BS EN ISO 21549-7:2024

BSI Standards Publication

Health informatics — Patient healthcard data

Part 7: Medication data

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National foreword

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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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Informatique de santé - Données relatives aux cartes de santé des patients - Partie 7: Données de médication (ISO 21549-7:2024)

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European foreword

This document (EN ISO 21549-7:2024) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2024, and conflicting national standards shall be withdrawn at the latest by August 2024.

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.

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The text of ISO 21549-7:2024 has been approved by CEN as EN ISO 21549-7:2024 without any modification.

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Foreword

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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 document 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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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 third edition cancels and replaces the second edition (ISO 21549-7:2016), of which it constitutes a minor revision.

The changes are as follows:

— update normative references;

— editorial update;

— correct errors in tables.

A list of all parts in the ISO 21549 series can be found on the ISO website.

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Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare funding institutions and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems. Administrative data objects may require linkage to external parties responsible for their own domains which are not within the scope of this document. For instance, cross-border reimbursement of healthcare services is usually regulated by law and intergovernmental agreements.

The advent of remotely accessible databases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card "de facto" contains device data and identification data and may in addition contain administrative, clinical, medication and linkage data.

Device data are defined to include:

— identification of the device itself, and

— identification of the functions and functioning capabilities of the device.

Identification data may include unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include the following:

— complementary person(s) related data;

— identification of the funding of healthcare, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefits;

— other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include

— items that provide information about health and health events;

— their appraisal and labelling by a healthcare provider (HCP), and

— related actions planned requested or performed.

Medication data may include

— a record of medications purchased by the patient for self-administration,

— copies of prescriptions including the authority to dispense records of dispensed medications,

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— records of medications dispensed by a pharmacist to the patient, and

— pointers to other systems that contain information that hold medication data, either medication history or prescribed medicines, (or both) and in the case of prescribed medicines, the authority to dispense.

Because a data card essentially provides specific answers to definite queries while having at the same time a need to optimize the use of memory by avoiding redundancies, “high level” Object Modelling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures

Patient Data Cards may offer facilities to

— communicate prescription information from one healthcare professional to another healthcare professional such as to a healthcare agent or healthcare organization, and

— provide indexes and/or authority to access prescription information held other than on the patient data card.

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Health informatics — Patient healthcard data —

Part 7: Medication data

1 Scope

This document applies to situations in which such data is recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO/IEC 7810.

This document specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data sets for storage on devices.

The purpose of this document is for cards to provide information to other health professionals and to the patient or its non-professional caregiver.

It can also be used to carry a new prescription from the prescriber to the dispenser/pharmacy in the design of its sets.

Medication data include the following four components:

— **medication notes**: additional information related to medication and the safe use of medicines by the patient such as medication history, sensitivities and allergies;

— **medication prescriptions**: to carry a new prescription from the prescriber to the dispenser/pharmacy;

— **medication dispensed**: the records of medications dispensed for the patient;

— **medication references**: pointers to other systems that contain information that makes up medication prescription and the authority to dispense.

The following topics are beyond the scope of this document:

— physical or logical solutions for the practical functioning of particular types of data cards;

— how the message is processed further "downstream" of the interface between two systems;

— the form which the data takes for use outside the data card, or the way in which such data is visibly represented on the data card or elsewhere.

NOTE Not only does the definition of "medicinal products" differ from country to country, but also the same name can relate to entirely different products in some countries. Therefore, it is important to consider the safety of the patient when the card is used across borders.

This document describes and defines the Medication data objects used within or referenced by patient-held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

This document does not describe nor define the common objects defined within ISO 21549-2.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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ISO 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*

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
attribute
characteristic of an object or entity

3.2
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance test requirements and produced during a defined validated process of manufacture

3.3
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

[SOURCE: ISO/TS 21089:2018, 3.33]

3.4
data object
instance of some *information object class* (3.10), being composed of a set of fields which conform to the field specifications of the class

3.5
dispenser
healthcare *professional* (3.9) which is a representation of an individual, professionally responsible for filling/dispensing the *prescription* (3.21)

Note 1 to entry: This is usually the pharmacist but it can be other individuals according to local jurisdictions.

3.6
healthcare
care
activities, services or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within the healthcare framework.

[SOURCE: ISO 13940:2015, 3.1.1, modified — The preferred term “care” has been added; “care activities” has been replaced by “activities”, “management or supplies” has been replaced by “supplies”; in Note 1 to entry “healthcare delivery framework and may also include the management of clinical knowledge” has been replaced by “healthcare framework”.]

3.7
healthcare data card
machine-readable card conformant to specific requirements intended for use within the healthcare domain

Note 1 to entry: The requirements are given in ISO/IEC 7810.

3.8
healthcare party
organization (3.15) or person involved in the direct or indirect provision of healthcare services to an individual or to a population

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3.9
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a *subject of care* (3.24) or a population of subjects of care

EXAMPLE Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk.

3.10
information object class
set of fields, forming a template for the definition of a potentially unbounded collection of information objects, the instances of the class

[SOURCE: ISO/IEC 8824-2:2021, 3.4.10, modified — Note 1 to entry has been removed.]

3.11
ingredient
substance (3.25) included as a component in a product

Note 1 to entry: In this context, product refers to *pharmaceutical product* (3.18).

3.12
magistral medicinal product
extemporaneous medicinal product
medicinal product (3.13) manufactured in a pharmacy or pharmacy department, which is based on a recipe and intended to be used for one and only one *subject of care* (3.24)

Note 1 to entry: A magistral/extemporaneous medicinal product is also a *pharmaceutical product* (3.18).

3.13
medicinal product
substance (3.25) or combination of substances, which can be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items and one or more *pharmaceutical products* (3.18).

Note 2 to entry: In certain jurisdictions, a medicinal product is be defined as any substance or combination of substances which can be used to make a medical diagnosis.

3.14
medicinal product package
delivery unit of a *medicinal product* (3.13) in an *outer container* (3.16)

3.15
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

Note 1 to entry: Groupings or subdivisions of an organization may also be considered as organizations where there is a need to identify them for information interchange.

3.16
outer container
container that serves as an external layer of a package

3.17
payment guarantor
organization (3.15) responsible for the total or partial reimbursement or payment of the price of the *medicinal product* (3.13)

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3.18
pharmaceutical product
qualitative and quantitative composition of a *medicinal product* (3.13) in the dose form approved for administration in line with the regulated product information

Note 1 to entry: A medicinal product may contain one or more pharmaceutical products.

Note 2 to entry: In many instances, the pharmaceutical product is equal to the manufactured item. However, there are instances where the manufactured item must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

[SOURCE: ISO 11616:2017, 3.1.24, modified — "administration" has been replaced by "administration in line with the regulated product information"; a new note 1 to entry has been added, the original note 1 to entry has become note 2 to entry.]

3.19
prescriber
healthcare professional (3.9) authorized to issue *prescriptions* (3.21)

3.20
prescribing
process of creating a *prescription* (3.21)

3.21
prescription
direction created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of a *medicinal product* (3.13) or medicinal appliance to be taken or used by a *subject of care* (3.24)

3.22
prescription item
specification created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of single *medicinal product* (3.13)/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

Note 1 to entry: A prescription item may contain administrative details needed for dispensing or derived from dispensing, but does not contain information about the *prescriber* (3.19) or the *subject of care* (3.24) for whom the prescription item is prescribed or to whom it has been dispensed.

3.23
prescription set
collection of one or more *prescription item(s)* (3.22) prescribed and/or dispensed as a unit

3.24
subject of care
person or defined group of persons receiving or registered as eligible to receive healthcare services or having received healthcare services

3.25
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

Note 1 to entry: Substances can be either single substances mixture substances or one of a group of specified substances. Single substances shall be defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together. Pharmacopoeial terminology and defining characteristics will be used when available and appropriate. Defining elements are dependent on the type of substance.

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Note 2 to entry: Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances can either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together.

[SOURCE: ISO 11238:2018, 3.84, modified — The original Note 1 to entry has been deleted, Notes 2 and 3 to entry have been adapted.]

4 Abbreviated terms

ATC Anatomical Therapeutic Chemical Classification System

DEA Drug Enforcement Administration Registration Number

NCDCP National Council for Prescription Drug Programs

UML Unified Modelling Language

5 Basic data object model for a healthcare data card

5.1 Patient healthcard data object structure

A set of basic data objects have been designed to facilitate the storage of clinical data in a flexible structure, allowing for future application specific enhancements. These tools should help the implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many types of data cards.

The tools consist of a generic data structure based on an object-oriented model represented as an UML class diagram as shown in Figure 1.

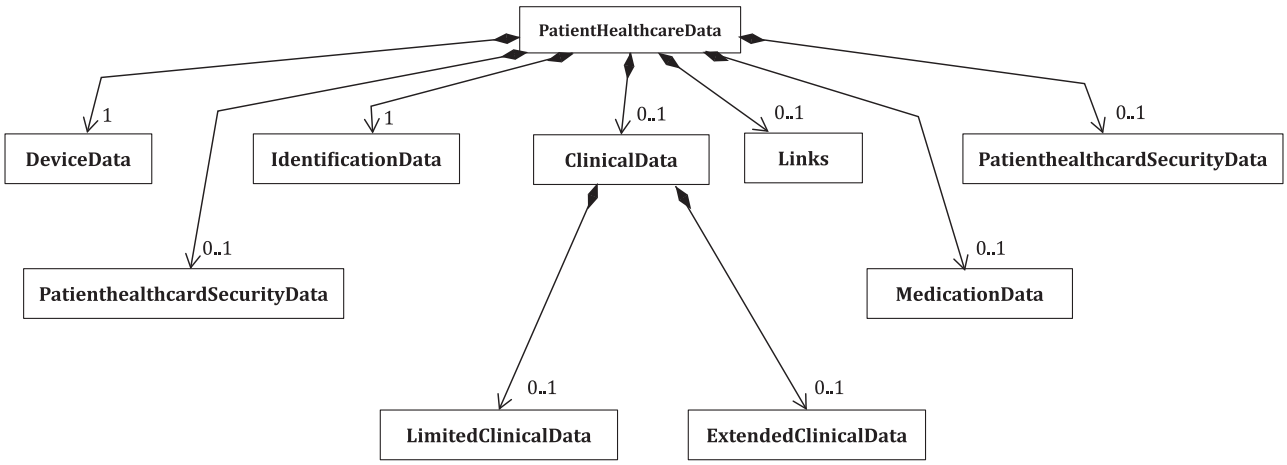

Figure 1 — Patient healthcard data — Overall structure

The content of this object-oriented structure is described both below and intrinsically will also require the use of data objects not defined within this document.

It is recognized that medication data is semantically a type of "clinical data". However, to enable more flexible implementation approaches, it is modelled as a direct child of the PatientHealthcardData object allowing a simpler and reduced model implementation where the full clinical data is not required.

NOTE It is possible to take the data objects and recombine them while preserving their context specific tags, and to define new objects, while still preserving interoperability.

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In addition to the capability of building complex aggregate data objects from simpler building blocks, this document allows for associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

5.2 Basic data objects for referencing

5.2.1 Overview

A series of generally useful data type definitions have been made that have no underlying meaning in themselves, but which are used to define other objects within this document. Operations may be performed with these objects in association with other information objects to add usability or business purpose. These objects have formal definitions within ISO 21549-2.

5.2.2 Coded data

Coded values are understood by reference to the coding system to which they apply. The general principle in this document is that it is not mandatory to use a particular coding system, unless specified within this document, when such codes act as parameters. One example is the use of the ISO 3166 series for country codes.

When a coding scheme is exclusively specified within this document, no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may however be modified in the future independent of the rest of this document.

The data object “CodedData” shall be constructed according to the definition contained in ISO 21549-2.

5.3 Device and data security attributes

Data stored in data cards used in health care may be personally sensitive. For this reason, this document utilizes a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this document, nor are the mechanisms that make use of these data elements. It is emphasized that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the data card.

Such rights of “access” are attributable to specific individuals with respect to discrete data items. These rights will be defined by local jurisdictions, organizational policies and local legal frameworks and implemented by application developers and can be controlled by automated systems such as health care professional cards. The rights may be defined at the application level, thereby providing application and potential country specificity.

The “SecurityServices” data object provides for the storage of data required to deliver these security functions and mechanisms. This data can be “attached” to individual data elements, thereby preserving the original author's security requirements when the data object is transferred between different forms of data card. This mechanism may therefore ensure that in the process of transferring data from active to passive media and then back to active media, the original security requirements are re-generated. This ability also allows exact replication of a data card such as on regeneration after failure.

5.4 Accessory attributes

The data object “AccessoryAttributes” shall consist of an ordered set of data that is essential to record of the resources which were accessed and/or used by whom regarding both the originator of the information and the means via which it arrives to the recipient as defined in ISO 21549-2.

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6 Functional requirements on card information for prescriptions

6.1 Overview of supported uses

Healthcards may be considered useful in many different functions in relation to medicine prescriptions. Two functions are for the identification of the patient and of the prescribing health professional toward the prescribing system. These two uses are considered to be outside of this document.

The major consideration in this document is for cards to provide information to other health professionals and to the patient or its non-professional care giver. However, the use for carrying a new prescription from the prescriber to the dispenser/pharmacy are also considered in the design of its data sets.

6.2 Carry a prescription from prescriber to the dispenser

6.2.1 General

A healthcard designed to carry a prescription between a prescriber and dispenser has, within its data set, to incorporate several different objects such as identifiers relating to the prescriber, dispensing agent, subject of care and the actual information in relation to the prescribed item/items. Information relating to the subject of care is considered to be static and provided/defined by other parts of the ISO 21549 series. Similarly are Prescriber and Dispensing agent, while there may be several different iterations of the same, these are essentially static and as such are covered by other parts of the ISO 21549 series.

6.2.2 Prescription set

A prescription issued for one patient by one prescriber at one occasion may contain several prescription items for individual medicinal products. The collection of items with some additional information relevant for all items is referred to as a prescription set.

6.2.3 Who

This is data relevant for the whole prescription set and has a series of specialisations of healthcare party.

<u>Patient</u>

This is the subject of care who is the intended recipient of a prescribed item.

NOTE For healthcards, only single patients are considered, not animals, nor groups of patients.

<u>Prescriber</u>

This is a specialization of a more generic concept that may be called a healthcare professional and is the healthcare professional who takes legal responsibility for the creation of the prescription and for providing the authority to dispense.

<u>Payment guarantor</u>

This is a specialization of healthcare party. These may be one or more insurance companies or other entity that, in one way or another, is involved with financial aspects of the prescription.

NOTE This can include the patient as guarantor.

<u>Dispenser</u>

This is a specialization of a healthcare professional which is a representation of an individual who has a pharmacist status who is filling/dispensing the prescription.

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6.2.4 What

These are the data relevant for a prescription item.

a) Name of the medicinal product:

— identified by brand name, generic name or code values for these (with reference to identification of code set, if used);

— this may include also medicinal appliance whereas magistral (extemporaneous) medicinal products are treated separately.

b) Strength;

c) Drug form;

d) Quantity;

e) Quantity units;

f) Manufacturer;

g) Code in respect to all above except possibly quantity units;

h) Magistral medicinal product.

6.2.5 Times

The followings are the points of time and intervals relevant for prescription and dispense:

a) time/date when a prescription is authorized;

b) time/date when a prescription is dispensed;

c) validity time (length of validity of prescription can be defined by legal framework of medicine supply regulations);

d) specified interval between multiple supplies of the same medication (for example, “not less than 21 d between supplies”).

6.2.6 How

The following information relates to a prescription item:

a) dosage instruction (plain text, CODED + numeric perhaps structure with time separate from amount);

b) comments of prescriber (to one item or the whole prescription);

c) special prescriptions (narcotics);

d) special license prescription;

e) substitution rules (if applicable in the local jurisdiction);

f) repeat prescription (no + possible time interval);

g) preferred language of the patient;

h) language of the prescription (these two refers to the prescription set).

6.3 Card information on dispensed prescriptions

Information on cards contains data on dispensed items. This information may be used at a future dispensing occasion by a health professional, in particular when considering new prescriptions. It is worth noting

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