|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
| Directorate / Programme | OTS | Project | OTS |
| Document Reference | | HSCIC-FNT-TO-TAR-0124.01 | |
| Project Manager | Shaun Fletcher | Status | Published |
| Owner | Mike Curtis | Version | 2.1 |
| Author | Brendan McEnroe | Version issue date | 14/05/2014 |

CDA Document Sender Requirements

Document Management

Revision History

|  |  |  |
| --- | --- | --- |
| Version | Date | Summary of Changes |
| 0.1 | 1/5/2011 | 1stdraft |
| 0.2 | 1/6/2011 | 2nd draft |
| 1.0 | 15/8/2011 | 1st Release for internal review |
| 1.1 | 22/8/2011 | Minor clarifications added to remove ambiguities |
| 2.0 | 15/9/2011 | Approved version |
| 2.1 | 14/05/2014 | Draft Brendan McEnroe |

Reviewers

This document must be reviewed by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer name | Title / Responsibility | Date | Version |
| Mike Curtis | GPSoC Lead Architect |  |  |
| Adam Hatherly | Senior Architect |  |  |

Approved by

This document must be approved by the following people:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Signature | Title | Date | Version |
| Mike Curtis |  | Lead Architect GPSoC |  |  |
| Shaun Fletcher |  | GPSoC Programme Manager |  |  |

Distribution

This document will be distributed to:

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer name | Title / Responsibility | Date | Version |
| GPSoC Suppliers |  |  |  |
| GPSoC Programme Office |  |  |  |

Related Documents:

The table below lists other related documents, which should be understood in the context of this document:

|  |  |  |  |
| --- | --- | --- | --- |
| Ref No | Doc Reference Number | Title | Version |
|  |  |  |  |

Glossary of Terms

|  |  |  |
| --- | --- | --- |
| Term | Abbreviation | What it stands for |
| CDA | CDA | Clinical Document Architecture – an HL7 standard for the structure (format, content) of clinical documents |
| CDA Document | - | An instance of a clinical document in CDA format |
| CRE Type |  | A Care Record Element categorisation predominantly designed for use with the Summary Care Record held on PSIS but also for more general use |
| Domain Message Specification | DMS | A set of documented requirements related to a specific messaging domain covering a range of messages interactions between systems across that domain. This is the successor to the MIM (Message Implementation Manual) that covered many different domains which reached version 8 – all further developments being spawned off into their own domains to become DMSs. |
| Data Transfer Service | DTS | A Store and Collect mail facility operated by BT and now part of the range of ‘Spine’ services |
| Interoperability Tool-Kit | ITK | Interoperability Tool-Kit – a set of technical standards covering the exchange of messages between the messaging components of systems. |
| Point to Point | P2P | Refers to sending messages directly from one system to another either directly or via an intermediary service such as DTS or TMS – in the case of TMS the message travels through TMS to another end point and not to any central sine service |
| Trading Partner | TP | A system and/or organisation which the host system exchanges messages with. An organisation may have many systems each with their own identifier which equates to a Trading Partner ID. A system (with a single Trading Partner ID) may support multiple organisations. Examples include the 5 character cipher used to identify GP systems and NHAIS systems for NHAIS registration links, 15-char EDI Sender/recipient IDs used in Pathology messaging, a Spine ASID, etc. |
| Trading Partner ID | TP | An identifier for a system to identify itself uniquely within messages it sends and/or receives messages electronically with other systems. |

Document Control:

The controlled copy of this document is maintained in the HSCIC corporate network. Any copies of this document held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

This document is valid from: **14th May 2014**

Contents

[1 Introduction 6](#_Toc388616760)

[1.1 Purpose 6](#_Toc388616761)

[1.2 Audience 6](#_Toc388616762)

[1.1 Document Topology 7](#_Toc388616763)

[1.2 Background 7](#_Toc388616764)

[1.3 Definitions 7](#_Toc388616765)

[2 Sender Responsibilities 9](#_Toc388616766)

[2.1 Triggers for Sending a CDA Document 9](#_Toc388616767)

[2.2 Identification of Recipients 10](#_Toc388616768)

[2.3 Completeness and Veracity of CDA Document Payload 10](#_Toc388616769)

[2.4 Error Handling Behaviour 11](#_Toc388616770)

[3 Communication Content 12](#_Toc388616771)

[3.1 General Principles 12](#_Toc388616772)

[3.2 Attachments 12](#_Toc388616773)

[3.3 Coding Schemes 12](#_Toc388616774)

[4 Operating Model 14](#_Toc388616775)

[4.1 Overview of Operating Principles 14](#_Toc388616776)

[5 Sending System Requirements 15](#_Toc388616777)

[5.1 Overview 15](#_Toc388616778)

[5.2 Demographic and Consent Preconditions 15](#_Toc388616779)

[5.3 Information Governance Preconditions 17](#_Toc388616780)

[5.4 Addressing Requirements 18](#_Toc388616781)

[5.5 General CDA Assembly and Sending Requirements 19](#_Toc388616782)

[5.6 Replacement Documents 20](#_Toc388616783)

[5.7 Withdrawing/Nullifying Documents 21](#_Toc388616784)

[5.8 List Functionality 21](#_Toc388616785)

[5.9 Handling Error Responses from Recipient Systems. 24](#_Toc388616786)

[5.10 Audit Requirements 25](#_Toc388616787)

[Appendix A. Process Flow Diagrams 26](#_Toc388616788)

[A.1. Send CDA Document 26](#_Toc388616789)

[A.2. Process Primary/Copy Recipient Response 28](#_Toc388616790)

[Appendix B. Managing Responses from Multiple Recipients 30](#_Toc388616791)

# Introduction

This document specifies the processing requirements for systems sending CDA documents as illustrated in Figure 1. It covers the interface between the clinical application and the MHS represented by the yellow circle with the dashed edge.

Figure 1: CDA Interoperability Architecture

## Purpose

The purpose of this document is to provide detailed system requirements to system developers of systems sending CDA documents. It must be read and understood within the context provided by the other documents published in the CDA Interoperability baseline.

## Audience

The audience for this document is primarily system architects, system developers and other supplier staff involved with the design, build and test of systems that will be sending CDA documents across the architecture illustrated in Figure 1. This document should also be read by people developing systems that will receive these documents as it provides useful information to assist with the understanding the full point to point business and technical processes.

This document ONLY covers the sending of documents in a Point to Point situation from a sending organisation’s system to a receiving organisation’s system. It DOES NOT cover the sending of documents to PSIS (aka Summary Care Record) or the retrieving of documents from PSIS. As such it does not consider a patient’s SCR consent status stored on the Spine ACS nor does it consider the sealing of documents, both covered by the previous CDA documentation.

## Document Topology

The diagram below illustrates the scope of the baseline documentation defining requirements across the generic CDA interoperability environment with the area covered by this document circled. Suppliers must read associated documentation from this CDA interoperability baseline in order to comply with the overall requirements for CDA interoperability.



Figure 2: CDA Interoperability Documentation Model

## Background

The requirements within this document have been drawn from the various requirements documents published by NHS CFH relating to ‘Spine messaging’ over TMS and CDA documentation published by NHS CFH as part of the Summary Care Record Release 2 requirements

## Definitions

Where used in this document set, the keywords MUST, SHOULD and MAY are to be interpreted as follows:

* **MUST**: This word, or the terms "**REQUIRED**" or "**SHALL**", means that the definition is an absolute` requirement of the specification.
* **SHOULD**: This word, or the adjective "**RECOMMENDED**", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications **MUST** be understood and carefully weighed before choosing a different course.
* **MAY**: This word, or the adjective “**OPTIONAL**”, means that an item is truly optional. One implementer may choose to include the item because a particular implementation requires it or because the implementer feels that it enhances the implementation while another implementer may omit the same item. An implementation which does not include a particular option **MUST** be prepared to interoperate with another implementation which does include the option, though perhaps with reduced functionality. In the same vein an implementation which does include a particular option **MUST** be prepared to interoperate with another implementation which does not include the option (except, of course, for the feature the option provides).
* **SHOULD NOT**: This phrase, or the phrase "**NOT RECOMMENDED**" mean that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

# Sender Responsibilities

## Triggers for Sending a CDA Document

A formal specification of the application sending roles is provided within the relevant Business Analysis Models published in the External Documents section of the MIM/DMS. This section provides a broader understanding of the care context within which the applications will be employed.

The question of which care information to include within communications is one for individual judgement by the Care Professional, informed by local and national policies and guidelines. However, it should be understood that the CDA Documents are not intended to replicate detailed care information that would be held within local repositories.

The CDA Documents should only be used to communicate summary care information relating to a complete episode of care or individual encounters deemed significant enough to warrant sending the information to the Patient’s GP Practice or other Care Providers. Therefore every encounter may not necessitate the sending of a CDA Document. For example, it might be that a Patient is treated within an Emergency Department and then transferred to an inpatient department where further treatment is provided. In this circumstance it might be deemed appropriate for only one CDA Document to be sent to the Patient’s GP Practice following discharge from the inpatient department, rather than sending two CDA Documents, one following the Patient’s departure from ED and another following the Patient’s discharge from the inpatient department.

Equally, within the context of Outpatient appointments, it might be the case that a number of outpatient encounters relate to what the treating Care Professionals would regard as a single episode of care. In circumstances such as this, Care Professionals should be free to exercise their judgement when assessing whether or not to send a CDA Document to the Patient’s GP Practice.

This requirement for flexibility regarding the composition and sending of a CDA Document is incompatible with fully automated and globally specified trigger conditions. That is, divergence in local care practices and individual Care Professionals’ judgements precludes a nationally applicable specification of the conditions that should be satisfied before a CDA Document is composed and sent. Consequently, local systems must allow Care Professionals to decide whether or not an encounter warrants the sending of a CDA Document to the Patient’s GP Practice.

There will be occasions on which the information contained within a CDA Document needs to be sent to a recipient who is unable to receive it electronically. Consequently, system users must be able to print off paper copies of the documents. In this circumstance, electronic copies should still be sent to the other recipients capable of receiving them.

Initially, only Medications and Allergies and Adverse Drug Reactions may be included as coded entries (where these exist) as some suppliers have built solutions to the earlier SCR requirements. All other entries may be coded where the coding is of benefit to the receiving system, but must not be indexed against CRE Types. Further guidance on coding and indexing requirements can be found within the Technical Guidance for the Implementation of CDA Domains.

It is important to note that there is no requirement for Receiver systems to systematically process coded data in this version of the requirements.

## Identification of Recipients

CDA Documents may be sent to any end point that is capable of receiving the documents. In most clinical circumstances, documents will be sent to the Patient’s registered GP Practice. In non-clinical contexts, such as Social Care, it will be less common for the Patient’s GP Practice to be sent documentation. The important point to note is that documents may be sent to recipients using any end point.

Except in the case of Health and Social Care Integration (HSCI) originating systems, the originating system should default the inclusion of the Patient’s GP Practice as a recipient provided the GP system is able to receive the interaction (the identity of the Patient’s GP Practice having been determined via the PDS and SDS lookups or other local configuration data).

There must be functionality to allow the sender of the CDA Document to indicate whether or not the recipient is required to act on the content of the CDA Document. In practice, this will be facilitated by identifying within the CDA Document all recipients and, for each recipient indicating whether it is a Primary or Copy recipient. Where a recipient has an action, they will be identified as a primary recipient; where a recipient has no action, they will be a copy recipient. Technical guidance on this functionality is provided within the relevant message specification.

## Completeness and Veracity of CDA Document Payload

The authoriser of the CDA Document is responsible for ensuring that the CDA Document contains sufficient and accurate information regarding the episode of care, or encounter, to which it relates. The local system should make available to the authoriser of the CDA Document:

* details of all professionals involved in delivering care during the episode of care, or encounter, to which the CDA Document relates;
* details of people present, but not involved in the act (e.g. those described as a Witness in HL7).
* all information relating to the encounter that has been recorded locally by these professionals.

To ensure accuracy of the Documents’ care content, a verification step must be included in the business process prior to the Document being sent. In many cases, the authenticator will be the author of the document. The act of verification needs to be stored in the audit trail and a tamper-proof version of the sent Document also needs to be kept for audit purposes.

## Error Handling Behaviour

Care Professionals need to be informed of the fact that a CDA Document has not reached, or is experiencing difficulty in reaching, its intended recipients. Since Application/Business Acknowledgement messages will be sent on successful receipt of the CDA document, the absence of such an acknowledgement or the receipt of a transport layer delivery failure, should be used by originating systems to trigger appropriate notifications to the document author. The manner in which this notification is managed is a matter for service providers to agree in consultation with their end user representatives.

Where a CDA Document does not reach its intended recipient, it might be necessary to send a paper copy of the CDA Document instead. In this case, it would be necessary to access the original CDA Document from the local system so that a copy might be printed off.

# Communication Content

## General Principles

The format of the communications for Discharge, Outpatient, Ambulance, Out of Hours, Admissions and Emergency Department is HL7 Clinical Document Architecture (CDA).

Documents comprise:

* Text Sections, which may be nested up to six levels, and must only contain standard CDA markup.
* Coded Entry Templates
* Care Record Element (CRE) Types
* Non-XML body parts (e.g. attachments such as PDF or HTML files)

*Medications* and *Allergies and Adverse Reactions* may be coded (where these exist) using SNOMEDCT and, if present, should be indexed against the respective CRE Types. Information other than *Medication* or *Allergies and Adverse Reactions* must be text only or text and equivalent codes and must **not** be indexed against CRE types until such time as HSCIC provides formal guidance on the use of additional CRE Types.

Care Professionals will want to link care information within a Document, to indicate that data items are related in clinically relevant ways. For example, a Care Professional might wish to indicate that a diagnosis is the reason for a medication. Detailed guidance is available within the message specifications on what is allowed and how it is achieved.

Detailed information relating to the content of each CDA document is provided in the relevant class models in the Business Analysis models.

## Attachments

The CDA messages documented in MIM 7.2.02 do not allow the inclusion of attachments or embedded binary objects, however, the later DMS versions of the CDA domains covered by this document do allow attachments (binary objects) to be included within CDA documents. Systems using the DMS CDA messages may therefore include attachments subject to the requirements included within the DMS documentation and the ‘Technical Guidance on the Implementation of CDA Domains’ document

## Coding Schemes

The CDA messages documented in MIM 7.2.02 only allow the use of SNOMED CT clinical codes within the ‘Coded Entry’ element of messages, however, the later DMS versions of the CDA domains covered by this document allow other coding schemes to be used together with a mapped/translated SNOMED CT equivalent where approved mapping/translations exist.

Systems using the DMS CDA messages may therefore include clinical codes other than SNOMED CT subject to the constraints included elsewhere on the use of Coded Entry and CRE Types. Note that CRE Types are SNOMED CT concepts and can only exist where a SNOMED CT (native or mapped) exists.

# Operating Model

## Overview of Operating Principles

This section provides a high level overview of the principles guiding the intended use of CDA Documents.

The following principles govern the use of the CDA documents:

* The CDA documents may be created in any care environment that would ordinarily produce the communication domains covered by the scope of this document.
* The CDA documents may be accessed and viewed from any system sending the document or any system receiving the document provided that the user accessing the document has the necessary access rights to do so.
* The CDA documents will be produced in order to summarise a Patient’s episode of care, they are not intended to capture detailed operational care information.
* The CDA Documents should serve as freestanding documents in their own right.

# Sending System Requirements

## Overview

This section sets out requirements for the sending of CDA documents. Suppliers **must** read this document within the context of all other documents contained within relevant Baselines.

## Demographic and Consent Preconditions

It is essential that the identity of the patient is consistently represented by systems that are interacting with one another via CDA documents.

Ideally, where sending systems are connected to PDS, full PDS Synchronisation will be carried out prior to any messaging interaction and therefore the locally held serial change number will be up-to-date. If the sending system is not connected directly to PDS but synchronises with PDS periodically, e.g. using the PDS Batch service (the replacement of NSTS), the latest available details should be sent. If the system is not connected to PDS at all then sufficient identifying attributes should be sent to enable a receiving system to match them to an existing record (If applicable) or create a new record (if applicable). In all cases the status of the NHS number must be indicated using the appropriate OID.

A single check can be used for a series of retrieving or sending interactions associated with a single patient. For user initiated interactions, the check will normally take place at the point that a patient record is selected and remain valid until the patient record is de-selected.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS01** | The system **MUST** include the verification status of the patient’s NHS number (where present) before sending a CDA Document to any recipient. | Must |
| CS01.1 | If the CDA document is being sent over TMS the system **MUST** synchronise the local record with the PDS record (see PDS compliance requirements).  (Note: This is subject to any local caching rules in place, e.g. no need to query PDS again if already queried during the current patient encounter.) | Must |
| CS01.2 | If the system is using a DMS version of the message interaction it **MAY** include additional patient demographics as well as the patient’s NHS number.  (Note: Additional demographic details are not available in the MIM 7.2.02 message variants of the CDA documents.) | May |
| CS01.3 | If the CDA document is not being sent over TMS and the NHS number is included in the document, the system **MUST** indicate the status of the patient’s NHS number (i.e. whether it has been ‘verified’ using the PDS Batch Trace Service or otherwise, by using the correct OID for the NHS number). | Must |
| **CS02** | The system **MUST** include additional patient demographics if the patient’s NHS number is not included or the NHS number has not been ‘verified’.  Note : Where the additional demographics are the patient demographic details contained within the message. | Must |
| CS02.1 | The system **SHOULD** include additional patient demographics if the patient’s NHS number is ‘verified’ as the receiving system may not be connected to PDS and may require additional demographics to assist with patient matching. | Should |
| CS02.2 | If the patient’s NHS number is not known AND the CDA Document is not being sent over TMS, the system **MUST** include an alternative local patient identifier with the appropriate OID (see DMS documentation) AND additional demographics. | Must |
| CS02.2.1 | When a system ONLY sends a local patient identifier it **MUST** also include the patient’s Date of Birth, Sex and Name. | Must |
| CS02.2.2 | When a system ONLY sends a local patient identifier it **SHOULD** also include the patient’s Address and Post Code. | Should |
| CS02.3 | When a patient’s address is included the system **SHOULD** use the following AD data type:  Address StreetAddressLine Typed, plus optional Postcode  AND **SHOULD** populate the 5 address lines according to the following rule:  (AddressLine1 or AddressLine2) is required AND AddressLine4 is required.  where:  AddressLine1 = House Name / prefix  AddressLine2 = Street Name  AddressLine3 = Locality  AddressLine4 = Post Town  AddressLine5 = County | Should |
| **CS03** | If the originating system is connected to PDS, prior to sending a CDA document, the originating system **MUST** check the PDS ‘flagged’ status of the Patient’s record. | Must |
| CS03.1 | Where a record is marked as ‘S’ (Sensitive) on the PDS, the system **MUST** still send the CDA document as normal but **MUST NOT** include any Patient address or contact details in the additional demographic data.  These items are (PDS data items):   * Addresses * Telecom Addresses * Patient Care (All types) * Alternative Contacts   Note: The current ‘PatientUniversal’ template for additional demographics allows Name, Sex, Date of Birth, Address (including Post Code) and Telecom and thus alternative contacts cannot currently be included in the patient element of messages. | Must |
| CS03.2 | Where an NHS number is known to be invalid on the PDS (error code ‘22’ upon a PDS Retrieval), CDA documents **MUST NOT** contain the patient’s NHS number and the CDA Document **SHOULD** not be sent until the issue has been resolved. If the CDA Document is sent (and this can only be done with DMS messages and not MIM 7.2.02 messages) other (non- NHS number) demographic details **MUST** be included. | Must |
| CS03.3 | Where a record is marked as ‘B’ (formerly meaning ‘Business Flagged’ prior to 2008-B but now meaning ‘Under Data Quality Investigation’ from spine release 2008-B onwards) on the PDS, CDA documents **MUST** be sent as normal. | Must |
| **CS04** | Where a Patient dissents from sharing their detailed care records and the document is a routine clinical communication, the originating system **SHOULD** still send CDA documents for that Patient to the Patient’s GP Practice.  Where routine clinical communication are Referral Letters, Discharge Notes, OOH Attendance letters, Clinic Letters, etc – anything that would have been sent by paper/fax. | Should |
| CS04.1 | Where a Patient dissents from sharing their detailed care records and the document is a routine clinical communication, the originating system **SHOULD** still send CDA documents for that Patient to other recipients.  Where routine clinical communication are Referral Letters, Discharge Notes, OOH Attendance letters, Clinic Letters, etc – anything that would have been sent by paper/fax. | Should |

## Information Governance Preconditions

The sending and receiving of information using CDA Documents is subject to NHS CFH’s overall Information Governance requirements. Suppliers should refer to IG compliance documentation cited within their relevant baseline. Some areas of special note are outlined here.

Messages must only be sent to systems which are known to be able to receive them.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS05** | If the system is sending a message over TMS the system **MUST** only send the message to a receiving system that has the appropriate message interaction and service name pairing registered against its ASID on SDS. (Note that this data may be cached within the system as part of the Trading Partner configuration). | Must |
| **CS06** | If the system is sending a message by other transport channels it **MUST** only send the message to receiving systems that are recorded in local configuration settings as receivers of the message. | Must |
| CS06.1 | If the system supports sending of messages over transport channels other than TMS, the system **MUST** have local configuration facilities to record, for each receiving system, its ability to receive each message/interaction representing a CDA document type. | Must |

## Addressing Requirements

Users of the system must be able to select who the recipient organisations or systems of a CDA document will be. This may be done manually but it is expected that in most cases it will be achieved by preconfigured settings within the system, e.g. always send Discharge reports to the patients registered GP practice.

The system needs to know, through the use of further configurations settings, which organisations or systems are capable of receiving which types of CDA documents and over which transport channels. The majority of the requirements for setting these values are contained in the ‘CDA Interoperability – MHS Requirements’ document but there are application related requirements which are detailed in the table below.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS10** | Sending systems **MUST** provide functionality to enable document authors to select any number of document recipients for a newly created document subject to any constraints of the message specification. | Must |
| CS10.1 | Sending systems **MUST** provide functionality to enable document authors to specify, for each recipient identified, whether or not that recipient is required to act on the contents of the document. | Must |
| CS10.2 | Where it is indicated that a document recipient is required to act on the contents of a document, the originating system **MUST** identify that recipient as a primary recipient. | Must |
| CS10.3 | Where it is indicated that a document recipient is not required to act on the contents of a document, the originating system **MUST** identify that recipient as a copy recipient. | Must |
| **CS11** | The contents of a CDA document **MUST** be the same for every (electronic) recipient.  This **MUST** be achieved by addressing an identical clinical message payload (document) to each of the recipients, including identical UUIDs (document, set, coded entry), version number, and content tag IDs. The payload must be syntactically and semantically identical regardless of the number of receivers or the transport mechanism used to send the document. | Must |
| CS11.1 | Some recipients are ‘Spine connected’ and will be sent the document over TMS whilst others are not spine connected and will be sent the document over non-TMS transport channels. The Sending system will therefore need to send local (i.e. non-SDS) identifiers and spine identifiers.  In this circumstance the CDA Document **SHOULD** EITHER be sent using the DMS message variant containing both SDS and non-SDS identifiers OR (not recommended) separate documents SHOULD be created and sent for TMS and non-TMS recipients. The latter variation does however present management difficulties if the document needs updating or withdrawing as there would be more than one document set. | Should |
| **CS12** | The system **MUST** allow users to update (add or remove[[1]](#footnote-1)) the recipient list when sending either a replacement CDA document or a Nullify CDA document. | Must |
| **CS13** | The system **MUST** inform the user which of the intended recipients are able to receive the CDA document electronically (i.e. via the CDA Interoperability Architecture) and which cannot receive it. The system MUST only allow selection of CDA recipients for end points that are able to receive CDA, | Must |
| **CS14** | When sending to multiple recipients and one or more of the recipients has the same destination address (e.g. the same ASID for TMS messages, or the same DTS mailbox ID or same ITK recipient address) the system **MUST** log this in the message logs so that subsequent action can be taken if required to resolve the addressing anomaly. | Must |

## General CDA Assembly and Sending Requirements

The requirements in the table below apply to the assembly of clinical content of the HL7 CDA Documents covered by this document.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS20** | When sending a CDA document over TMS to the patient’s GP Practice System, the sending System **MUST** use the Practice Code held on PDS (or an appropriately synchronised local record) and system information held against the Practice in SDS, to identify the recipient's GP system. | Must |
| **CS21** | When sending a CDA document over other transport channels to the patient’s GP Practice system, the sending System **MUST** use local configuration settings to identify the recipient GP system. | Must |
| **CS22** | The originating system **MUST** provide functionality to print copies of CDA documents so these can be sent to recipients that are unable to receive the documents electronically or where a sent CDA document was not received. | Must |
| CS22.1 | When printing CDA documents, originating systems **MUST** ensure the Patient’s name and NHS number appear on each page as per appropriate NHS CUI standards. | Must |
| CS22.2 | If an attachment (binary object) is included within a CDA Document the system **MUST** be able to print the attachment when it is in a printable form (See Handling Attachments section above). | Must |
| **CS23** | The system **MUST** comply with the requirements contained in the CDA Document Technical Requirements document that covers the construction and population of CDA documents. | Must |
| **CS24** | The system **MAY** include attachments (binary objects such as embedded documents or images) if the message definition being used supports them. | May |
| **CS25** | Sending systems **MUST** provide facilities (e.g. a ‘verification’ step) to ensure the content of CDA Documents is checked/verified by the document author, or other approved user, prior to the sending of the Document. | Must |
| CS25.1 | Sending systems **SHOULD** display the resultant CDA Document to the author according to the rendering requirements within the CDA Document Technical Requirements. | Should |
| CS25.2 | Sending systems **MAY** display the contents of a CDA document in alternative formats but **MUST** ensure that the document author has access to ALL document content so that verification can take place. | May |
| CS25.3 | The user performing the verification **MUST** have access to all the Document contents, including any attachments | Must |
| CS25.4 | The act (i.e. who, when, what) of verifying a CDA Document prior to being sent **MUST** be recorded in the audit trail and a tamper-proof copy of the sent Document MUST be retained for audit purposes. | Must |

## Replacement Documents

CDA Document updates are performed by replacement: the submission of a new document which refers to the document it replaces as the parentDocument (with typeCode ‘RPLC’) as per the MIM/DMS.

The requirements in the table below relate to the sending of a replacement document for a previously sent document. Note that in general, replacements will only be sent to recipients of the original document but there may be occasions where an update to a document may dictate sending the document to an additional receiver.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS30** | Where there is a well established care practice of distinguishing between interim and final documents (i.e. each document, although it can be linked to the same ‘EncompassingEncounter.ID’, exists as its own stand-alone document and therefore will have its own ‘SetID’ attribute) systems **SHOULD** regard these as separate CDA Documents. | Should |
| **CS31** | The author of a document replacement **MAY** differ from the author of the parent document. | May |
| CS31.1 | Where the author of a replacement differs from the author of the parentDocument, the originating system **MUST** ensure it records the actual author and not the author of the parentDocument. | Must |
| **CS32** | Originating systems **MUST** only allow replacements to a CDA Document to be sent where the custodian organisation of the replacement is the same as the custodian organisation for the parentDocument.  Note: The ONLY exception to this requirement is where the CDA document is expected to be updated by multiple organisations/users that are each entitled to make updates to it, e.g. an Integrated Care Plan in the HSCI domain. | Must |
| **CS33** | Where a document is replaced, the replacing document **SHOULD** be sent to all recipients who were sent the original document except when local business practice requires otherwise. | Should |

## Withdrawing/Nullifying Documents

The system must support the withdrawing of a previously sent CDA document. This is to support situations where the document was sent in error. It should not be used because part of the information in the original document has been updated – a replacement document should be sent in this instance.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS37** | The system **MUST** provide a facility for a user to nullify a previously sent document and for the nullify message to be sent to all previous recipients. | Must |
| **CS38** | CDA document withdrawal **MUST** be performed by replacing the document to be withdrawn (referred to in parentDocument, relatedDocument.typeCode=”RPLC”) with a *Nullify* document. This Nullify document contains a coded entry containing reason code and associated text for withdrawal. See MIM/DMS or later for further details | Must |
| **CS39** | Where a document is withdrawn, the ‘nullify’ document **SHOULD** be sent to all recipients who were sent any version of the original document. | Should |
| CS39.1 | When withdrawing a document, recipients that were primary recipients of the latest version of the document being withdrawn **SHOULD** be included as primary recipients of the nullification, and those were copy recipients **SHOULD** be included as copy recipients of the nullification. | Should |

## List Functionality

The architecture of sending systems varies. Some systems will send a message immediately a user approves them whilst other may queue documents at various points in the architecture. For example, a sent document may be queued in the clinical application and be passed to the local MHS at pre-determined times or intervals and/or the MHS may connect to a transport channel (e.g. DTS) at predetermined times to send and receive messages.

The system needs to provide an ‘list’ type facility ,which could be workflow, task list, inbox type functionality. A ‘list’ is a generic term applied to a means for a user to show clinical communications they need to action, the implementation method and design is up to the supplier within the remit of the requirements detailed in this document.

One of the concepts associated with this generic ’list’ functionality is that there are also individual user, or team, views of the messages to be processed. Users of individual or team ‘lists’ would see items assigned to them/their team. The system ‘list’ view is mainly for assignment and management purposes and not for clinical processing. A user would generally only have access to their ‘list’ view, or if a member of a team, to the team ‘list’ also. Users may also have deputies for times when they are away and a deputy will be able to deal with any items during those times. The system must control access to the documents in the inbox in such a way that only users authorised to access clinical[[2]](#footnote-2) data are allowed to view the contents of documents and other users (e.g. administration staff) are only able to see sufficient summary information to carry out administration tasks (e.g. assign clinical reviewer, match patient).

The management function within sending organisations often have a need to check upon the status of a ‘sent’ Documents to see if it has been sent and/or acknowledged. In the same way that Receiver systems have ‘list’ functionality, Sending systems are required to have facilities to be able to confirm if a message was sucsefully sent and acknowledged. Where the system expects an Application/Business Acknowledgement to be returned, the system needs to indicate the status of the Application/Business Acknowledgement for sent messages. The system may provide individual, team or departmental workflow, task lists facilities, especially where large numbers of authors, teams or departments exist.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS40** | The system MUST support the concept of a system ‘list’ and where it is clear outgoing CDA messages can be shown. These facilities MUST be available within the clinical application for authorised users to access. | Must |
| **CS41** | It MUST be possible to view a list of CDA Documents in a ‘list’ showing which ones are yet to be sent to the recipient. | Must |
| CS41.1 | A message that has been sent and is awaiting an Application/Business Acknowledgement **MUST** be clearly visible in the 'lis**t'** with a status of ‘Awaiting Ack’ (or equivalent) until an acknowledgement message has been received or has timed out, whereupon it’s status can be updated accordingly (e.g. ‘no Ack received’) and moved to ‘Sent Items’. | Must |
| **CS42** | The ‘’list’ view **MUST** list all messages successfully passed onto the MHS for sending, with their acknowledgement status – ‘timed out’, ‘successful’ or ‘error’). | Must |
| **CS43** | For any message in the ‘list’, that has been sent it **MUST** be possible to view the selected CDA Document. | Must |
| CS43.1 | Viewing **MUST** be controlled according to the users access rights with clinical data only being displayed to users with an appropriate RBAC profile | Must |
| CS43.2 | When displaying a CDA document (or part) the system **MUST** comply with the rendering requirements detailed in ‘CDA Document Technical Requirements (NPFIT-FNT-TO-TAR-0081.xx). | Must |
| CS44 | If the 'list' containsitems other than clinical documents, the system **MUST** provide facilities to show only clinical documents (e.g. CDA Documents) and only non clinical documents. | Must |
| CS45 | The system MUST provide suitable facilities to order and filter items in the 'list'. | Must |
| CS45.1 | The system MUST provide a system wide view of the 'lists' defined, showing messages sent. | Must |
| CS45.2 | The system MUST provide individual author views of sent messages in the 'list' showing only those documents by that author. | Must |
| CS45.3 | The system **SHOULD** provide team or departmental views of the 'list'if appropriate for the type of system. | Should |
| CS45.4 | * It SHOULD be possible to order the 'list' view by the following fields once filtered by sent messages:Author * Date/Time sent (by clinical application) * Recipient * Patient * Document Type * Status (‘timed out’, ‘successful’, & ‘error’) | Should |
| CS45.5 | * It SHOULD be possible to further filter the 'list' view by the following fields once filtered by sent messages:Author * Date/Time sent range * Recipient * Document Type * Status (‘timed out’, ‘successful’, & ‘error’) | Should |
| CS46 | It **MUST** be possible to view the status details for any selected item in the the 'list', e..g. if an error response has been received what the error code and text is; if it has timed out - when. | Must |

## Handling Error Responses from Recipient Systems.

All responses to sending clinical documents will contain a 3-digit and zero or more 5-digit codes, each encoded as a detectedIssueEvent within the ControlAct (MCAI\_MT040101UK03) of an Application Acknowledgement (MCCI\_IN010000UK13) or ITK Business Acknowledgement message.

Point to Point responses will use the following OID for both categories of error response (the same for both 3-digit and 5-digit responses): 2.16.840.1.113883.2.1.3.2.4.17.33.

Users of Sending system must have a suitable range of facilities available to them to support them in handling error responses – these are detailed in the table below.

See Appendix B for a more detailed description and guidance for handling error responses.

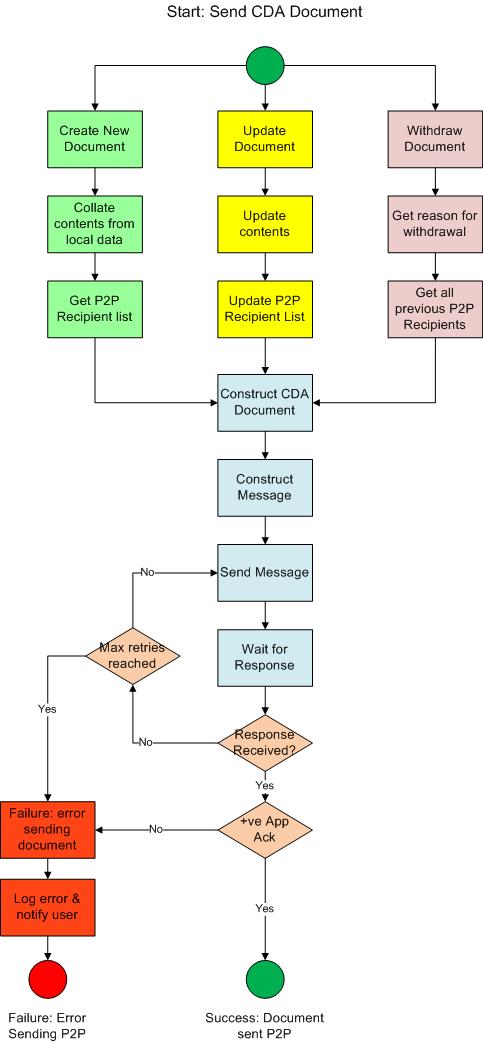
| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS50** | Systems receiving an Application/Business Acknowledgement **MUST** examine both ‘detectedIssueEvent’ objects included in the message to retrieve the three-digit response code as listed in the Point to Point Error Codes document, and take the action prescribed. | Must |
| CS50.1 | Most three-digit response codes have a prescribed action which does not require inspection of the 5-digit code. Where this is the case, the 5-digit code **MAY** be ignored by the receiving system. For each of the three-digit codes which require further detail to determine the action, a separate detailed actions table is provided on the basis of the 5-digit codes. (see Point to Point Error Codes document) | May |
| **CS51** | If the system detects an error, either via a message(s) returned by a recipient or the absence of any responses (e.g. retries expired), the system **MUST** proactively notify authorised user of such errors. It is not acceptable to rely on users accessing message logs to see if errors have occurred – the system **MUST** notify nominated users in some way (e.g. email, system messaging) | Must |
| CS51.1 | The system **MUST** make available appropriate information to the user to help them decide whether to re-send a message, e.g. access to message logs to determine the status of previously sent messages, access to error codes and text returned by receiving systems | Must |
| **CS52** | The system **MUST** provide a facility for a user to re-send a previously sent CDA document to one or more of the previous recipients, i.e. the user **MUST** be able to select the recipients from the previous recipients list. The original recipient list **MUST** be retained even though the document may be sent to a subset of recipients. | Must |
| **CS53** | The system **SHOULD** provide a facility for a user to send a replacement document for the previously sent document to all previous recipients who accepted the document (See Replacement Documents above). | Should |
| **CS54** | If one or more, but not all, recipients fail to respond to, or rejects, a CDA document message (e.g. the patient is not known to the system, the NHS number is invalid or some other system specific error message), and a replacement document is being sent, the system **SHOULD** allow a user to modify the recipient list to only send to recipients who accepted the previous message (see CS12 re recipient removal use case) | Should |

## Audit Requirements

The sending of CDA Documents forms part of a patient’s record and as such the audit requirements need to be of an equivalent standard. The additional audit requirements relating to CDA documents are detailed in the table below.

| Req. ID | Requirement Text | Rating |
| --- | --- | --- |
| **CS60** | Sending systems MUST record an audit record for each CDA document sent, including replacements and nullify versions, containing   * timestamp * the Document UUID, * setID * version number * the user who initiated the transaction * the users role identifier * the patient NHS Number (or other identifier if no NHS number present) | Must |
| **CS61** | A CDA document, once sent and successfully received by one or more recipients **MUST** not be modified in any way. If a modification is required a new document version **MUST** be created. | Must |

1. Process Flow Diagrams
2. Send CDA Document



|  |  |
| --- | --- |
| ***Endstate*** | ***Description*** |
| Success: [document] Sent Point-to-Point | Successful completion of this branch of the Point to Point flow (Send to primary or copy recipient). |
| Failure: Error sending point-to-point | A problem has arisen which makes delivery of the message to a selected direct recipient impossible. The failure needs to be logged and the sender (user/author/administrator) notified so that investigations can be carried out to determine whether it can be re-sent or the business process has to revert to other means (e.g. manual processes)is typically an application fault at the recipient.  See Failure Scenarios below for further details. |

**Notes**

1. Flows are independently managed on a per-recipient basis, and not as a single transaction. They are not rolled back in the case of individual flows failing.

2. The asynchronous behaviour of this process is driven by the messaging architecture (see (1) above) as responses to messages are sent independently to recipient systems, the process waits for each message response to come back asynchronously. These responses need to be processed asynchronously and may involve a local application user. This process therefore assumes a message status/message log facility exists and a mechanism for escalating problems to users to investigation/action.

1. Process Primary/Copy Recipient Response

This process described the error handling for systems that send or receive documents Point to Point only.



Diagram above – explain fatal error

**Endstate Descriptions – Process Primary/Copy Recipient Response**

|  |  |
| --- | --- |
| ***Endstate*** | ***Description*** |
| Success | Successful response received |
| Failure: replacement version error | Sending a document update has failed because the update was attempting to make an update which the destination application believes would create a logical inconsistency in the CDA information model. (e.g. replacement of a withdrawn document, previous version not held).  Process stop. |
| Failure: retry sending to recipient | The document failed to be delivered to the destination application, but may be retried. |
| Failure: restart business process | The parent process must restart at an appropriate point, dependent on response returned (i.e. 5-digit detailed response). |
| Failure: contact local support | A system-level error has occurred, either within the local or remote application, This cannot be retried so must be escalated with local application support. This must be reported to the user, and should also be reported direct (either through communication or logs) to the local support process. The business process must use alternative communication methods. The sending system should provide support for this, e.g. by allowing the content to be printed, or faxed, or sent as an email attachment. |
| Failure: no further action | The context of the request is such that there is no system error but the request is denied by the service. An example would be an attempted security violation from the local user. |

***Notes***

1. All failure states may result in the error being reported to the user (this includes the ‘no further action’ endstate, which may report the reason why it is not possible to retry **the** request).

1. Managing Responses from Multiple Recipients

The Sender of a document is responsible for managing the coordination of actions necessary to resolve situations where a Clinical Document has been sent to multiple recipients, and one or more of the recipient systems either does not return a response, or returns an error response.

This section provides guidance. It is the supplier’s responsibility to ensure that appropriate system actions are taken, and that appropriate system support to users is provided, for each condition that could occur.

This section is only applicable to systems capable of sending CDA documents Point to Point.

**Actions to be supported**

The sending system must provide facilities that allow users to take appropriate action to cover the cases where it is not possible for the system to determine what action to take.

The system may determine that the following action should be taken:

* Do nothing (a special case);
* Resend the same message to one or more recipients;
* Invoke the local support process.

The user may require one or more of the following options to be taken:

* Send a replacement message to a (potentially new) list of multiple recipients;
* Withdraw (Nullify) the Clinical Document from all recipients;
* Send a new Clinical Document to a (potentially new) list of multiple recipients;
* Invoke alternative communication plans.

Systems must provide support for these actions.

**Dependencies**

When managing responses from multiple recipients, the actions to be taken will depend on:

* Whether all systems return the same response or whether different responses are returned by different recipients.
* Whether the issue can be resolved by the user in a timely fashion or not.

The actions must be consistent with the following rules:

* If a Clinical Document is nullified, the nullification must be sent to all recipients that successfully processed any version of that Clinical Document.
* Similarly, if a Clinical Document is replaced, the replacement must be sent to all recipients that successfully processed any version of that Clinical Document.
* When a document is sent, the content must be identical for all recipients. (This includes the content that lists the primary and copy recipients.)

**Examples of Actions to be taken**

The following is a set of examples of the types of actions that are appropriate for various conditions.

**Condition 1: Document Already Processed**

In the circumstance that the message is rejected as a duplicate message (Detected Issue codes “401” with “30132”.), or a duplicate document (Detected Issue codes “410” with “41003”.), and it was indeed intentionally sent more than once, then the error condition does not require any further action to be taken.

(This condition may occur when no response was received from the first message sent, and the message is re-sent but the message had actually been processed. The second attempt would return this condition.)

**Condition 2: No Response**

If no acknowledgement is received (e.g. no ebXML ack for TMS messages), then the message should be automatically retried for those recipients for which this is the case.

**Condition 3: Retries Expired**

If message retries continue to get no response, then it will be necessary for alternative communication methods to be used.

1. It is necessary to use an alternative communication method for the failing recipient(s). The system should provide support for this.
2. Since the list of recipients in the Clinical Document does not match the list of recipients that have received the Clinical Document, a new version should be produced with the reduced list of recipients, excluding the failed recipient(s), and this should be sent all the recipients that accepted the message.

**Condition 4: Validation Error**

The condition may arise where some systems accept a Clinical Document as valid, and others may reject the same message as invalid. If this is a technical validation error, Detected Issue code “400” will be returned. If it is a clinical validation error, then some other form of communication will have been used to inform the sender.

On detection of this condition, local support will be needed to determine the cause of the problem. The user must also have been informed.

The cause may be either:

1. The Message is valid, but the validation by the rejecting system(s) is incorrect.
2. The Message is invalid (therefore the sending system is at fault) but some systems have not detected this and have accepted the message.

Cause not Determined

If the cause is not determined within an acceptable time period, the user should:

1. Withdraw the message. The system should provide the set of recipients for which the message must be withdrawn – i.e. all those that provided a successful response, or for which no response has been received.
2. Use alternative communication methods (e.g. paper, email). The system should provide as much support for this as possible.

Document is Valid

If the cause is determined to be that the validation error is incorrect and the document is indeed valid:

1. It is necessary to use an alternative communication method for the failing recipient.
2. Since the list of recipients in the Clinical Document does not match the list of recipients that have received the Clinical Document, a new version should be produced with the reduced list of recipients, excluding the failed recipient(s), and this should be sent all the recipients that accepted the message.

Document is Invalid

If the document is found to be invalid (meaning that there is a fault in the Sending system), the Sending system must be able to:

1. Withdraw the message from all recipients that did not return a failure response.
2. Provide support for using alternative communication methods to communicate to all recipients.

**Condition 5: Patient not Accepted**

This condition is where one or more recipients respond with an error for the reason that the patient is not known to the system, and the system does not accept documents for unknown patients. (Detected Issue codes “410” with “41002”.)

The sending system must be able to:

1. Send a replacement document with a revised list of recipients.

**Condition 6: Patient not Valid**

If a system has detected that the patient’s NHS Number is not valid, then, assuming that this is (now) the case, the system must be able to:

1. Withdraw the message for all recipients that have accepted the message, or from which no response has been received.

The business process should be restarted at an earlier point with the correct NHS Number.

If the patient is valid, and the system that sent the error is incorrect, then the local support route should be followed to investigate the cause. In the meantime:

1. Send a replacement document with a revised list of recipients to successful recipients.
2. Use alternative communication methods (e.g. paper, email) to the failed recipient. The system should provide as much support for this as possible.

**Condition 7: Service Failure**

Service failures that return detected issue code 500 are not likely to succeed if retried immediately. The problem is will require investigation prior to resolution. The sending system must be able to:

1. Retry sending to the failed recipient if advised by support staff.

Or

1. Use alternative communication methods to the failed recipient.
2. Send a replacement document with a revised list of recipients to successful recipients.

1. It is only permissible to remove a recipient if a previous transmission failed and it is inappropriate to send any further documents. [↑](#footnote-ref-1)
2. Or equivalent in social care settings [↑](#footnote-ref-2)