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BSI Standards Publication

Health Informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2016)

bsi.

National foreword

This Published Document is the UK implementation of CEN ISO/TS 17251:2016.

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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Health Informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2016)

Informatique de santé - Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux (ISO/TS 17251:2016)

Medizinische Informatik - Geschäftsanforderungen an eine Syntax zum Austausch von Dosisinformationen für Arzneimittel (ISO/TS 17251:2016)

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European Foreword

This document (CEN ISO/TS 17251:2016) 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.

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Endorsement notice

The text of ISO/TS 17251:2016 has been approved by CEN as CEN ISO/TS 17251:2016 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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The committee responsible for this document is ISO/TC 215, *Health informatics*.

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. Implementation of the requirements within a suitable medium designed to support communication of healthcare information can provide support to clinicians and their applications in storing, retrieving, using, and above all, communicating dose instructions information to other clinicians, their applications, and most importantly, to the patient.

The primary audiences for this Technical Specification are software developers building clinical IT systems.

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

1 Scope

This Technical Specification 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.

NOTE See 2.9, note to entry, regarding the use of "medication order" and "prescription".

Comprehension of dose instructions by the patient is an overarching consideration for patient safety and the best patient outcomes. Related factors are discussed, but are not part of the primary scope.

This Technical Specification 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 Technical Specification are:

— 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:

  — wide range of knowledge about medicines that would be handled in drug knowledge databases and decision support systems;

  — the complete medical record (EHR);

  — a medicinal product dictionary.

2 Terms and definitions

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

2.1
dose instructions
instructions pertaining to the medication, which describe the amount of medication per dose, method of administration, the frequency or interval of dose, associated instructions for dosing or skipped doses, and other associated parameters necessary for appropriate administration of the medication

2.2
dose syntax
structured dose instructions
structured set of data elements which represent the dose instructions in a consistent, computable format

2.3
structured information
information assembled from predefined concepts (vocabulary or code set) using an organizational scheme (information model)