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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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Contents

Page

Foreword ... **iv**

Introduction ... **vi**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 Abbreviated terms ... **5**

5 Basic data object model for a healthcare data card ... **6**
5.1 Patient healthcard data object structure ... 6
5.2 Basic data objects for referencing ... 6
5.2.1 Overview ... 6
5.2.2 Coded data ... 6
5.3 Device and data security attributes ... 7
5.4 Accessory attributes ... 7

6 Functional requirements on card information for prescriptions ... **7**
6.1 Overview of supported uses ... 7
6.2 Carry a prescription from prescriber to the dispenser ... 7
6.2.1 General ... 7
6.2.2 Prescription set ... 8
6.2.3 Who ... 8
6.2.4 What ... 8
6.2.5 Times ... 9
6.2.6 How ... 9
6.3 Card information on dispensed prescriptions ... 9
6.4 Medication notes ... 9

7 Medication data ... **10**
7.1 General ... 10
7.2 "MedicationNotes" class ... 11
7.2.1 General ... 11
7.2.2 "MedicationHistory" class ... 12
7.2.3 "MedicationRelevantCharacteristics" class ... 13
7.2.4 "KnownMedicationRisks" class ... 14
7.3 "MedicationPrescriptions" class ... 15
7.4 "MedicationsDispensed" data object ... 23
7.5 MedicationReferences ... 30

Annex A (normative) **ASN.1 data definitions** ... **32**

Annex B (informative) **Example of medication notes** ... **48**

Bibliography ... **50**

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 21549-7:2007), which has been technically revised with the following changes:

— medication notes definition in Clause 1 is modified;

— the list of definitions in Clause 3 is shortened and several definitions are corrected and clarified;

— the list of abbreviation in Clause 4 is shortened;

— an explanation is added in 5.1 why MedicationData is modelled as a direct child of the PatientHealthcardData;

— "healthcare person" in 6.2.3 is replaced by "healthcare professional";

— "factor of the quantity" in 6.2.4 is replaced by "quantity units";

— "medication history" in 6.4 is changed to "medication notes" in the title and an explanation of a major use is modified;

— in Clause 7, all the names of attributes in the tables are harmonized with the class diagrams. The term "data object" is replaced by "class". Additional comments are included in the tables. For implementer's convenience, the fragments of ASN.1 definitions are gathered together in the new Annex A;

— explanation of MedicationNotes in 7.2.1 is modified;

— comments in Table 3 are modified;

— comments in Table 4 are modified;

— comments in Table 5 are modified;

— Example in 7.2.5 is moved to informative Annex B;

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— Figures 7 and 8 are merged. Class “Prescriber” is defined as an attribute. The attribute “qualification” is replaced by the attribute “qualifier” having datatype “CodedData”. The attribute “medicinalProduct” is renamed as “prescribedMedicinalProduct”. The class “MedicinalProduct” is renamed as “PrescribedMedicinalProduct”. The class “ManufacturedMedicinalProduct” is renamed as “PrescribedManufacturedMedicinalProduct”. The class “MagistralMedicinalProduct” is renamed as “PrescribedMagistralMedicinalProduct”. Datatype of the attribute “strength” is replaced by “Strength”, the definition of this new datatype is added. Datatype of the attribute “quantityOfMedicinalProduct” is replaced by “Quantity”. Datatype of the attribute “amountOfIngredient” is replaced by “Amount”. The class “AmountOfIngredient” is replaced by the class “Amount”;

— Figures 17 and 18 are merged. Class “Dispenser” is defined as an attribute. The attribute “dispensedMedicinalCode” is replaced by the attribute “dispensedMedicinalProduct” having new datatype “DispensedMedicinalProduct”. This new datatype is a generalization of the classes “DispensedManufacturedMedicinalProduct” and “DispensedMagistralMedicinalProduct”. The attributes “strength”, “form”, manufacturerOfMedicinalProduct” are moved from the class “ActualDispensedItem” to the class “DispensedManufacturedMedicinalProduct”. The attributes “batchIdentifier”, “genericSubstitution” are moved from the class “DispensingInformation” to the class “DispensedManufacturedMedicinalProduct”. Datatype of the attribute “quantityDispensed” is replaced by “QuantityToDispense”, so the class “QuantityDispensed” becomes unused and is deleted. The attributes “magistralMedicinalProductName” and “dispensedQuantity” are added to the class “DispensedMagistralMedicinalProduct”. The attribute “nameOfIngredient” is deleted from the class “DispensedIngredient”. Datatype of the attribute “quantityOfIngredient” is replaced by “Amount”. The attribute “nameOfContainerOrApplicationAid” is deleted from the class “DispensedContainerOrApplicationAid”;

— Figures 26 and 27 are merged;

— new ASN.1 definition is added in Annex A.

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 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 databases and support systems has led to the development and use of "Healthcare Professional" 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, medication and linkage data.

Device data is 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 health care, 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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