TECHNICAL SPECIFICATION

ISO/TS 23030

First edition
2020-12

Traditional Chinese medicine — Clinical document specification for prescription of traditional Chinese medicine decoction pieces

Reference number
ISO/TS 23030:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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.

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 249, *Traditional Chinese medicine*.

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

HL7 CDA® Release 2.0[1)], which has been adopted as ISO/HL7 27932, is a document mark-up standard that specifies the structure and semantics of clinical documents for the purpose of exchange between healthcare providers and patients. It is necessary to establish a clinical document specification for prescription of traditional Chinese medicine decoction pieces to support the implementation of ISO/HL7 27932 in the context of the traditional Chinese medicine community. For implementers of HL7 CDA® Release 2.0, the prescription of traditional Chinese medicine decoction pieces can be provided as a use case to maximize the use of shared semantics.

A clinical document consists of a clinical document header and a clinical document body. A clinical document header consists of many sections, including identification and classification, participant author and custodian. A clinical document body consists of many sections, including diagnosis, medication administration, cost and medication plan. Usually, the core data of the prescription of traditional Chinese medicine decoction pieces includes information about the names and amounts of the decoction pieces, the form of processing, the dose, preparation and decoction methods, the route of administration, frequency, the timing of consumption and the number of packages.

This document can be applied in medical institutions that need to share their prescriptions of decoction pieces to ensure that both or multiple parties exchange documents following the specification with consistent syntax and semantics. This document can be used to support the data collection, transmission, storage and exchange of decoction piece prescriptions for electronic records.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “can” indicates a possibility or a capability;

— “may” indicates a permission.

1) HL7 and CDA are registered trademarks of Health Level Seven International and their use does not constitute an endorsement by HL7.

Traditional Chinese medicine — Clinical document specification for prescription of traditional Chinese medicine decoction pieces

1 Scope

This document provides a referenced entry-level implementation template for traditional Chinese medicine decoction piece prescriptions based on HL7 CDA® Release 2.0 to support the data collection, transmission, storage and exchange of decoction piece prescriptions for electronic records. This document focuses on the description of core data of traditional Chinese medicine decoction piece prescriptions which constitute the 'medication administration' section of the clinical document body. This document does not specify the detailed content of the clinical document header or other sections and entries of the clinical document body.

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 terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
cardinality
number of times that a data element can repeat within an individual occurrence or object view

Note 1 to entry: In the XML documents specified by this document, the cardinality of an element defines the number of times the element can repeatedly appear at a specified position, which is used to specify the number of allowed values for data attributes expressed by the name of the element. It is denoted by 'm..n': 'm' means the minimum number of occurrences and 'n' means the maximum allowed number of times.

[SOURCE: ISO/TR 12300:2014, 2.1.5, modified]

3.2
CONF
conformance requirement
precise text definition of a characteristic required to be present in a conforming implementation

Note 1 to entry: In CONF-nnnn, nnnn is a four-digit integer. The document is based on the CDA POCD_HD000040 and XML schema document (XSD). For XML elements, cardinality, terminology and data type in CDA XSD, no specific explanation is given in this document

[SOURCE: ISO 13584-25:2004, 3.6, modified]

3.3
prescription
direction created by an authorized healthcare 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 21549-7:2016, 3.22]

3.4
dose instructions
instructions pertaining to the medication, which describe the amount 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

[SOURCE: ISO/TS 17251:2016, 2.1]

4 Entries related to core data of prescription for traditional Chinese medicine decoction pieces

The entries related to core data of prescription for traditional Chinese medicine decoction pieces are described in Table 1, including entry of traditional Chinese medicine Medication Administration and entry of Decoction Pieces Administration. The implementation entry template is based on 'substanceAdministration' of HL7 CDA® Release 2.0. Annex B is the xml example based on the template of core data of prescription for traditional Chinese medicine decoction pieces.

Table 1 — Entries related to core data of prescription for traditional Chinese medicine decoction pieces

Name of entry	Explanation and description
Traditional Chinese medicine medication administration	The entry includes information about the route of administration, frequency of drug taking and total number of packages.
Decoction pieces administration	The entry includes information about the name, dose instruction and special decoction method of decoction pieces.

5 Entry templates of prescription for traditional Chinese medicine decoction pieces

5.1 Entry template of traditional Chinese medicine medication administration

The entry template of traditional Chinese medicine medication administration is described in Table 2. The entry conforms to entry-level template 'substanceAdministration' in CDA schema of HL7 CDA® Release 2.0.

Table 2 — Elements of traditional Chinese medicine medication administration entry

Name of element	Cardinality	Verb	Explanation and description
substanceAdministration	1..1	SHALL	@classCode="SBADM" @moodCode="RQO"
-templateId	1..1	SHALL	@root="2.16.840.1.113883.2.23.11.5.1.1"
-text	0..1	MAY	A detailed description of traditional Chinese medicine administration
-effectiveTime	1..1	SHALL	Execution time, number of days of drug - taking @xsi:type="IVL_TS"
--low	1..1	SHALL	Starting time of drug taking
--high	0..1	MAY	Ending time of drug taking

Table 2 *(continued)*

Name of element	Cardinality	Verb	Explanation and description
-effectiveTime	1..1	SHALL	Frequency of drug taking @xsi:type="PIVL_TS"
-- period	1..1	SHALL	@value=" " @unit=" h"
-repeatNumber	1..1	SHALL	The total packages
-routeCode	1..1	SHALL	@code=" " @codeSystem="2.16.840.1.113883.6.96" @codeSystemName=" SNOMED-CT" @displayName=" "
-approachSiteCode	0..1	MAY	@code @codeSystem=" 2.16.840.1.113883.6.96" @codeSystemName=" SNOMED-CT" @displayName=""
-doseQuantity	1..1	SHALL	@value=" " @unit ="packages"
-consumable	1..1	SHALL	
--manufacturedProduct	1..1	SHALL	@classCode=" MANU "
---manufacturedMaterial	1..1	SHALL	@classCode="MMAT" @determinerCode="KIND"
- entryRelationship	1..1	SHALL	@typeCode="COMP"
--Observation	1..1	SHALL	@classCode="OBS" @moodCode="RQO"
--code	1..1	SHALL	@code=" " @displayName=" "
--value	1..1	SHALL	@xsi:type="CD" @code=" " @displayName=" " @codeSystem="2.16.840.1.113883.2.23.11.5.2.1" @codeSystemName=" Decoction method"
- entryRelationship	1..1	SHALL	@typeCode="COMP"
-Observation	1..1	SHALL	@classCode="OBS" @moodCode="RQO"
--code	1..1	SHALL	@code=" " @displayName=" "
--value	1..1	SHALL	@xsi:type="CD" @code=" " @displayName=" " @codeSystem="2.16.840.1.113883.2.23.11.5.2.2" @codeSystemName="Decoction service"
- entryRelationship	1..1	SHALL	@typeCode="COMP"

Table 2 *(continued)*

Name of element	Cardinality	Verb	Explanation and description
--organizer	1..1	SHALL	@classCode="BATTERY" @moodCode="DEF"
---component	1.. *	SHALL	
----substanceAdministration	1..1	SHALL	@classCode="SBADM" @moodCode="RQO"
----- templateId	1..1	SHALL	@root="2.16.840.1.113883.2.23.11.5.1.2"

CONF-0001. substanceAdministration **SHALL** have [1..1] entry under it, indicating the medication entry, the attribute classCode = "SBADM", moodCode =" RQO ".

CONF-0002. substanceAdministration/templateId **SHALL** have [1..1] entry under it, and the value shall be @root = "2.16.840.1.113883.2.23.11.5.1.1".

CONF-0003. substanceAdministration/text **MAY** have [0..1] entry under it, describing the details of medication.

CONF-0004. substanceAdministration/effectiveTime **SHALL** have [1..1] entry under it, and the attribute xsi: type = "IVL_TS" indicates the drug execution time and the interval of drug-taking hours.

CONF-0005. substanceAdministration/effectiveTime/low **SHALL** occur [1..1], indicating the starting time.

CONF-0006. substanceAdministration/effectiveTime/high **MAY** occur [0..1], indicating the ending time.

CONF-0007. substanceAdministration/effectiveTime **SHALL** have [0..1] entry under it, the attribute xsi: type = "PIVL_TS" indicate the drug execution frequency.

CONF-0008. substanceAdministration/effectiveTime/period **SHALL** occur [1..1],indicating the drug taking intervals.

CONF-0009. substanceAdministration/repeatNumber **SHALL** have[1..1] entry under it,indicating the number of total packages of combination of decoction pieces.

CONF-0010. substanceAdministration/routeCode **SHALL** have [1..1] entry under it, and its value may be taken from the range SNOMED-CT or the extended range approved by the specific RHIN implementation organization, indicating route of administration of patient in template examples (e.g. oral, injection, topical administration), in which the value of codeSystemName is "2.16.840.1.113883.6.96", and codeSystemName is "SNOMED-CT".

CONF-0011. substanceAdministration/approachSiteCode **MAY** have [0..1] entry under it, indicating the data element of body surface parts (e.g. hands, feet, eyes) in drug use operation by patients in the template examples (e.g. external application, drip-feeding, coating), and all coded values in the range shall be taken from the coding system HL7 "HumanSubstanceAdministrationSite", in which the value of codeSystemName is "2.16.840.1.113883.6.96", and codeSystemName is "SNOMED-CT".

CONF-0012. substanceAdministration/doseQuantity **SHALL** have [1..1] entry under it, indicating the single dose.

CONF-0013. substanceAdministration/consumable **SHALL** have [1..1] entry under it.

