* (3.10) 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* (3.10) to obtain a specific level of assurance in the result.

[SOURCE: [2], 3.3.1, modified]

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

[SOURCE: [3], 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* (3.12) 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: [2], 3.2.1, modified]

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* (3.13).

[SOURCE: [2], 3.2.4, modified]