INTERNATIONAL STANDARD

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Health informatics — Patient healthcard data —

Part 7:
Medication data

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 7: Données de médication

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21549-7 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

— *Part 6: Administrative data*

— *Part 7: Medication data*

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 insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases 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" has to contain device data and identification data and may in addition contain administrative, clinical, prescription and linkage data.

Device data is defined to include:

— identification of the device itself;

— 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:

— 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 benefit;

— 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);

— related actions planned, requested or performed;

Prescription data may include:

— a record of medications received by the patient;

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

— records of medications dispensed by the pharmacist to the patient;

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

Because a data card essentially provides specific answers to definite queries whilst 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

a) communicate prescription information from one healthcare person to another healthcare person such as to a healthcare agent or healthcare organization;

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

This part of ISO 21549 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 part of ISO 21549 does not describe and define the common objects defined within part 2 of ISO 21549 even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 7:
Medication data

1 Scope

This part of ISO 21549 is applicable to situations in which such data are recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO 7810.

This part of ISO 21549 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 part of ISO 21549 is for cards to provide information to other health professionals and to the patient or to their non-professional care giver.

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

Medication data includes the following four components:

— **medication notes**: the list of all medication for a patient;

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

— **medication dispensed**: the records of medications bought by the patient;

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

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with this part of ISO 21549, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in Clauses 6 to 8. These shall then be used in conjunction with other data defined in other parts of this part of ISO 21549. The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549 (although its structures can accommodate suitable data objects elsewhere specified):

— the encoding of free text data;

— security functions and related services that are likely to be specified by users for data cards depending on their specific application, e.g.: confidentiality protection, data integrity protection and authentication of persons and devices related to these functions;

— access control services that may depend on active use of some data card classes such as microprocessor cards;

— the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

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

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

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

It should be noted that not only the definition of "medicinal products" differs from country to country, but also the same name may relate to entirely different products in some countries. Therefore, special attention should be made for the safety of patient, when the card is used across borders

As a matter of course, exchange of prescription across borders must follow all laws, instructions, rules, terms and treaties between the said two countries.

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 7810, *Identification cards — Physical characteristics*

ISO 7498-2, *Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture*

ISO/IEC 7826-1, *Information technology — General structure for the interchange of code values — Part 1: Identification of coding schemes*

ISO/IEC 7826-2, *Information technology — General structure for the interchange of code values — Part 2: Registration of coding schemes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

ENV 13607:2000, *Health informatics — Messages for the exchange of information on medicine prescriptions*

3 Terms and definitions

Please note that there are many different terms used to describe the basic concepts in healthcare for different purposes available from ISO, CEN, HL-7 and various national organizations. The following definitions are not meant to be universal in ISO work in health informatics, only to facilitate the understanding of this part of ISO 21549.

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

3.1
attribute
characteristic of an object or entity

3.2
audit trail
record of the resources that were accessed and/or used and by whom

NOTE   This may involve a formal monitoring technique for comparison between the actual use of a medical information system and pre-established criteria.

3.3
authentication
process of reliably identifying security objects by securely associating an identifier and its authenticator

3.4
availability
property of being accessible and useable upon demand by an authorized entity

[ISO 7498-2, definition 3.3.11]

3.5
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

[EN 375:1992 E] [EN 376:1992 E]

3.6
clinical information
information about a subject of care, relevant to the health or treatment of that subject of care, which is recorded by or on behalf of a healthcare person

NOTE   Clinical information about a subject of care can include information about the subject of care's environment or about related people where this is relevant.

[ENV 1613]

3.7
code meaning
element within a coded set

EXAMPLE   "Paris Charles-de-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

3.8
code value
result of applying a coding scheme to a code meaning

EXAMPLE   "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

3.9
coding scheme
collection of rules that maps the elements of one set on to the elements of a second set

3.10
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989, definition 3.3.16]

3.11
data integrity
property that data has not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989, definition 3.3.21]

3.12
data object
collection of data that has a natural grouping and may be identified as a complete entity

3.13
data origin authentication
corroboration that the source of data received is as claimed

[ISO 7498-2:1989, definition 3.3.22]

3.14
dispenser
specialization of a more qualified healthcare person, which is a representation of an individual who has a pharmacist status and who is filling/dispensing the prescription

3.15
electronic healthcare record
healthcare record concerning the subject of care in computer-readable form

[ENV 13606-1]

3.16
healthcard holder
individual transporting a healthcare data card that contains a record with themselves identified as the major record person

3.17
healthcare
provision of health related services

NOTE   This includes more than performing procedures on subjects of care. It includes also, e.g., the management of information about patients, their health status and their relationship with their healthcare framework.

[CEN TC/251 PT30]

3.18
healthcare agent
healthcare person, healthcare organization, healthcare device or healthcare software component that performs a role in a healthcare activity

[ENV 13607]

3.19
healthcare data card
machine-readable card conformant to ISO 7810 intended for use within the healthcare domain

3.20
healthcare organization
organization involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE 1   Groupings or subdivisions of an organization, such as departments or sub-departments, may also be considered as organizations where there is need to identify them.

NOTE 2   "Healthcare organizations" is a subset of "healthcare agents".

[ENV 13607] [ENV 1613]

3.21
healthcare party
organization or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE   "Healthcare parties" is a subset of "healthcare agents".

[ENV 13607]

3.22
healthcare person
person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE   "Healthcare persons" is a subset of "healthcare parties", which again is a subset of "healthcare agents".

EXAMPLE   Primary care physician, dentist, nurse, social worker, pharmacist, medical secretary.

[ENV 13607]

3.23
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

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

[ENV 1613:1995]

3.24
immediate container
container that is in direct contact with the pharmaceutical product

[ENV 12610]

3.25
ingredient
substance included as a component in a product

NOTE   In this context product refers to pharmaceutical product.

[ENV 13607]

3.26
international coding scheme identifier
unique permanent identifier of a coding scheme registered for use in information interchange under the terms of ISO/IEC 7826-1 and ISO/IEC 7826-2

[ENV 13607]

3.27
linkage
ability to join together two or more entities or parts

NOTE   A linkage can be physical, electrical or relational.

3.28
magistral medicinal product
extemporaneous medicinal product
medicinal product manufactured in a pharmacy or a pharmacy department, which is based on a recipe and is intended to be used for one and only one subject of care

NOTE 1   A magistral/extemporaneous medicinal product is also a pharmaceutical product.

NOTE 2   The term extemporaneous medicinal product is not be used, as it is more appropriate in describing a medicine processed during the administration of a medicinal product, especially when a mixture is made just before, e.g., intravenous administration.

[ENV 13607] [ENV 12610]

3.29
medicinal appliance
device or piece of equipment which may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

NOTE   In order to be prescribable a medicinal appliance should fall within the purpose of prescribing as accepted by local rules/traditions in the area. The purpose of prescribing may be a requirement for formal reimbursement, restrictions on general sale of the appliance or need for labelling the appliance with individual instructions for use.

EXAMPLE   Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, nappies for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

[ENV 13607]

3.30
medicinal product
any substance or combination of substances, which may 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   Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this part of ISO 21549 as medicinal products.

[ENV 13607]

3.31
medicinal product package
package
delivery unit of a medicinal product in an outer container

[ENV 12610]

3.32
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

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

3.33
outer container
container that serves as an external layer of a package

[ENV 12610]

3.34
payment guarantor
organization responsible for the total or partial reimbursement or payment of the price of the medicinal product

[ENV 13607]

3.35
pharmaceutical product
product consisting of one or more ingredients

[ENV 13607]

3.36
prescriber
healthcare person authorized to issue prescriptions

[ENV 13607]

3.37
prescribing
process of creating a prescription

[ENV 13607]

3.38
prescription
direction created by an authorized healthcare person, 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   The term "prescription" alone should be avoided as it is colloquially used at random for the following terms: new prescription message, prescription set and prescription item. Further, it is also used to describe a prescription form. The use of the terms prescription set, prescription item and new prescription message where appropriate is recommended.

[ENV 13607]

3.39
prescription item
specification created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of single medicinal product/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

NOTE   A prescription item may contain administrative details needed for dispensing or derived from dispensing, but not contain information about the prescriber or the subject of care for whom the prescription item is prescribed or to whom it has been dispensed.

[ENV 13607]

3.40
prescription set
collection of one or more prescription item(s) prescribed and/or dispensed as a unit

[ENV 13607]