International Standard

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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.

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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.

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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*

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