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.

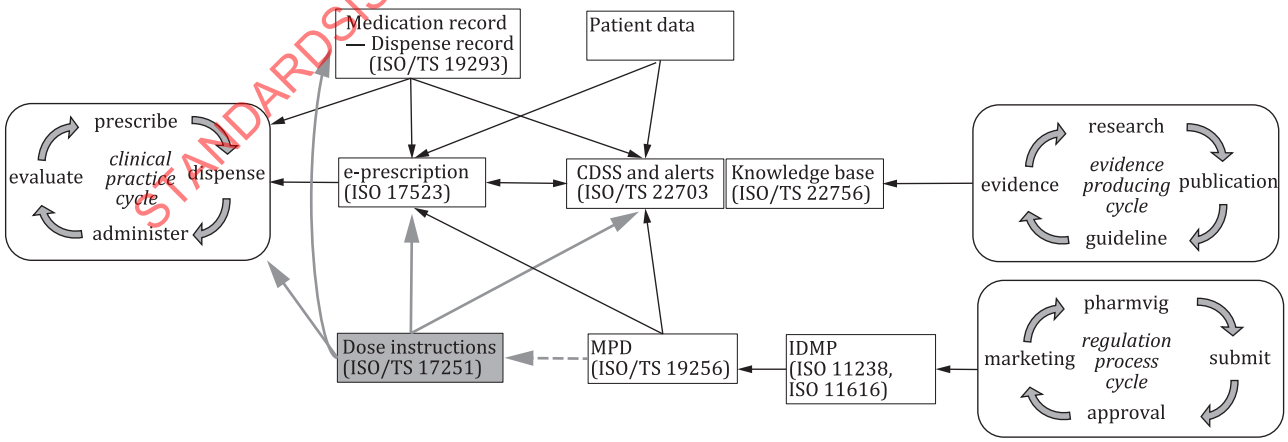

Figure 1 — Relationships between ISO deliverables

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

and the textual content, if both are present, shall agree, neither omitting nor adding any significant content between the two.

— Amount of medication to be administered at each dose event.

  — This may be comprised of a number of units of presentation (e.g. “1 tablet”) or a number and unit of measurement (e.g. “5 ml”, “500 mg”). Calculated amounts (e.g. “50 mg/kg body weight") may be appropriate in some cases, however an explicit amount is generally preferred over an implied amount.

  — The amount to be administered may vary over time (e.g. tapered dose or alternating doses during day or week) or relative to other parameters (e.g. insulin sliding scale).

  — The administered amount may be a range (1 to 2 tablets).

  — Indeterminate terms (e.g. “apply a thin film”, “use a pea-sized amount”) should be quantified wherever possible (e.g. “apply 1 to 2 ml”, “use 1 to 2 g”) or the non-quantifiable portion included in a text representation element.

— Route of administration.

— Timing of dose event(s). A wide range of dose timing shall be considered. Possibilities include the following.

  — Dosing by frequency (e.g. “twice a day”, “once a month”), dosing by time interval (e.g. “every 6 hours”). Both frequency and interval require a numeric portion and a time portion, frequency being “<number> per <time unit>” and interval expressing “every <number> <time unit>”. The numeric portions may involve ranges (e.g. “every 3 to 4 days”).

  — Dosing at specific times (e.g. “at 9 am”), or relative to other events (e.g. meals, sleep, procedures).

  — There may be a date and/or time for administration events. This may be specific (e.g. “begin on 3 October 2015”) or relative (e.g. “the day prior to the procedure”).

  — Dose timing can also be a combination of timing patterns running consecutively (e.g. tapers) or concurrently (e.g. “daily and as needed”).

— Conditional administration. Administration may be dependent upon other factors. Such factors may be symptoms (e.g. “as needed for cough”), measurable parameters (e.g. “blood glucose > 200 mg/dl”, “temperature > 38 °C”), event or encounter (e.g. “after bee sting”). The use of unspecified or indeterminate conditions (e.g. “as needed” without condition) is not supported in this document.

— Ancillary information. As with the textual representation, this information is not typically represented in the structured dose instructions and is included here as they are often discussed in relation to dose instructions. Examples include:

  — storage and handling information (e.g. keep refrigerated, shake well before use);

  — advice on proper administration (e.g. take with food);

  — reference to dosing information provided elsewhere (e.g. medications following a documented protocol).

Dose instructions do not exist on their own; they are a component of the medication order, and thus the prescriber and dispenser systems. These systems are, in turn, related to other health, clinical, and/or pharmacy information systems. Some aspects of the dose instructions, and the dose syntax model, may be dependent on information in these other systems. Examples of such “other information” include subject of care weight for weight-based dosing, and procedure schedules for doses administered relative to that event. It is recognized that this document includes requirements which are not specifically elements of dose instruction but may be needed for appropriate interpretation and implementation of the dose instructions. Conformance of a dose syntax model, and dose instructions produced from that model, are not dependent on these “other information” requirements.

6.4 Information requirements

6.4.1 General

The requirements for structured dose information, or the "dose syntax," are described in 6.4. These requirements build on the elements discussed in 6.3.

Dose syntax can only be assessed for structured (no textual representation present) and semi-structured (textual representation present) dose instructions. The requirements are defined for structured dose instructions, and the structured portion of semi-structured dose instructions. Some of these requirements describe "capabilities" or "features" which will not be used in all structured dose instruction instances.

Dose instructions can be very complex. Aggregates of sequential and alternating dosing are not uncommon [e.g. "4 tablets once a week (2 in the morning, 2 in the evening)" for methotrexate]. Another complex example involves dosing multiple products dispensed as one "kit" [e.g. Didrokit, "once a week 1 tablet (=Didronel) in the morning, 6 times a week 1 tablet (=Cacit) in the evening"]. This document addresses the information requirements for dose syntax models and derived dose instructions. This document does not address all the possible combinations and permutations of the elements.

6.4.2 Terminologies and Code Systems

6.4.2.1 The need for standardized terminologies and code systems

Defining an information model assures that structured information is provided in a consistent manner, this is syntactic interoperability. However, for information to be understood by the receiver, the sender shall use terminologies and code systems the receiver recognizes. This is semantic interoperability. Therefore, a basic information requirement is that an information model support terminologies and code systems which are reasonably assured to be known to all parties to whom the information may be communicated.

This document does not identify specific terminologies and code systems to be used. The appropriate selection needs to take into consideration relevant local, regional, and national prescribing practices. System designers and implementers are encouraged to employ internationally recognized and standardized terminologies and code systems.

6.4.2.2 Regarding Latin abbreviations

Medication orders, and healthcare generally, are known for the use of Latin abbreviations. Latin abbreviations can refer to dose timing (e.g. qd, bid), route of administration (e.g. po, pr), conditional administration (e.g. prn), site of administration (e.g. os, od), other components of dose instructions or the medication order (i.e. sig). While there is a trend to retire the use of Latin abbreviations in healthcare, they are still in use and this document does not preclude their use in dose instructions.

However, to maintain semantic interoperability, any abbreviations used shall be known and understandable to the receiver. Many terminologies and code systems recognize this and have incorporated Latin and other abbreviations as either synonyms or defined concepts. Therefore, this document supports the use of Latin and other abbreviations which are incorporated into recognized terminologies and code systems.

6.4.3 Information model

— The dose syntax shall employ an information model. [DOSESYN-001]

— The information model shall support the use of standardized vocabularies. [DOSESYN-002]

— The dose syntax and the information model may or may not directly produce the dose instructions presented to the subject of care/caregiver but shall always provide a consistent presentation to

the pharmacy/dispenser from which subject of care/caregiver -friendly dose instructions can be created. [DOSESYN-003]

— The information model should use, or be mapped to, the information model(s) used by related health information systems. [DOSESYN-004]

6.4.4 Text representation

Text representation may be supplied by the prescriber to provide the prescriber's intent of what should be presented to the subject of care/caregiver.

— If both the text representation of the dose instructions and a coded representation of the dose instructions (including any ancillary information [see 6.4.10]) are present, then the text representation of the dose instructions shall be consistent with any coded representation of the dose instructions. [DOSESYN-005]

— The text representation may include wording and grammatical differences from the coded representation, but the full intent of the coded representation shall be present in the text representation. [DOSESYN-006]

— The text representation may exist in the absence of all coded representation [DOSESYN-007]. For example, a large volume pre-colonoscopy bowel preparation is often a long narrative which is difficult (or impossible) to codify. In such a case, the text representation can include the long narrative without any coded content.

6.4.4.1 Administration method

The administration method is the action, which the subject of care or caregiver must take to effectuate the administration. For example, a subject of care must "take" and oral dosage form, or "apply" a topical product.

— The dose syntax model shall support the expression of the administration method for each dosing event. [DOSESYN-008]

— The dose syntax model should support the expression of the administration method based upon a standardized terminology. [DOSESYN-009]

6.4.5 Administration amount

The administration amount can be expressed as an amount of the active ingredient (e.g. 500 mg) or an amount of units of presentation (e.g. 2 tablets, 15 ml). The selection of unit of measurement or unit of presentation in the dose instructions is situational, e.g. a home setting may favour the unit of presentation (e.g. 1 tablet) while a clinical setting often favours an amount of the active ingredient (e.g. 250 mg).

— The dose syntax model shall support both unit of measurement and unit of presentation for the administration amount. [DOSESYN-010]

— The dose syntax model shall support an expression of the numeric value of the quantity to be administered at each dosing event. [DOSESYN-011]

— The dose syntax model shall support both a single value (e.g. 1) and a value range (e.g. 1 to 2) for the numeric value of the dose to be administered at each dosing event. [DOSESYN-012]

— The dose syntax model shall be clear and consistent on presentation of single-value/value-range for the dose to be administered [DOSESYN-013]. A dose syntax implementation may support single-value/value-range in various structures, for example (1) three terms (e.g. value, value-range-low, value-range-high), and (2) two terms (value = value-range-low, value-range-high). This document is agnostic on the implementation of single value/range, but the dose syntax model shall be clear and consistent.

— The dose syntax model shall support the expression of the unit of measurement /unit of presentation for each dosing event (e.g. tablet, ml, puff, mg/kg). [DOSESYN-014]

— The dose syntax model should support the expression of the unit of measurement /unit of presentation for each dosing event (e.g. tablet, ml) based upon a standardized vocabulary. [DOSESYN-015]

— The dose syntax model may support the expressions of calculated administration amounts (e.g. 50 mg/kg of body weight). [DOSESYN-016]

— The dose syntax model may support calculation conversion between units of presentation and units of measurement. For example, if a 500 mg of an active ingredient is ordered and tablets contain 250 mg of that ingredient, the model may support the dose instructions stating 2 tablets. [DOSESYN-017]

6.4.6 Route/site of administration

— The dose syntax model shall support the expression of the route of administration for each administration event (e.g. “oral”, “topical”, “ocular”). [DOSESYN-018]

— The dose syntax model should support the expression of the route of administration for each administration event (e.g. “oral”, “topical”, “ocular”) based upon a standardized vocabulary. [DOSESYN-019]

— The dose syntax model shall support the expression of the site of administration for each administration event (e.g. “left deltoid”, “right eye”). [DOSESYN-020]

— The dose syntax model should support the expression of the site of administration for each administration event (e.g. “left deltoid”, “right eye”) based upon a standardized vocabulary. [DOSESYN-021]

6.4.7 Timing of dose event(s)

6.4.7.1 Timing

— The dose syntax model shall support expressing the timing of administration events as a number of events per period of time (frequency) (e.g. “3 times a day”, “twice a week”), as a numeric value and a value to express the time unit. [DOSESYN-022]

— The dose syntax model should support expressing the timing of administration events as a number of events over an extended period of time (i.e. not a simple unit of time) (e.g. “2 times over 3 days”). [DOSESYN-023]

— The dose syntax model shall support expressing the timing of administration events as spaced at equal intervals of time (interval) (e.g. “every 8 hours”), as a numeric value and a value to express the time unit. [DOSESYN-024]

— The dose syntax model shall support expressing the timing of administration events as a range of events per interval of time (frequency range) (e.g. “3 to 4 times a day “), as a numeric range and a value to express the time unit. [DOSESYN-025]

— The dose syntax model shall support expressing the timing of administration events as spaced at a range of intervals of time (interval range) (e.g. every 6 to 8 weeks), as a numeric range and a value to express the time unit. [DOSESYN-026]

— The dose syntax model shall be clear and consistent on presentation of single value/value range for the interval/interval range and frequency/frequency range. [DOSESYN-027] A dose syntax implementation may support single value/value range in various structures, for example (1) three terms (e.g. value, value-range-low, value-range-high), and (2) two term (value = value-range-low, value-range-high). This document is agnostic on the implementation of single value/range, but the dose syntax model shall be clear and consistent.

— The dose syntax model shall support expressing the timing of administration event as specific points of time (e.g. “9 am”, “10 am and 6 pm”). [DOSESYN-028].

— The dose syntax model shall support expressing the timing of administration events related to activities of daily living (e.g. “with breakfast”, “every morning”, “at bedtime”). [DOSESYN-029]

— The dose syntax model shall support expressing the timing of administration events as offsets to activities of daily living (e.g. “take 30 min prior to breakfast”, “take 30 minutes prior to appointment”). [DOSESYN-030]

— The dose syntax model shall support expressing the timing of administration events as day(s) within a week (e.g. “every Monday”, “every Tuesday, Thursday, Saturday”). [DOSESYN-031]

— The dose syntax model shall support expressing the timing of administration events as day(s) within a month (e.g. “on the first of every month”, “on the 1st and 15th of each month”). [DOSESYN-032]

— The dose syntax model should support the expression of the timing (e.g. ‘per day’, ‘per week’) and time (e.g. “hour”, “day”) based upon a standardized vocabulary. [DOSESYN-033]

6.4.7.2 Sequential and alternating dosing

— The dose syntax model should support sequential sets of dose instructions (e.g. “2 now, then 1 every day”, “3 tablets on first day, 2 tablets on second day, 1 tablet on third day”). Sequential sets may use an “and then” construct (e.g. “2 now, then 1 every day”, “3 tablets on first day and then…”). [DOSESYN-034]

— The dose syntax model should support alternating set of dose instructions (e.g. “Take 80 mg in the morning and 40 mg in the evening”, or “1 tablet on Monday, Wednesday, Friday, 2 tablets on Tuesday, Thursday, and Saturday, no dose on Sunday”). [DOSESYN-035]

6.4.7.3 Start/Duration

— The dose syntax model shall support the date and/or time on which administration should start. [DOSESYN-036]

— The dose syntax model should support the date and/or time on which the administration should end. [DOSESYN-037]

— The dose syntax model should support administration start and end as relative to other events (e.g. “begin 1 day prior to procedure”). [DOSESYN-038]

— The dose syntax model shall support termination of dosing events, i.e. that the subject of care should continue taking the medication until an event occurs (e.g. “until gone”, “then stop”). [DOSESYN-039]

— The dose syntax model should support dosing event duration (e.g. “for 10 minutes”, “over 30 minutes”, “continuous”). [DOSESYN-040]

— The dose syntax model should support dosing rate for parenteral products (e.g. “250 mg/h”, “125 ml/h”, “continuous”). [DOSESYN-041]

— The dose syntax model should support therapy duration (e.g. “for 10 days”, “for 6 months”, “for 21 doses”). [DOSESYN-042]. This is the intended duration of the therapy, not the calculated date on which the supplied medication should be used up.

— The dose syntax model should support maximum therapy durations (e.g. not longer than 7 days). [DOSESYN-043]

6.4.8 Conditional administration

Conditional administration provides additional, typically non-temporal, criteria for the administration or non-administration of a medication dose. For example, "take 1 tablet every 6 hours while temperature is greater than 38 °C."

Conditional administration may be related to but does not represent the reason (or indication) for the medication order. The reason for the medication order is not addressed in this document.

— The dose syntax model shall support a textual expression of conditions for administration (e.g. "as needed for pain", "for temperature above 37,8 °C"). [DOSESYN-044]

— The dose syntax model may support a structured expression of conditions for administration. [DOSESYN-045] The structured expression shall adhere to the following conformance statements:

  — The dose syntax model should support a prefix to the structured expression of condition for administration (e.g. "as needed for", "when") [DOSESYN-046]

  — The dose syntax model shall support comparator operators for conditions for administrations (e.g. "greater than", ">", "less than"). [DOSESYN-047]

  — The dose syntax model shall support a numerical value for an observed condition for administration. [DOSESYN-048]

  — The dose syntax model should support value ranges for the numerical value of an observed condition for administration. [DOSESYN-049]

  — The dose syntax model shall support a codified representation of the unit of measurement for an observed condition for administration (e.g. "degrees Celsius"). [DOSESYN-050]

  — The dose syntax model shall support a codified representation of the observation related to the condition for administration (e.g. "temperature"). [DOSESYN-051]

  — The dose syntax model shall employ controlled vocabularies in the expression of conditions for administration; this includes both valued concepts (e.g. "equal to or greater than" and "37,8" and "°C") and unvalued concepts (e.g. "as needed for pain"). [DOSESYN-052]

— The dose syntax model shall support limitations on the number of doses permitted in a specified period (e.g. "not more than 4 doses in 24 hours"). [DOSESYN-053]

NOTE As part of the directions for the subject of care or caregiver. Health care professionals can have other sources (e.g. clinical decision support) with dose limitation recommendations.

— The dose syntax model should support the expression of conditions that result in alteration of administration (e.g. "discontinue if rash develops", "skip dose when prior to dental appointment"). [DOSESYN-054]

6.4.9 Subject of care-specific information

6.4.9.1 General

This information is not specifically part of the dose instructions. This information may influence how the dose instructions are prepared or rendered for the subject of care /caregiver. This information is typically communicated other aspects of the medication order. For guidance how to develop a knowledge base that includes this type of data for decision support, including dose checking, see ISO/TS 22756.

Since these elements might not be under the control of the same system containing the dose syntax model, these "requirements" are not binding on the dose syntax model, or dose instructions produced by that model. The dose syntax model may state conformance to this document without addressing this subject of care-specific information.