Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

National Standard for a Dispensing Note including a Clinical Document Architecture specification

November 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services –** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation –** Registering and inspecting designated centres.
- **Monitoring Children's Services –** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality –** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment –** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information –** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of Health Information function

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests – if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions – where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to

this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe, effective, transfer of information. This results in service users being asked to provide the same information on multiple occasions.

Information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high-reliability healthcare system.

ePrescribing was identified in the National eHealth Strategy (2013) as a key priority for Ireland. The benefits of ePrescribing and the electronic transfer of prescriptions initiatives are well documented and an increasing number of countries adopt the use of ePrescribing and the electronic transfer of prescriptions (ETP). These benefits include a reduction in medication errors, prescription and transcription errors with a corresponding improvement in patient safety. In order to support the implementation of ETP, multiple standards are required including an electronic medicinal product reference catalogue and messaging and document standards to define the information which should be transmitted between prescriber and pharmacist. The dataset and Clinical Document Architecture Standard (for trial use) for a dispensing

note supports the implementation of the electronic transfer of prescriptions in Ireland.

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1. Introduction

ePrescribing was identified in the National eHealth Strategy (2013)[1] as a key priority for Ireland. The benefits of ePrescribing initiatives are well documented and an increasing number of countries have adopted their use. These benefits include a reduction in medication errors, prescription and transcription errors, with a corresponding improvement in patient safety.

2. Background

The standard a *National Standard for a Dispensing Note including a Clinical Document Architecture specification* presented in this document was developed as per HIQA's current legislative remit under the Health Act 2007 and subsequent amendments to the Act. This gives HIQA a remit to set standards for the HSE, the Child and Family Agency (Tusla) and services funded by the HSE and to monitor compliance with those standards. Under the Health Act 2007**,** HIQA currently has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. The responsibilities of HIQA in this regard are outlined in the following sections of the Act:

- Section 8(1)(i): to evaluate available information respecting the services and the health and welfare of the population
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i)
- Section 8(1)(k): to set standards as HIQA considers appropriate for the HSE and service providers respecting data and information in their possession in relation to services and the health and welfare of the population.
- Section 8(1)(l): to advise the Minister for Health and the HSE as to the level of compliance by the HSE and service providers with the standards referred to in paragraph (k).

Under Section 8(1)(k) of the Health Act 2007, HIQA is charged with setting standards for health information. This includes standards for the communication of health information between healthcare providers.

HIQA undertook an international review of ePrescribing and the electronic transfer of prescriptions in 2012.[2] The review demonstrated that in the six jurisdictions reviewed, each has commenced implementation or already implemented ePrescribing solutions. Each of the jurisdictions reviewed focused mainly on prescribing and dispensing of medication in the community, rather than from the hospital setting to the community pharmacies. This is explained as a consequence of both general practitioners (GPs) and pharmacists having similar processes across their practices and hence being able to support computerisation of the process. By contrast, hospital medication management processes are typically a lot more complex, making standardisation and computerisation more complicated.

Each jurisdictions reviewed had undertaken the implementation of community-based electronic prescribing in a phased and incremental approach, with paper systems either included as part of the solution or paper systems supported in parallel with the electronic solution.

With the exception of Northern Ireland, each solution involved the transmission of an electronic prescription document from a GP's practice management system to a message or transaction broker, where the message was stored. Each solution then allowed pharmacists to retrieve the electronic document from the transaction broker and verify a prescription prior to providing the patient with their medication.

The international review provided information and evidence to aid the development of an electronic transfer of prescriptions solution for Ireland. Based

on this international review, it is clear that a number of fundamental building blocks must be in place prior to developing an electronic transfer of prescriptions solution. These include:

- introducing an individual health identifier (IHI) and an identifier for health and social care professionals and organisations
- developing an interoperability framework and supporting infrastructure to facilitate the safe and secure electronic transfer of prescriptions between prescribers and dispensing pharmacists
- developing a data model to support the implementation of a national drugs reference catalogue
- developing messaging and document standards to support electronic transfer of prescriptions.

In order to support the implementation of the electronic transfer of prescriptions, multiple standards are required to define the information that should be transmitted between prescriber and pharmacist.

In recent years, HIQA has undertaken multiple projects in the area and has published two standards in this regard. Firstly, a *Data model for an electronic medicinal product reference catalogue – a National Standard* (2015)[3] which outlines a data model for a medicinal product reference catalogue, and secondly an *ePrescription dataset and clinical document architecture standard* (2015)[4] which is a dataset and technical specification for electronic prescriptions. In addition, HIQA's general practice messaging standard (version 3.0)[5] was revised and information was included to describe the messaging standards for the electronic transfer of prescriptions. They included the messaging requirements for the electronic transfer of prescriptions between GPs and community pharmacy and included scenarios, clinical examples, message flows

and use cases relevant to the electronic transfer of prescriptions in the community.

2.1 Benefits of the electronic transfer of prescriptions

There are many benefits which can arise out of implementation of electronic transfer of prescriptions for patients, healthcare practitioners and organisations that fund the health and disability sector.

Patients, people in care and the health and disability sector will benefit from the electronic transfer of prescriptions and ePrescribing through:

- safer care because the electronic transfer of prescriptions and ePrescribing reduces manual data entry and therefore transcription errors resulting in reduced risk of a prescribed medicine not being correctly dispensed
- safer care because prescribed medicines descriptions are more accurate and there is improved legibility of prescription details
- fewer hospital admissions or unwanted adverse effects because prescribers and pharmacist can monitor patient compliance with prescribed medicines
- having prescriptions dispensed more quickly through more efficient processes.

Healthcare practitioners who prescribe medicines will benefit from the electronic transfer of prescriptions through:

- the ability to receive notification when a patient collects prescribed medicines enables patient compliance and patient follow-up

- reduced interruptions from pharmacies querying prescriptions fewer prescriptions having to be returned to the prescriber for correction because they do not comply with legal or subsidy requirements
- better clinical decision-making, leading to safer and higher quality care, through timely access to selected health information about an individual if the electronic transfer of prescriptions solution is linked to an electronic patient record.

Pharmacists who dispense medicines will benefit from the electronic transfer of prescriptions through:

- the use of a common list of medicines in both prescriber and pharmacy systems. This means the pharmacy can more quickly and accurately select the intended medicine for the patient
- improved quality of prescription information and therefore a reduction in time spent contacting prescribers to clarify or correct prescriptions
- the ability to download prescription details and not having to enter this manually can potentially make the process more efficient with less room for error

Organisations that fund the health and disability sector will benefit from the electronic transfer of prescriptions through:

- improved efficiency to health information flows and a reduction in duplicate prescribing
- potential reductions in costs from improved patient compliance and reduced hospitalisation by being able to monitor collection of prescriptions by individuals

- efficiency gains enabling pharmacists to provide other patient orientated services.
- improved consistency with the adoption of electronic transfer of prescriptions (ETP) standards (and therefore better consumer understanding and control of) the policies, processes and mechanisms that are put in place to ensure the privacy of electronic healthcare records.

Further, where prescribing and dispensing information is sent to electronic health Rrecords, organisations responsible for the delivery of healthcare outcomes through population-based strategies can also benefit through:

- support for optimised prescribing, for example, improving the management of long-term health conditions
- being able to recall prescribing and dispensing history when seeing a different healthcare practitioner
- enabling the development of quality programmes, for example, reducing wastage by prescribing appropriate quantities of medicines, addressing and reducing unexplained variability in prescribing patterns among providers, and establishing an evidence base for use of new and or potentially expensive medicines
- improved support for future permissible secondary uses of data to deliver further public benefits, such as more targeted health initiatives, public health planning, research, education and disease detection when the ETP solution is linked to a longitudinal electronic patient record.

3. Scope of Standard

The purpose of the standard is to define a minimum dataset for a dispensing note and to define a Health Level 7 (HL7) Clinical Document Architecture (CDA) specification based on the dataset. A dispensing note identifies the actual medication supplied by the dispensing pharmacist to the patient when fulfilling a prescription. The scope of the dataset in this standard is to define a minimum dataset of medication(s) dispensed to a patient in a community pharmacy for use in a summary care record. International evidence identifies that for the purpose of a summary care record, only a subset of a dispensing record is required.

The dataset defined in this standard does not attempt to cover all of the information - clinical, financial and legal, which should be recorded in a pharmacy at the time of dispensing medication to a patient which is a much broader dataset than the dataset required in a dispening note generated for the purpose of a summary care record. This information could include substitutions, alterations to a prescription or seeking clarification from the prescriber.

The development of a standard for recording medications dispensed is a key enabler for the effective and accurate exchange of information and ultimately for increasing patient safety.

4. Approach

The standard was developed as trial for use. It was developed by HIQA in collaboration with a technical subgroup. The technical subgroup was made up of members from HIQA's eHealth Standards Advisory Group (eSAG) and other representatives from:

- the General Practioner Information Technology Group
- the Irish Pharmacy Union

- the National Standards Authority of Ireland
- the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
- a subject matter expert in Pharmacy
- the Health Service Executive (HSE) National ePharmacy Programme.

The technical subgroup defined a draft dataset based on analysis of specifications and standards developed in other jurisdictions. Other jurisdictions reviewed produced very minimal datasets for the purpose of this use case, that is to say, records the medication dispensed in community pharmacy for use in a summary care record. The datasets analysed included:

- Australian Digital Health Agency - PCEHR Prescription and Dispense View - Structured Content Specification v1.0.
- openEHR- Clinical Knowledge Manager Medication Order Archetype.
- European Union - Smart Open Services for European Patients D3.1.2 Final definition of functional service requirements – ePrescription.
- HL7 FHIR Resource Medication Dispense.

Relevant data from national clinical datasets already developed by HIQA such as the demographic dataset, referrals and discharge summary datasets also informed the standards development process, as did contributions from the subgroup members acting as subject matter experts in the field of pharmacy.

Following development of the dataset, a CDA specification was developed. Several international CDA implementation guides were researched to inform this specification. They included the:

- HL7 Implementation Guide: CDA R2 Continuity of Care Document (CCD).[6]
- epSOS Semantic Implementation Guidelines.[7]
- Integrating the Healthcare Enterprise, Patient Care Coordination Technical Framework (IHE PCC).[8]
- Australian eDispensing CDA Implementation Guide Version 2.1.[9]

This standard was based primarily on a CDA specification developed by the epSOS project. epSOS was a large European initiative to facilitate cross-border transfer of electronic patient summary documents and electronic prescriptions and electronic dispensing. The epSOS project reused information and specifications from other leading organisations who are considered experts in the area of CDA implementations including the HL7 CDA Standard, the HL7 clinical care document specification and the Integrating the Healthcare Enterprise Patient Care co-ordination specification.

4.1 Targeted consultation

The standard was developed in conjunction with the members of the HIQA eHealth Standards Advisory Group. A targeted five-week consultation was undertaken. A consultation feedback form outlined five questions (see Appendix 1) and a general comments section. This consultation form was made available on HIQA's website together with the consultation document itself.

In order to engage with as many people as possible, emails were sent to 45 stakeholders inviting them to participate in the targeted consultation.

Information about the consultation was also circulated to the Council of Clinical Information Officers.[1]

A total of 11 submissions were received, submitted by email and online correspondence. Four respondents completed the online form and seven respondents submitted their comments by email. Of the 11 submissions, eight were submitted on behalf of organisations and three were submitted in a personal capacity. Appendix 1 outlines the organisations that made a submission.

Each submission was read in its entirety and was broken down into general comments and individual items that directly relate to the data items in the standard. Appendix 1 provides a review of the qualitative comments made and the changes to the standard that were agreed as a result of the submissions received.

[1] The Council of Clinical Information Officers has been established to provide clinical governance to the delivery of eHealth solutions across the Irish Healthcare system. Its role is primarily as an advisory group, with primary governance oversight provided by the Office of the CIO and the eHealth Ireland board.

5. Minimum dataset for a Dispensing note

A high-level class model for the standard is illustrated in Figure 1 representing the clinical aspect of the dataset. The model consists of a pharmacist who is associated with the dispense note. Each dispense note is associated with multiple dispensed items. The dispensed items correspond to each unique entry in a dispense note.

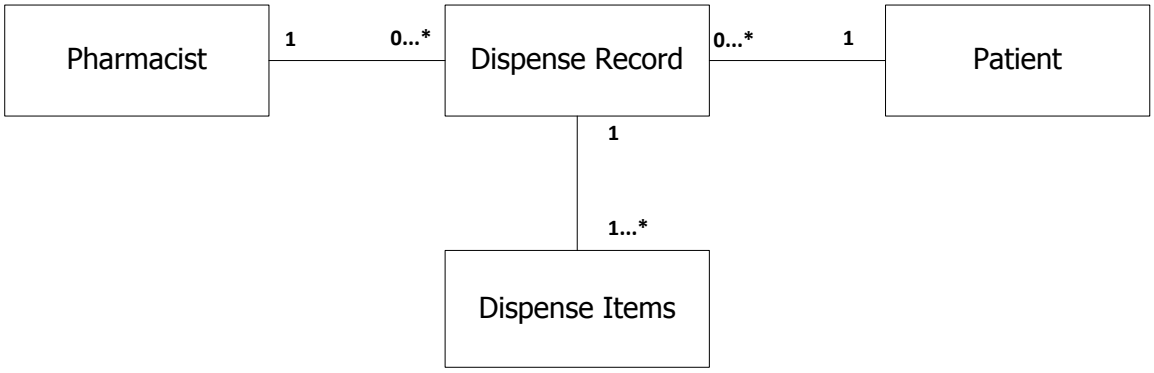

Figure 1: Model for a Dispense note

The dataset includes information for the subject of care (the patient), the pharmacist, dispense note and dispense items. Table 1 defines the clinical dataset to be supported by this standard. In addition to the clinical dataset, the CDA standard requires information about the document identification and the custodian and author of the document. These requirements are listed in Appendix 2 and Appendix 3.

Each of the classes and associated attributes are described in the tables below which define the name of the data element, definition, optionality and usage of the data elements.

5.1 Minimum Dataset

Table 1: Minimum dataset for dispensing note

Data Element	Definition	Optionality	Usage
1.1 Date of creation of dispensing note	The date (and optionally time) when a pharmacist created a dispense note of item(s) for the patient.	Mandatory	Date field which indicates when the prescription was dispensed.
1.2 Medicinal Product	The name of the medicinal product or package. This should be sufficient to identify the medicinal product dispensed. It may be a trade name or a generic name.	Mandatory	A coded textual description associated with the medicinal product.
1.3 Medicinal Product ID	A unique identification number associated with the medicinal product referred to in 1.2.	Optional	This will cater for a product-id for a national product catalogue.
1.4 Medicinal product package	Size and or type of package prescribed.	Optional	When prescribing occurs at a package level, this field is used to describe the size and type of the package to dispense.

1.5 Number of packages	Number of complete packages required to fulfil the prescription.	Optional	When prescribing occurs at a package level, this field is used to describe the number of the package(s) to dispense
1.6 Dose form (strength)	Content of the active ingredient expressed quantatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.	Conditional	This field consists of a size value and unit, a combination of both defines the strength, for example 250mg or 1g. If 1.4 and 1.5 are populated, then this field does not need to be populated.
1.7 Dose form (type)	A description of the dose type.	Conditional	This field describes the dose type, such as tablet or vial. If 1.4 and 1.5 are populated, then this field does not need to be populated.

1.8 Total number of dose instances	Total number of instances of the medicinal product supplied to the patient by the pharmacist	Conditional	This field is used to describe the number of the unit(s) to dispense. If 1.4 and 1.5 are populated then this field does not need to be populated.
1.9 Instruction	Instructions to the subject of care concerning the medication.	Mandatory	A textual description associated with instructions to the subject of care.
1.10 Comments	Any additional information that may be needed to ensure the continuity of supply, proper use, or appropriate medication management.	Optional	A textual description associated with additional information.

6. Clinical Document Architecture (CDA) standard

This section defines the CDA specification for a dispensing record and is based on the dataset defined 5.1 above. Section 6.1 provides guidance on how to interpret the CDA dispensing note specification. Section 6.2 details the CDA specification for dispensing. The background information on the CDA is provided in Appendix 4.

6.1 Description of the CDA specification tables

The specification is defined using a table structure as illustrated in Table 2. The purpose of each of the columns is explained in this section.

Table 2: Attribute Table for defining CDA documents, sections and entries

Num	Data element	CDA xpath expression	Optionality/ Cardinality	HL7 v3 Data Type	Vocabulary

A. The 'Number' column

The 'Num' or 'Number' column contains a unique number that identifies the data element and is used for reference purposes.

B. The 'Data element' column

The data element defines the name of the field.

C. The 'CDA xpath expression' column

The CDA xpath expression is used to search through an XML document and locates and extracts information from the nodes (any part of the document, such

as an element or attribute) in that document. This is used to help in the implementation of a CDA specification and corresponds to the XML representation required for implementation.

D. The 'Optionality and Cardinality (Opt/Card) column

The optionality, as well as the cardinality information is associated with each data element in the table. The optionality used for this specification is based on the optionality included in the epSOS specification. The optionality descriptions and acronyms are included in Table 3.

Table 3: Optionality used in the CDA Diagnosis specification

Value	Meaning
R	Required - the mapped CDA element shall be present and shall not contain the nullFlavor attribute.
RNFA (or R use NullFlavor)	Required Null Flavor Allowed - the mapped CDA element shall be present and it may contain the nullFlavor attribute. In some cases, the recommended nullFlavor value is also indicated.
O	Optional - the mapped CDA element may be omitted unless required by the CDA and/or by the template specifications.
NA	Not applicable since the data element is not applicable in the respective document.

The cardinality rules that may be used for sections and data elements are described in Table 4.

Table 4: Cardinality used in the CDA Diagnosis specification

Value	Meaning
0..1	The section or data element may have zero or one instance.
1..1	The section or data element may have one and only one instance.
0..*	The section or data element may have zero or more instances.
1..*	The section or data element may have one or more instances.

For example, the cardinality of a Patient Identifier for example the Individual Health Identifier is [1...1]. This is a one-to-one relationship which means that we require the Patient Identifier. A cardinality of [0...*] means that that there are optionally many (more than one) additional identifiers.

E. The 'HL7 v3 Data Type' column

Each data element has a data type associated with it. This column indicates the HL7 v3 data type that must be used for the field. Information about HL7v3 data types may be found in Appendix 5.

F. The 'Vocabulary' column

The vocabularies or terminologies that are used throughout this specification include epSOS value sets that are sourced and SNOMED CT and are listed in Appendix 6.

6.2 Clinical Document Architecture specification

The CDA data attributes for the dispense note is outlined in Table 5.

Table 5: Dispense note

Num	Data Element	Description	CDA xpath Expression	HL7 V3 Data Type	Card /Opt	Vocab
Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2 Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3						
1.1	Date of creation of dispensing record	The date (and optionally time) when an pharmacist created a dispense note of item(s) for the patient.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value	TS	R [1..1]	
1.2	Dispensed Medicine ID	A string generated by an EDS (Electronic Prescribing System) to uniquely identify an action of dispensing a medication.	entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProduct/manufacturedMaterial/id	II (Instance Identifier)	R[1..1]	

1.3	Medicinal Product	The name of the medicinal product or package. This should be sufficient to identify the medicinal product dispensed. It may be a trade name or a generic name.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/consumable/manufacturedProduct/manufacturedMaterial/name	Coded TXT	R [1...*]	
1.4	Medicinal product package	Size and or type of package prescribed.	entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProduct/manufacturedMaterial/asContent/containerPackageMedicine/formCode	CD	RNFA [1..1]	epSOSPackage 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
1.5	Number of packages	Number of complete packages required to fulfil the prescription.	1.3.6.1.4.1.12559.11.10.1.3.1.3.3 entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/quantity	PQ, PQ	0[1..*]	

1.6	Dose form (strength)	Content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.	entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity	PQ, PQ	R[1..1]	
1.7	Dose form (type)	Form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorisation holder, manufacturer and or distributor.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/consumable/manufacturedProduct/manufacturedMaterial/formCode	CD	R[1..1]	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
1.8	Total number of dose instances	Total number of instances of the medicinal product required to fulfil the prescription.	1.3.6.1.4.1.12559.11.10.1.3.1.3.3 entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/quantity	PQ, PQ	0[1..1]	
1.9	Label	Dispensing pharmacists instructions to the subject of	<text><reference	ST	R[1..1]	

	instruction	care concerning the medication.	value='#comment'/></text>			
1.10	Comments	Any additional information that may be needed to ensure the continuity of supply, proper use, or appropriate medication management	<text><reference value='#comment'/></text>	ST	O[0..*]	
1.11	Prescription ID	A link back to the original prescription identifier.	/ClinicalDocument/component/structuredBody/component/section[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/id	II (Instance Identifier).	R[1..1]	

Appendix 1. Statement of Outcomes

A total of 11 submissions were received during the consultation process. HIQA welcomed all submissions and would like to thank all those who contributed. The organisations that made submissions to the targeted consultation include:

- The Irish Pharmacy Union
- Health Service Executive (HSE) group engaged with Dublin City University, School of Nursing and Health Sciences, International Classification for Nursing Practice Centre
- DMF Systems Ltd.
- HSE - Knowledge Management/Health Intelligence
- Irish Pharmaceutical healthcare association (IPHA)
- Pharmaceutical Society of Ireland (PSI)
- Nurse Midwife Medicinal Product Prescribing Team (HSE)
- National General Practice Information Technology Group.

Submissions were also made by individuals in a personal capacity. All submissions have received an acknowledgement of their contribution. All submissions to the consultation informed the development of the final national standard.

1.1 Changes to the Dispense note Draft Standard

Each submission received was read in its entirety, analysed and a decision was made to either include or exclude responses to the standard. A rationale for inclusion or exclusion of a response was given. The responses received were identified as a qualitative comment or as feedback that related to the individual data items of the dataset and Clinical Document Architecture (CDA) specification.

1.2 Changes to minimum dataset and CDA standard.

There were four changes made to the dataset following the targeted consultation. Table 1 below outlines the changes that were made to the data items of dataset.

Table 1: Changes to dataset

Number (as defined in existing dataset)	Data item	Change agreed
1.1	Date	Change title to 'date of creation of dispensing record'.
1.1	Date	Change definition to 'the date (and optionally time) when an authorised dispensing pharmacist created a dispense note of item(s) for the patient'.
1.2	Medicinal Product	Change the usage for the medicinal product to coded text.
N/A	Medicinal Product ID	Add a new data item called the Medicinal Product ID. The optionality should be 'optional'. This will cater for a product ID for a national product catalogue.

1.3 Feedback on consultation questions

Consultation Question 1
Are there benefits in having a standardised eDispensing Dataset and Clinical Document Architecture specification and, if so, what are the main benefits?

Overall respondents were satisfied that there are benefits in having a standardised dispense note dataset and Clinical Document Architecture specification. Some of the feedback comments included:

"Yes as it will allow interoperability going forward and play a role in improving patient safety".

"*As a component of EHR, eDispensing links directly with medication management particularly in regard to facilitating the safe and effective use of the medication prescribing processes for citizens in Ireland. Publication of a standardised eDispensing Dataset and Clinical Document Architecture capitalizing on the extensive toolkit created by epSOS over the past 10 or more year makes absolute sense. If adopted and deployed at a system and service level the anticipated benefits should be significant not only for patient safety but also to the tax payer."*

Consultation Question 2
Have the appropriate classes been included in the eDispensing data model?

Overall respondents agreed that there appropriate classes were included in the Dispense note data model.

"Consultation with HSE EA National Data Dictionary group would indicate that this standard provides the core classes and associated attributes as outlined in the document. HSE is progressing towards a National Data Dictionary, as this document has used the epSOS Toolkit we anticipate that the classes value and attributes listed will adequately meet the anticipated requirements".

Consultation Question 3
Have all of the appropriate data items been included in the eDispensing dataset? Would you leave out any of the data items listed? Would you suggest additional data items?

Table 1 reflects the changes that were suggested by respondents in relation to the dataset.

Consultation Question 4
Do the explanations provided in Table 1 of the consultation document adequately explain each of the data items? If not, please suggest improvements?

"Yes we consider that the appropriate explanations on the data items have been included".

"They are clear and well explained".

Consultation Question 5 Are there any alterations needed for the clinical document architecture specification? If so, please suggest improvements?

Overall respondents were satisfied with the CDA specification.

"Yes. The CDA standard supports the implementation of local requirements by allowing additional XML elements and attributes (local extensions) to be included in implementation guides. Please minimise the use of Local Extensions this is where issues around data integration become complex. It's best if possible to control these extensions at a National level."

1.4 Overall feedback

Qualitative comments were identified during the analysis. The overall consensus from respondents is that the development of draft standards for a dispensing note is highly beneficial. The standards can facilitate the unambiguous sharing of information between providers.

"We consider this draft standard for eDispensing dataset and clinical document architecture to be well written and fit for purpose".

"We consider this draft standard to be an integral component (building block) in progressing the eHealth Ireland Knowledge and Information Strategy to achieve integrated care across and between service providers in Ireland."

Appendix 2. Datasets

The following datasets defined here are needed for the Dispensing note standard: Subject of care, Pharmacist, Document, Author and Custodian.

Subject of care (Patient)

The subject of care is the person who the medication is dispensed for.

Table 1: Subject of care

Name	Definition	Optionality	Usage
1.1 Title	Coded value that contains the title relevant to the subject of care.	Optional	To be selected from a predefined list.
1.2 Forename	A patient's first name or given name(s) as per their birth certificate.	Mandatory	A patient's first name or given name (s) as per their birth certificate.
1.3 Surname	The second part of a patient's name which denotes their family or marital name.	Mandatory	The second part of a patient's name which denotes their family or marital name.
1.4 Address	The location to be used to contact or correspond with the patient. This would	Mandatory	The particulars of the place where the patient lives.

	normally be the patient's usual home address.		
1.5 Date of birth	Date of birth indicating the day, month, and year when the patient was born.	Mandatory	The date of birth should be supplied in dd/mm/yyyy format.
1.6 Gender	Gender identity is a person's sense of identification with either the male or female sex, as manifested in appearance, behaviour and other aspects of a person's life.	Mandatory	Gender identity is a person's sense of identification with either the male or female sex, as manifested in appearance, behaviour and other aspects of a person's life.
1.7 Health identifier	A number or code assigned to an individual to uniquely identify the individual within an organisation.	Mandatory	Both the code and the code type the code relates to should be provided e.g. 0987654321 Healthcare Record Number (HcRN). When a national individual healthcare number is available this should be carried in this attribute. Other identifiers which may be carried in this field include the General

			Medical Scheme, Drug Payment Scheme, Long term illness scheme and Hardship scheme identifier.

Dispensing pharmacist

The pharmacist who dispenses the medication is known as the dispensing pharmacist.

Table 2: Dispensing pharmacist

Name	Definition	Optionality	Usage
2.1 Title	Coded value that contains the title relevant to the healthcare practitioner.	Optional	To be selected from a predefined list.
2.2 Forename	First name or given name of the pharmacist.	Mandatory	Where the pharmacist is registered with a regulatory body, the forename should be the forename registered with the regulatory body.
2.3 Surname	The second part of a pharmacist's name which denotes their family or	Mandatory	Where the pharmacist is registered with a regulatory

	marital name.		body the surname should be the surname registered with the regulatory body.
2.4 Address	The particulars of the place used to correspond with the healthcare practitioner including the name and address of the pharmacy premises where the medication is dispensed.	Mandatory	The particulars of the place used to correspond with the pharmacist.
2.5 Telephone number	The telephone number of the pharmacist.	Mandatory	The phone number to contact the pharmacist.
2.6 Email address	A secure email address for the pharmacist .	Optional	The secure email address to contact the pharmacist.
2.7 Fax Number	The fax number for the pharmacist.	Optional	The fax number to contact the pharmacist.
2.8 Health identifier	A number or code assigned to an individual to uniquely identify the individual within an organisation or regulatory body.	Mandatory	The number or code assigned to the professional by its regulatory authority or the health services providers identifier when it is

			implemented.

Document identification

Table 3: Document identification

Name	Definition	Optionality	Usage
Clinical Document	The ClinicalDocument class is the entry point into the CDA R-MIM.	Mandatory	This data element is fixed and must always be included in the document. The <ClinicalDocument> XML element is the root element of a CDA document.
Type ID	This element represents the type of clinical document (for example, ePrescription, Dispense note) and identifies the constraints imposed by CDA R2 on the content, essentially	Mandatory	This data element is fixed and must always be included in the document. The @root and @extension values of this element are specified as a long fixed identifier which is in two

	acting as a version identifier.		parts: root and extension.
Template ID	TemplateID is used to indicate any number of templates which might be defined at the document level, sections and clinical statement entries. Allows for the identification of templates that specify additional constraints above and beyond the base CDA R2 structure.	Mandatory	This data element is fixed and must always be included in the document.
Document ID	This is the identifier of the Clinical Document which uniquely identifies the document instance.	Mandatory	The extension typically contains the institution assigned identifier. The root is an OID that identifies the assigner of the identifier. Each revision of a clinical document is assigned a distinct identifier.
Document Title	This is the human readable name of the clinical document.	Optional	The document title can be rendered by the browser as the caption of the document.
Date of creation	The time and date that the document	Mandatory	The time and date that the

	came into being.		document came into being.
Date of last update of document	This element represents the last effective date when the summary content has been updated.	Optional	This element represents the last effective date when the summary content has been updated.
Clinical document code	Determines the document type.	Mandatory	A coded value typically drawn from LOINC (HL7 LOINC Document Type Vocabulary Domain).
Confidentiality code	Codes that identifies how sensitive a piece of information is and or that indicate how the information may be made available or disclosed.	Mandatory	A coded value, CDA defines a limited set which can be extended as needed. The HL7 coding system contains the following codes: N-Normal/R-Restricted and V-Very restricted. Other coding systems may be used.
Legal Authenticator	Legal authenticator may be a person or an organisation that is responsible for	Mandatory	Legal authenticator may be a person or an organisation that is responsible for the medical

	the medical content of the document.		content of the document.
Document Language Code	Language Code as defined by RFC3066.	Mandatory	The language code shall be in the form nn-CC. The nn portion SHALL be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage. The CC portion SHALL be an ISO-3166 country code in upper case derived by the value Set epSOSCountry. For example: <Language Code> <COUNTRY CODE><languageCode code="en-GB"/>
Set ID	Identifier for a set of related documents. The original document and replacement documents versions thereof all share one and the same setId – they all have a unique document identifier (the ID attribute as	Optional	This element is not mandatory, but you should include them if you are sending a new version of a document that has been published before. Implementers are recommended to use this

	present in the header).		attribute.
Version Number	Contains the version number of this version of the document within a set of related documents.	Optional	For additional information see the description of *Other Participants: relatedDocument:* it is used to link a later version of a document to a previous version of a document. Example: ClinicalDocument/versionNumber/@number="1"

Author

This section defines the author data items required by the CDA specification. The author is the person responsible for the document. This information is required by the CDA standard.

Table 4: Author information

Name	Definition	Optionality	Usage
Author ID number	The identifier number of the health practitioner who is responsible for	Mandatory	The number or code assigned to the professional by its

	dispense note.		regulatory body or the health service's provider's identifier when it is implemented. This could be the superintendent pharmacist. The author is the individual that has logged in at the terminal at the time of record generation.
Author title	Coded value that contains the title relevant to the author of the document.	Optional	To be selected from a predefined list.
Author forename	The author's first or given name(s) as per their birth certificate.	Mandatory	Where the author is registered with a regulatory body, the forename should be the forename registered with the regulatory body.
Author surname	The second part of the author's name which denotes their family or marital name.	Mandatory	Where the author is registered with a regulatory body the surname should be the surname registered with the regulatory body.

Author profession	Coded element that specifies theauthor's particular profession.	Mandatory	This value can be selected from a predefined list.
Author telephone number	The author's telephone number.	Mandatory	The phone number to contact the author.
Author's email address	The author's email address.	Mandatory	The secure email address to contact the author.
Author's address	The particulars of the place used to correspond with the author i.e. the name and address and of the of the pharmacy premises where the medication was dispensed	Mandatory	The particulars of the place used to correspond with the author.

Custodian

The custodian represents the organisation that is in charge of maintaining the document. This information is required by the CDA standard.

Table 5: Custodian information

Name	Definition	Optionality	Usage
Custodian	Defines the person or organisation	Mandatory	Every CDA document has

	responsible for the document.		exactly one custodian. The custodian could be the superintendent pharmacist.
Custodian ID	A unique identifier for the custodian.	Mandatory	Unique identifier for the custodian.
Custodian name	The name of the organisation that is responsible for maintaining the document.	Mandatory	For example, the name of the GP practice.
Custodian address	The location of the organisation that is responsible for maintaining the document. This would usually be the healthcare provider's address.	Mandatory	This could be the healthcare provider's address.
Custodian's telephone number	The custodian's telephone number.	Mandatory	The custodian's telephone number.
Custodian's email address	The custodian's email address.	Mandatory	The custodian's email address.

Appendix 3. Clinical Document Architecture Specification

Record target (Patient information)

In clinical document architecture (CDA) documents, the person the clinical information relates to is known as the record target. The recordTarget class represents the medical record that this document belongs to. A clinical document typically has exactly one recordTarget participant. The data attributes for patient information are outlined in Table 1.

Table 1: Record Target

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
CDA header level template The template id for patient information is 1.3.6.1.4.1.19376.1.5.3.1.1.1 (epSOS)						
1.1	**Individual health identifier**	User ID of individual.	/ClinicalDocument/recordTarget/patientRole/id	II	0[0...1]	
1.2	**Family Surname**	Patient's second name which denotes their family or marital name.	/ClinicalDocument/recordTarget/patientRole/name/family	PN	R [1...*]	

1.3	**Given Name**	Patient's identifying name.	/ClinicalDocument/recordTarget/patientRole/name/given	PN	R [1...*]	
1.4	**Prefix**	Coded value that contains the title relevant to a specific family name for the patient.	/ClinicalDocument/recordTarget/patientRole/prefix	PN	O [0...*]	
1.5	**Date of Birth**	The date of birth of the subject of care.	/ClinicalDocument/recordTarget/patientRole/patient/birthtime	TS	R [1..1]	
1.6	**Gender**	Sex is the biological distinction between male and female. Where there is inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.	/ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	CE	R use nullFlavor = UNK [1..1]	
1.7	**Address**	The assignedEntity.addr is a mixed content element so if the individual components of an address are not available then the entire address could be put in this	/ClinicalDocument/recordTarget/patientRole/patient /addr	AD	R [1..1]	

		element.				

Dispensing pharmacist

The electronic dispensing information consists of both the dispensing pharmacist and the medication information. Appendix 1 outlines the data attributes for pharmacist. Table 2 outlines the data attributes for the medication information. Both tables are outlined below.

Table 2: Dispensing pharmacist information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/Opt	Vocabulary
The templateId for pharmacist (Author) is 1.3.6.1.4.1.19376.1.5.3.1.2.3 (without the PCC patient identifier extension) (epSOS) The template ID referenced here refers to HCP information in the ClinicalDocument/author/assignedAuthor/assignedPerson structure						
1.1	**Time of dispensing**	The timestamp of dispensing the document. The date and time stamp when the dispense note	/ClinicalDocument/author/time	TS	R [1...*]	

		was created.				
1.2	**Pharmacist ID number**	User ID of individual that is clinically responsible for the document.	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	
1.3	**Pharmacist family surname**	Pharmacist's second name which denotes their family or marital name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/family	PN	R [1...*]	
1.4	**Given name**	Pharmacist's identifying name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	PN	R [1..*]	
1.5	**Pharmacist prefix**	Coded value that contains the title relevant to a specific family name for this author.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix	PN	O [0...*]	
1.6	**Pharmacist profession**	Coded element that specifies the health practitioner's particular profession.	/ClinicalDocument/author/functionCode	CD	R [1..*]	For example, using the ISCO coding system, the code for a general practitioner is

						2211, while the code for a pharmacist is 2262
1.7	**Pharmacist telephone number**	The pharmacist's telephone number	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	R use nullFlavor [1..*]	
1.8	**Pharmacist email address**	The pharmacist's secure email address	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/ /telecom/@value	TEL	O [0..*]	
1.9	**Pharmacist fax number**	The pharmacist's fax number	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	O [0...*]	

Document Identification

This section defines the document identification and data items required by the CDA specification. This information is required by the CDA standard.The header identifies and classifies the document and provides information on the authentication, the encounter, the patient, and the involved providers. The attributes for the document header are outlined in Table 3.

Table 3: Document identification

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
CDA header level template The templateId for the document identification is 1.3.6.1.4.1.19376.1.5.3.1.1.1 (epSOS)						
1.1	**Clinical Document**	The ClinicalDocument class is the entry point into the CDA 1..1 R-MIM, and corresponds to the <ClinicalDocument> XML element that is the root element of a CDA document.	/ClinicalDocument	CS	Fixed[2]	
1.2	**Type ID**	This element represents the type of clinical document (e.g. ePrescription, Dispense note). The clinical document typeId identifies the constraints	/ClinicalDocument/typeId Example :<typeId extension="POCD_HD000040"	II	Fixed	

2 A fixed or default value element must always be included in the document and entered exactly as shown to ensure conformance to the CDA 2.0.

		imposed by CDA R2 on the content, essentially acting as a version identifier. The @root and @extension values of this element are specified as a long fixed identifier which is in two parts: root and extension.	root="2.16.840.1.113883.1.3"/> which is the unique id & extension for the CDA, Release Two Hierarchical Description.			
1.3	**Template ID**	templateID is used to indicate any number of templates which might be defined at the document level, sections and clinical statement entries. Allows for the identification of templates that specify additional constraints above and beyond the base CDA R2 structure. Example: The template ID for an ePrescription document is ClinicalDocument/templateId/@root="1.3.6.1.4.1.12559.11.10.1.3.1.1.3"/	/ClinicalDocument/templateId	II	Fixed	
1.4	**Document**	This is the identifier of the	/ClinicalDocument/id	II	R	

	ID	Clinical Document. The extension typically contains the institution assigned identifier. The root is an OID that identifies the assigner of the identifier. Each revision of a clinical document is assigned a distinct identifier. Uniquely identifies the document instance. Refer to the RIM for II data types (instance identifiers). <id extension="a123" root="2.16.840.1.113883.19.2744.1.1" />			[1..1]	
1.5	**Document title**	This is the human readable name of the clinical document. The document title <title></title>. can be rendered by the browser as the caption of the document.	/ClinicalDocument/title	ST	O[0...1]	
1.6	**Date of**	The time and date that the	/ClinicalDocument/effectiveTime	TS	R	

	creation	document came into being.			[1..1]	
1.7	**Date of last update of document**	This elements represents the last effective date when the summary content has been updated (even if it may happen that this instance of the CDA has been authored later.	ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high	TS	O [1..1]	
1.8	**Clinical document code**	Determines the document type. For example "HIQA ePrescribing Document". This is a LOINC code that classifies the kind of clinical document. Example: <code code="57833-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName=" Prescription for medication " />	/ClinicalDocument/code	CE	R [1..1]	
1.9	**Confidentia**	Codes that identify how	/ClinicalDocument/confidentialityCode/	CE	R null	The value of

	lity code	sensitive a piece of information is 1..1 and/or that indicate how the information may be made available or disclosed. Example: <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>	@code		flavor [1..1]	@code shall be drawn from value set epSOSConfidentiality A coded value, CDA defines a limited set which can be extended as needed. The HL7 coding system contains the following codes: N-Normal/R-Restricted and V-Very restricted. Other coding systems may be used.
1.10	**Legal Authenticat**	Legal authenticator may be a person or an organisation that is responsible for the medical	/ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson or ClinicalDocument/legalAuthenticator/as	PN/ON	R [1..*]	

	or	content of the document.	signedEntity/representedOrganization			
1.11	**Document Language Code**	Language Code as defined by RFC3066. <Language Code> <COUNTRY CODE><languageCode code="en-GB"/>	/ClinicalDocument/languageCode	CS	R [1..1]	The language code SHALL be in the form nn-CC.The nn portion SHALL be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage. The CC portion SHALL be an ISO-3166 country code in upper case derived by the value Set epSOSCountry.
1.12	**Set ID**	Identifier for a set of related documents. The original document and replacement	ClinicalDocument/setID	II	O[0...1]	

		documents versions thereof all share one and the same setId – they all have a unique document identifier.				
1.13	**Version number**	Contains the version number of this version of the document within a set of related documents. Example: ClinicalDocument/versionNumber/@number="1"	ClinicalDocument/versionNumber	INT	O[0...1]	

Author

"The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills." [From Implementation Guide for CDA Release 2: Imaging Integration – UV Realm, March 2009].

Table 4: Author information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary

CDA header level template The templateId for Author is 1.3.6.1.4.1.19376.1.5.3.1.2.3 (without the PCC patient identifier extension) (epSOS)						
2.1	**Author ID number**	User ID of individual that is clinically responsible for dispensing.	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	
2.2	**Author family surname**	Author's second name which denotes their family or marital name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/family	PN	R [1...*]	
2.3	**Author given name**	Author's identifying name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	PN	R [1..*]	
2.4	**Author prefix**	Coded value that contains the title relevant to a specific family name for this author.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix	PN	O [0...*]	
2.5	**Author profession**	Coded element that specifies the health practitioner's particular profession.	/ClinicalDocument/author/functionCode	CD	R [1..*]	For example, using the ISCO coding system, the code for a general practitioner is 2211, while the code for a

						pharmacist is 2262.
2.6	**Author's telephone number**	The author's telephone number.	/ClinicalDocument/author/assigned Author /telecom/@value	TEL	R use nullFlavor [1..*]	
2.7	**Author's email address**	The author's secure email address.	/ClinicalDocument/author/assigned Author /telecom/@value	TEL	O [0...*]	
2.8	**Author's Fax number**	The author's fax number.	/ClinicalDocument/author/assigned Author /telecom/@value	TEL	O [0...*]	

Custodian

The custodian is the organisation that is in charge of maintaining the document. This information is required by the CDA R2 standard and shall be recorded in the ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization element. The data attributes for custodian are outlined in Table 5.

Table 5: Custodian information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
CDA header level template The template id for the epSOSCDAcustodian is 2.16.840.1.113883.2.4.3.11.60.22.10.11 - (epSOS)						
3.1	**Custodian**	Represents the organisation in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The steward organisation is an entity scoping the role of AssignedCustodian.	/Custodian/assignedCustodian		M[1..1]	
3.2	**CustodianID**	A unique identifier for the custodian.	Custodian/assignedCustodia/representedCustodian/Organisation/id	II	M[1..1]	
3.3	**Name of custodian**	The name of the organisation that that is in charge of maintaining the document.	Custodian/Organisation/name	ON	R [1..1]	
3.4	**Custodian's**	The assignedEntity.addr is a mixed content element so if the	/ClinicalDocument/assignedCustodian/representedCustodian	AD	R [1..1]	

	Address	individual components of an address are not available then the entire address could be put in this element.	/Organization/addr			
3.5	**Custodian's telephone number**	The custodian's telephone number.	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/telecom/@value	TEL	R use nullFlavor [1..*]	
3.6	**Custodian's email address**	The custodians secure email address.	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/telecom/@value	TEL	O [1..*]	

Appendix 4. HIQA's Clinical Document Architecture (CDA) Standard

The purpose of this standard is to develop a minimum dataset that covers a record of the medications dispensed in community pharmacy for use in a summary care record. The Health Level Seven (HL7) clinical document architecture, which is an internationally recognised standard that has been implemented in many countries, was used to define the structure and content of the dispensing record. The clinical document architecture facilitates the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. Clinical document architecture supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. It can be processed by unsophisticated applications making it easy to render in web browsers so that end users can view the clinical document. It can also be integrated into clinical information computer systems so the data can be reused.

The international standards organisation HL7 developed the CDA standard to facilitate the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. CDA supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing.

Several countries have adopted CDA as the basis for their standards-based health information exchange architecture. Countries who have undertaken CDA projects include Australia, Canada, Germany, Greece, Finland, Japan, UK and US. Implementers can refine the generic CDA specification by defining the structure and coding requirements to meet their local requirements.

CDA allows for three different levels of conformance to the standard. Level one enable implementers to develop documents that are displayed and presented to clinicians in a readable format. More complex documents can be created that are coded for machine processing using level two and three. This feature is referred to as the 'migration path' and provides a flexible approach to CDA implementation. Level one is considered relatively easy to implement and will ensure that clinical

documents are brought up to a standard format. Over time, it is possible for implementers to add greater levels of sophistication by incrementally adding in more structure and coding (entries) to the clinical document.

HL7 defines clinical documents as historical, human readable healthcare records that combine data and free text and are always (at least theoretically) attested. The following list describes the goals of an electronic clinical document expressed in CDA as:

- Persistent: A clinical document continues to exist in an unaltered state, for a period defined by local and regulatory requirements.
- Stewardship: A clinical document is maintained by an organisation entrusted with its care.
- Potential for authentication: A clinical document is a collection of information that is intended to be legally authenticated.
- Context: A clinical document establishes the default context for its content
- Wholeness: Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability: A clinical document is human readable .

In summary, some of the key benefits of CDA are:

- It is machine computable and human readable.
- It provides a standardised display of clinical information without loss of clinical meaning.
- It provides assurance of clinical quality and safety more effectively than message-based interfaces by storing and displaying the clinical data as entered by the clinician.
- It supports legal attestation by the clinician (requiring that a document has been signed manually or electronically by the responsible individual).

- It can be processed by unsophisticated applications (displayed in web browsers).
- It provides a number of levels of compliance to assist with technical implementation and migration.

CDA templates

HL7 templates are constraints (additional validation) on the CDA R2 object model. Constraints specify how CDA can be used for particular purposes and specific use cases. Template definitions can be generated at the document-level (See Figure 1), section-level and entry-level such as patient identification, provider organisation or an observation entry respectively.

HL7 templates are required to have a templateID indicating that a CDA instance (document), conforms to both the CDA specification and the constraints specified in an implementation guide. The templateID, which could be an OID or locally defined, is used to indicate which template is being used.

Templates are used throughout this specification and are taken from the epSOS project. This specification has made adaptations or is a specialisation of the epSOS templates because there are instances where optional elements have been made more strict, for example, (0..1 · 1..1) and elements have been added that were not originally described in the epSOS specification in order to meet the dataset requirements.

Each template has a set of metadata to describe the purpose and use of the template, allowing templates to be stored in repositories which can be queried. This makes it possible for templates to be shared internationally.

Figure 1. epSOS templateID for a dispensing record at document level

Document	Template id
epsos eDispensation	1.3.6.1.4.1.12559.11.10.1.3.1.1.2

Local Extensions

The CDA standard supports the implementation of local requirements by allowing additional XML elements and attributes (local extensions) to be included in implementation guides. These local extensions should only be included when the there is no corresponding representation in the CDA specification.

Appendix 5. HL7 v3 Data Types

Each data element has a data type associated with it.

Table 1: HL7 Data Types

HL7 v3 Data Type	Name	Description
AD	Postal Address	Home or office address. A sequence of address parts.
ANY	Any	Defines the basic properties of every data
CD	Concept Descriptor	A concept descriptor represents any kind of concept usually by giving a code defined in a code system. A concepts descriptor can contain the original text or phrase that served as the basis of the coding and one or more translations into different coding systems.
CE	Coded with Equivalents	Coded data that consists of a coded value (CV) and optionally coded values from other coding systems that identify the same concept. Used when alternative codes may exist.
CS	Coded Simple Value	Coded data in its simplest form, where only the code is not predetermined. The code system and code system version is fixed by the context in which the CS value occurs. CS is used for coded attributes that have a single HL7-defined value set.
ED	Encapsulated Data	Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7. This includes unformatted or formatted written language, multimedia data or structured information in as defined by a different standard.
EN	Entity Name	A name for a person, organisation, place or thing. A sequence of name parts, such as first name or

		family name, prefix, suffix.
II	Instance Identifier	An identifier that uniquely identifies a thing or an object. Examples are object identifier for HL7 RIM objects, medical record number, order id, service catalogue item id. Vehicle Identification Number (VIN) and so on. Instance Identifiers are defined based on ISO object identifiers..
IVL	Interval	A set of consecutive values of an ordered based data type. Any ordered type can be the basis of an interval: it does not matter whether the base type is discrete or continuous. It the base data type is only partially ordered, all elements of the interval must be elements of a totally ordered subset of the partially ordered data type.
ON	Organisation Name	A name for an organisation. A sequence of name parts.
PN	Person Name	A name for a person. A sequence of name parts such as first name, family name, prefix, suffix. A name part is a restriction of entity name part that only allows those entity name part qualifiers applicable to person names. Since the structure of entity name is mostly determined by the requirements of person name, the restriction is very minor. This data type is of mixed content.
PQ	Physical Quantity	A dimensioned quantity expressing the result of measuring.
RTO	Ratio	A quantity constructed as the quotient of a numerator quantity divided by a denominator quantity. Common factors in the numerator and denominator are not automatically cancelled out. The data type supports quantities produced by laboratories that truly represent ratios.
SC	Character String with Code	The character string that optionally may have a code attached. The text must always be present if a

		code is present. The code is often local code.
ST	Character String	The character string data type stands for text data, primarily intended for machine processing (for example, sorting, querying, indexing). Used for names, symbols, and formal expressions.
TEL	Telecommunication Address	A telephone number (voice or fax), email address, or other locator for a resource mediated by telecommunication equipment. The address is specified as a Universal Resource Locator (URL) qualified by time specification and use codes that help in deciding which address to use for a given time and purpose.
TS	Timestamp	A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression. Note: An IVL TS (Interval Timestamp) has to be fully formed, whereas a regular timestamp can be truncated.

The ClinicalDocument class is the entry point into the CDA 1...1 R-MIM, and corresponds to the <ClinicalDocument> XML element that is the root element of a CDA document.

Appendix 6. Value sets

Six standards, vocabularies or classification systems are used to define the allowable values for twelve of the thirteen data attributes that have coded element data types. Currently, no code-value set has yet been defined for the data attribute, medicinal product code. These are:

- ISO/TS 22220:2011: Health Informatics – Identification of Subject of Care
- ISO 3166-1:2013
- The International Standard Classification of Occupations
- The Anatomical Therapeutic Chemical Classification System
- European Directorate for the Quality of Medicines[3]
- HL7v3.0 Vocabulary Specification

This appendix provides a list of tables that contain the code-value sets for these data attributes.

ISO/TS 22220:2011: Health Informatics – Identification of Subject of Care

Table 1: Data attribute: name title

Name title	Abbreviation	Name Title	Abbreviation
Admiral	Adm	Master	Mstr
Bishop	Bish	Miss	Miss
Brother	Br	Mister	Mr
Canon	Canon	Missus	Mrs
Captain	Capt	Ms	Ms
Constable	Con	Pastor	Pst
Corporal	Corp	Private	Prv

Dame	Dame	Professor	Prof
Damen	Dam	Reverend	Rev
Doctor	Dr	The Right Honourable	The Rt. Hon
Father	Fthr	The Right Reverend	The Rt. Rev
General	Gen	Sergeant	Sgt
Herr	Herr	Sir	Sir
The Honourable	Hon	Sister	Sr
Madame	Mdm	The Venerable	The Ven

Table 2: Data attribute: street type element of street name including street type

Code	Description	Code	Description
Ally	Alley	Gr	Grove
Arc	Arcade	Hwy	Highway
Ave	Avenue	Jnc	Junction
Bvd	Boulevard	Lane	Lane
Bypa	Bypass	Ln	Line
Crc	Circle	Link	Link
Cct	Circuit	Mews	Mews
Cl	Close	Pde	Parade
Crn	Corner	Pl	Place
Ct	Court	Ridge	Ridge
Cres	Crescent	Rd	Road

Cds	Cul-de-sac	Sq	Square
Dr	Drive	St	Street
Esp	Esplanade	Tce	Terrace
Grn	Green		
Note that this is not an exhaustive list.			

Table 3: Data attribute: electronic communications medium

Code	Description	Alternative code
1	Telephone (excluding mobile)	T
2	Mobile (cellular) telephone	C
3	Facsimile machine	F
4	Pager	B
5	e-mail	E
6	URL	U
8	Other	O

Table 4: Data attribute: sex

Code	Descriptor	Alternative code
1	Male	M
2	Female	F
3	Indeterminate	I
9	Not stated/inadequately described	N

ISO 3166-1:2013

The full listing for this classification can be found HERE.[3] It is used to populate the Country Identifier data attribute.

The International Standard Classification of Occupations (ISCO)

Relevant professions and codes that have been extracted from the ISCO.

Table 5: Data attribute: profession

Code	Profession
22	Health professionals
221	Medical doctors
2211	Generalist medical practitioners
2212	Specialist medical practitioners
222	Nursing and midwifery professionals
2221	Nursing professionals
2222	Midwifery professionals
223	Traditional and complementary medicine professionals
224	Paramedical practitioners
225	Veterinarians
226	Other health professionals
2261	Dentists
2262	Pharmacists
2263	Environmental and occupational health and hygiene professionals
2264	Physiotherapists
2265	Dieticians and nutritionists

[3]http://www.iso.org/iso/country_codes.htm

2266	Audiologists and speech therapists
2267	Optometrists and ophthalmic opticians
2269	Health professionals not elsewhere classified
32	Health associate professionals
321	Medical and pharmaceutical technicians
3211	Medical imaging and therapeutic equipment technicians
3212	Medical and pathology laboratory technicians
3213	Pharmaceutical technicians and assistants
3214	Medical and dental prosthetic technicians
322	Nursing and midwifery associate professionals
3221	Nursing associate professionals
3222	Midwifery associate professionals
323	Traditional and complementary medicine associate professionals
325	Other health associate professionals
3251	Dental assistants and therapists
3252	Medical records and health information technicians
3253	Community health workers
3254	Dispensing opticians
3255	Physiotherapy technicians and assistants
3256	Medical assistants
3257	Environmental and occupational health inspectors and associates
3258	Ambulance workers

3259	Health associate professionals not elsewhere classified

The Anatomical Therapeutic Chemical Classification System (WHO/ATC)

A searchable online database can be found at http://www.whocc.no/atc_ddd_index/, which contains the allowable values for the data attribute active ingredient code.

European Directorate for the Quality of Medicines (EDQM)

Data attribute: medicinal product package[41] Taken from https://decor.nictiz.nl/epsos/epsos-html-20131203T170006/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.3-2013-06-03T000000.html

Pharmaceutical dose form[5] Taken from https://decor.nictiz.nl/epsos/epsos-html-20131203T170006/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.2-2013-06-03T000000.html

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