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Health informatics — Requirements for electronic prescriptions

Informatique de santé — Exigences pour les exigences électroniques

ICS: 35.240.80

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 17523 was prepared by Technical Committee ISO/TC 215, *Health informatics*, and by Technical Committee CEN/TC 251, *Health informatics* in collaboration.

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 electronic prescription messages. Therefore it becomes increasingly important to set up international standards that in the end will facilitate safe and reliable dispensing of the prescribed product to the patient. Also, since international travelling becomes integrated in daily life it is of importance 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 minimally required to accompany the prescription in order to have exactly the required medicine dispensed to the patient, including all relevant information with regard to its correct and safe use. This standard will provide the basic set of requirements that is needed to accomplish this goal.

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 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 to this legislation (preferably without paying to much attention). An international standard on prescription messages translates (international) legislation on medicinal products to health informatics. (For instance, the definition of the term 'prescription' should comply with that of national legislations and multinational directives.)

The prescription written on paper has a deeply rooted cultural history for both healthcare practitioners and patients. Using an electronic prescription instead of paper is a change that must be guided to ensure trust of society in healthcare practitioners. Requirements for the processing of electronic prescriptions may fulfil this need.

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

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

Examples of use in practice of this specification include the following: A general practitioner prescribes a medicinal product for a patient and sends the electronic prescription to the local pharmacy where the patient picks up the medication a short while thereafter.

Health informatics — Requirements for electronic prescriptions

1 Scope

This standard describes the requirements that apply to electronic prescriptions. It specifies generic principles that are considered important for all electronic prescriptions effecting in a list of elements that are considered core elements for all electronic prescriptions. The scope is constrained to the content of the prescription itself. The prescribed product is to be dispensed directly or through an appointed person and administered.to a human patient. Other messages, roles and scenarios are out of scope of an international standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare and reimbursement of care. The way in which electronic prescriptions are made available or exchanged fall outside the scope of this standard.

2 Normative references

The following referenced documents are indispensable for the application 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 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 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/TR 22790:2007, *Health informatics — Functional characteristics of prescriber support systems*

ISO 21549-7:2007, *Health informatics — Patient healthcard data — Part 7: Medication data*

ISO/TS 22220:2011, *Health informatics — Identification of subjects of health care*

ISO/TS 27527:2010, *Health informatics — Provider identification*

N1228 ISO/DTS 17251, *Health informatics – Business requirements exchange structured dose instructions for medicinal products*

3 Terms and definitions

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

3.1
core element
essential data that should be included in the electronic prescription. Without the core elements, the electronic prescription is not complete and hence not valid

Note 1 to entry: The information from the core elements sometimes can be derived from other core elements, making them redundant.

3.2
electronic prescription
ePrescription
any system which allows a prescriber to communicate with a dispenser regarding the dispensing of medications via an electronic medium

[SOURCE: Standards Knowledge Management Toolkit (SKMT): Canada Health Infoway Glossary]

3.3
electronic signature
electronic 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: This term is usually reserved for digital values or checksums calculated using asymmetric techniques, where only the originator of the message can generate the digital signature but many people can verify it.

[SOURCE: HIPAA, through SKMT]

3.4
optional element
non-essential data which may be included in the electronic prescription. The validity of the electronic prescription is independent of optional elements

3.5
prescriber
healthcare person authorized to issue prescriptions

[SOURCE: ISO/TR 22790:2007]

3.6
prescribing
process of creating a prescription

[SOURCE: ISO/TR 22790:2007]

3.7
prescription
a direction created by an authorized health professional, to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

[SOURCE: ISO/TR 22790:2007]

4 General Remarks

4.1 Structure of this Standard

This standard lists the requirements for electronic prescriptions. Section 5 describes the generic requirements considered important for any electronic prescription, regardless of the data elements presented in the electronic prescription. Annex A has two parts: A.1 lists a number of core data elements

that are considered sufficient to satisfy these requirements, A.2 lists additional optional data elements that are not considered essential with respect to the requirements in Section 5, but are commonly considered useful or required under specific legislations. Annex B has three parts: B.1 lists examples and code snippets belonging to either the core or optional elements. B.2 lists examples of ePrescription implementations in other countries. B.3 provides an overview of data structures and standards.

4.2 Usage of this standard

This standard provides a basis for a common understanding of the data elements contained in an electronic prescription across legislations. The standard is therefore intended to be used in the process of development of standards and information systems handling prescription information.

4.3 Conformance

4.3.1 Generic Conformance

An ePrescription is conformant to this standard when it fulfils all requirements in Section 5.

4.3.2 Data Element Conformance

An ePrescription is conformant to Annex A (normative) of this standard when it contains all core data elements listed in Annex A.1.

NOTE Data Element conformance implies generic conformance.

5 Requirements for electronic prescriptions

5.1 Identification of the patient

A patient is a person in the role of a patient. Data content shall support reliable long-term identification, provide contact information (e.g. location or telecom). In cases were the identity of the patient may not be revealed to the dispenser (e.g. in special healthcare situations due to national legislation), the prescriber needs to document sufficient information for re-identification.

The prescriber needs to make sure that he knows the following information about the patient. The patient should be able to identify him/herself using an identification method that is legal in the country of the prescriber. The identification should state contact information to be able to track the patient in case of emergency, such as a misprescribed drug or dose.

NOTE In cases where identification information cannot be provided due to national legislation (in special healthcare situations) other reliable mechanisms for traceability and possibly obtaining patient-specific information shall be available.

5.2 Authentication of the prescription

Authentication includes testing the integrity of the prescription, testing the authorization of the prescribing professional, and testing the commitment of the prescriber to the content. This requires a signature on the prescription or an equivalent mechanism for electronic signatures.

5.3 Identification of the prescribing health professional

A prescriber must be a professional health care provider, i.e. a person who is involved in or associated with the delivery of health care to a subject of care, or caring for the well-being of a subject of care [ISO/TS 27527:2010]. A prescriber is a healthcare person authorized to issue prescriptions [ISO 21549-7:2007]. Data content shall support testing the legitimate use (identification, authentication, authorization), traceability/auditing, and non-repudiation.

5.4 Identification of the prescribed product

The information provided on the prescription should be able to result in reliable identification of the prescribed product for the dispenser. Preferably and in the case of a medicinal product, the information should be derived from a medicinal product dictionary (ISO 19256 under development). If this is not available or if a product other than a medicinal product is prescribed, enough information should be given on the prescription for the dispenser to dispense the correct product.

5.5 Prescription information

This section contains information on the therapeutic use of the prescribed product. The prescription shall contain all information that is needed to use the prescribed product as agreed between the patient and the prescriber. This contains data on the route of administration, strength, the dose regimen quantity, directions of use. This information is also needed by the dispenser in order to dispense the correct amount of the prescribed product e.g. number of tablets.

5.6 Additional requirements

An important requirement is to ensure semantic equivalence between the human readable contents and machine process able contents of electronic prescriptions. Some simple examples are presented here

There must be a deterministic way for a recipient of an arbitrary electronic prescription to render the attested content [HL7 CDA R2].

Human readability applies to the authenticated content. There may be additional information conveyed in the document that is there primarily for machine processing that is not authenticated and need not be rendered. [HL7 CDA R2]. However, such course of action might lead to patient safety risks. Therefore it is recommended to specify and test at implementation level which must be rendered to the human reader and which can remain machine process able only.

Using HL7 Pharmacy messages is possible, for instance via the Medication Order Topic. This is described as followed: “This topic deals with all content related to the ordering of medications, both for dispensing (supply) and for administration. It is intended to cover community prescribing, discharge prescriptions and institutional medication orders. The models are intended to support the requirements of all jurisdictions (HL7, 2014).” And thereafter several message types for specific use cases are specified, each leading to some variants in additional requirements. Further on, XML snippets from such a message will be used to illustrate how particular data elements can be included in electronic prescriptions.

