PD CEN ISO/TS 17251:2023



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of CEN ISO/TS 17251:2023. It is identical to ISO/TS 17251:2023. It supersedes PD CEN ISO/TS 17251:2016, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2023)

Informatique de santé - Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux (ISO/TS 17251:2023)

Medizinische Informatik - Geschäftsanforderungen an eine Syntax zum Austausch von Dosierungsinformationen für Arzneimittel (ISO/TS 17251:2023)

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European foreword

This document (CEN ISO/TS 17251:2023) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN ISO/TS 17251:2016.

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Endorsement notice

The text of ISO/TS 17251:2023 has been approved by CEN as CEN ISO/TS 17251:2023 without any modification.

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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/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;

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— 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”.

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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).

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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.

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