TECHNICAL SPECIFICATION

ISO/TS 17251

Second edition
2023-02

Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

Informatique de santé — Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux

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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).

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 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/TS 17251:2016), which has been technically revised.

The main changes are as follows:

— editorial corrections and clarifications;

— added Clause 4 on the relationship to other standards;

— updated Clause 3;

— Clause 4 includes discussion on the relationship to the IDMP standards and clarifies the use of IDMP terms;

— Subclause 6.4.9: removed height, added optional laboratory observations;

— Subclause 6.4.5 and 6.4.7.1 for elements described as a range (e.g. max/min dose, range for interval or frequency) added discussion of 2-term and 3-term representations;

— Subclause 6.4.1: added discussion on complex instructions (e.g. multiple schedules, multiple dose amounts);

— Subclause 6.4.5: clarified language around selection of unit of measurement versus unit of presentation;

— Subclause 6.4.8: clarified that conditional administration is not necessarily the indication for the medication order;

— Subclause 6.4.9.4: added capability to provide date and/or time for subject of care characteristics;

— Subclause 6.4.4.1: added description and conformance for administration method;

— Subclause 6.4.7.1: added the option to have frequency based upon a period of time, such as “2 times over 3 days”.

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

The requirements for the exchange of structured dose instructions are intended to be independent of any technology standard or software platform and have been developed with the aim of specifying the necessary clinical and business requirements precisely and unambiguously. Precise, unambiguous, structured, and codified dose instructions permit the prescriber, pharmacy, and other clinical systems to utilize that information for dose checking and other clinical decision support. Ultimately, precise and unambiguous dose instructions are essential for the subject of care or caregiver to appropriately use the medication for optimal benefit.

The primary audiences for this document are software developers building IT systems in the healthcare sector.

The intent of this document is that all prescribing and dispensing systems can build and recognized unambiguous dose instructions, preferably with structured and codified content which can enable additional system capabilities (e.g. Clinical Decision Support).

Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

1 Scope

This document specifies the business requirements for the structured content of structured or semi-structured dose instructions for recording dose instructions in the electronic health record (EHR), supporting clinical decision support, and in exchanging medication orders, as applicable to primary, secondary and tertiary care.

This document is focused on the dose instructions as will be presented to the individual subject of care or caregiver. Comprehension of dose instructions by the subject of care or caregiver is an overarching consideration for subject of care safety and the best outcomes. Related factors are discussed but are not part of the primary scope.

This document does not define an information model, except to the extent that those information model concepts are necessary to define business requirements.

Outside the scope of this document are:

— The implementation of dose instructions, i.e. assembling the structured elements into a form appropriate for the patient or caregiver;

— The content of a medication order (see ISO 17523) beyond content related to dose instructions;

— The content of a record of dispense of a medicinal product (see ISO/TS 19293);

— The functionality of health, clinical and/or pharmacy systems;

— Other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of health care providers, such as:

  — A drug knowledge database (see ISO/TS 22756);

  — A decision support system (see ISO/TS 22756 and ISO/TS 22703);

  — A complete medical record (EHR);

  — A medicinal product dictionary (see ISO/TS 19256);

  — Verification of the medicinal product and dose being administered.

— Some concepts from Identification of Medicinal Products are referenced, but not defined, in this document. See Clause 4 for discussion of the relationship of this document with IDMP.

2 Normative references

There are no normative references in this document.

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
administration method
action taken by the *subject of care* (3.14) or *caregiver* (3.2) for the administration of a medication

EXAMPLE Take, apply, inject.

3.2
caregiver
carer
person who provides care

Note 1 to entry: A carer can be a healthcare professional or an informal caregiver.

[SOURCE: ISO 13131:2021, 3.2.1]

3.3
dose event
dosing event
administration of a medication to a *subject of care* (3.14) based upon specified *dose instructions* (3.4)

3.4
dose instructions
instructions pertaining to the medication, which describe the amount of medication per administration, method of administration, the frequency or interval of administration, associated instructions for dosing or skipped administrations, and other associated parameters necessary for appropriate administration of the medication

Note 1 to entry: Dose instructions can apply to a specific *subject of care* (3.14) or can be general statements, for example, as the set of appropriate dose instructions for a given medication or dose instructions in a treatment protocol.

3.5
dose syntax
structured information (3.13), which represents the *dose instructions* (3.4) in a consistent, computable format

3.6
medication order
documented instruction on intended therapy for an individual person with a medicinal product issued by an authorized health professional

Note 1 to entry: A medication order contains information on the medicinal product(s), the intended dosage instruction and the period of time during which the medication was intended to be given.

Note 2 to entry: There is no inherent limitation on the setting for the medication order (inpatient, ambulatory, etc.)

3.7
message syntax
structured information (3.13), which represents the medication order in a consistent computable format

3.8
prescription
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

Note 1 to entry: The term “prescription” alone is best avoided as it is colloquially used at random for the following: "new prescription message", "prescription set" and "prescription item". It is also used to describe a prescription form. The use of "new prescription message", "prescription set" and "prescription item" where appropriate is recommended.

Note 2 to entry: In the context of this document, “prescription” or “medication order” could be used. This document uses “medication order”. In this sense, it is implied that “medication order” is inclusive of “prescription.”

[SOURCE: ISO/TS 19256:2016, 3.34, modified — Note 2 to entry added.]

3.9
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011, 3.45]

3.10
semi-structured dose instructions
dose instructions containing both *structured information* (3.13) and *unstructured information* (3.18)

3.11
sig
directions written on a package or label for the use of the *subject of care* (3.14) or *caregiver* (3.2)

Note 1 to entry: Sig (sometimes written as SIG) appears to be an acronym but is an abbreviation of the Latin term “signā”.

Note 2 to entry: In the context of this document, “sig” had the same meaning as “*dose instructions*” (3.4)

3.12
storage and handling information
information provided to the *subject of care* (3.14)/*caregiver* (3.2) regarding the appropriate conditions to maximize the shelf life of the medicinal product

3.13
structured information
information assembled from predefined concepts (vocabulary or code set) using an organizational scheme (information model)

3.14
subject of care
person who uses, or is a potential user of, a health care service

Note 1 to entry: Subjects of care may also be referred to as patients, health care consumers or subjects of care.

[SOURCE: ISO/TS 22220:2011, 3.2]

3.15
syntactic interoperability
capability of two or more systems to communicate and exchange data through specified data formats and communication protocols

[SOURCE: ISO 18308:2011, 3.48]

3.16
unit of measurement
measurement unit
real scalar quantity, defined and adopted by convention, with which any other quantity of the same kind can be compared to express the ratio of the two quantities as a number

Note 1 to entry: Depending on the nature of the reference scale, the unit of measurement expression may stand either for a physical unit of measurement that is related to a system of quantities (e.g. SI units) or for an arbitrarily defined unit of measurement, which may refer to a certain reference material, a standard measurement procedure, a material measure or even to a combination of those.

[SOURCE: ISO 11240:2012, 3.1.33]

3.17
unit of presentation
qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

EXAMPLE 1 To describe strength: puff, spray, tablet "contains 100 mcg per spray" (unit of presentation = spray).

EXAMPLE 2 To describe quantity: bottle, box, vial "contains 100 ml per bottle" (unit of presentation = bottle).

Note 1 to entry: A unit of presentation can have the same name as another controlled vocabulary, such as a basic dose form or a container, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

[SOURCE: ISO 11240:2012, 3.1.34]

3.18
unstructured information
information assembled from narrative words and word fragments, following either casual conventions or language-specific grammatical rules

4 Relationship to other ISO deliverables

There are several International Standards, Technical Specifications, and Technical Reports addressing elements of medications and prescribing. Figure 1 illustrates some of the relationships between relevant ISO deliverables.

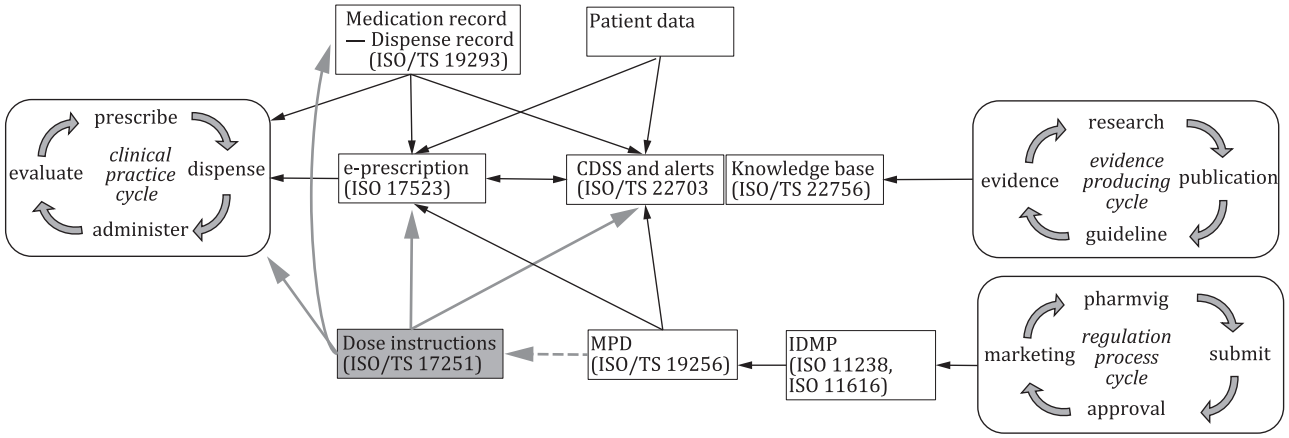

Figure 1 — Relationships between ISO deliverables

5 Conformance

Systems that create or consume electronic medication orders can claim conformance to this document when they fulfil all requirements in Clause 6. Each requirement or recommendation is labelled with an identifier in the form of "[DOSESYN-NNN]" (where NNN is a sequential, zero left-filled, number).

6 Business requirements for structured dose instructions

6.1 General

The goal of this document includes

— that structured information will be available for clinical decisions support and other system functions, to ensure that dose and administration information is appropriate for the subject of care, and

— that the dose instructions provided to subject of care or caregiver are clear and understandable.

In addition to requirements related to the dose instructions specifically, there are subject of care information elements as well. The following requirements address both subject of care and information aspects.

The following conformance statements refer to either, or both, the message syntax and the dose syntax. Requirements which are not unique to the dose instructions, or useful in other components of a medication order, are described as part of the "message syntax". Requirements which are specific to the dose instructions are described as part of the "dose syntax".

6.2 Use cases

Dose instructions serve the following use cases.

— Indicating the intended dosage during prescribing.

— Recording the indicated dosage in the EHR:

  — to be used in clinical decision support systems, e.g. dose checking;

  — exchange of information between health care providers.

— To provide instructions for administration by a healthcare professional.

— Indicating comprehensible dose instructions on the label to make clear how to use the medicine. Comprehension may not be a component of the dose instructions specifically, but comprehension does influence the presentation of the dose instructions to the subject of care or caregiver. Subject of care/caregiver comprehension information shall be present in the medication order in some manner such that the dispenser can create appropriate instructions for the subject of care/caregiver.

6.3 Elements of a dose instruction

Based on the use cases, the elements of a dose instruction include the following.

— Text representation. The purpose of this document is to specify requirements for structured dose instructions. However, some parts of a dose instruction cannot be captured in structured information. To support a human readable text of the whole dose instruction of a certain medicine, a textual representation of the whole dose instructions will remain an important element. This textual representation includes both the structured and the unstructured parts of the dose instruction. Also, if a scenario occurs which prevents the structured content from being produced, the textual representation is then necessary for communicating the dose instruction. The structured content