



EPS Dispensing Systems Compliance Specification			
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EPS Dispensing Systems Compliance Specification

Document Management

Revision History

Version	Date	Summary of Changes
1.0	17/06/2004	EPS Release 1 compliance
2.0	05/10/2005	EPS Release 2 compliance
3.0	27/03/2007	Updated for EPS Release 2 compliance
4.0	03/07/2008	Updated for EPS Release 2 compliance
5.0	17/10/2013	Updated for Spine 2 compliance
		Some requirement referenced re-numbered
		Replaced the term 'NCRS' with 'Spine'
		Replaced the abbreviation 'CFH' with 'HSCIC'
		Updated 'Glossary of Terms'
		All references to the 'PPD' replaced by the 'NHS BSA Prescription Services' or by 'BSA'
		All references to 'PCT' replaced by 'CCG'
		Updated requirements and supporting guidance to align with the "EPS Clarification of Requirements" document
		Removal of "Protocol Supply" requirements
		New requirements for grouping prescribed medication by patient and status
5.1	06/01/2014	New section (6.13.1) and requirements (6.13.6 to 6.13.10) for Claim Amendment
5.2	27/11/2014	Amended section 6.11.1 The "Dispensing Window" to remove the reviewDate attribute from dispensing window calculations
		New "Not Dispensed" reason code added for "Patient did not collect medication"
5.3	15/07/2015	Updated references throughout the document to align with Spine 2 terminology
		Grouped all requirements with each section for easier reading
		Section 3.1; remove exclusion of Schedule 2 or 3 controlled drug prescriptions; include exclusions for personal administration and private prescriptions.
		Section 4.1; updated to align with Spine 2 terminology
		Section 5.1; guidance for patient consent updated
		Section 6.1; requirements for Schedule 2 & 3 controlled drugs
		Section 6.4; requirement to handle invalidated prescribed dm+d concepts; recommendation that MIM 3.1.07 dispensing interactions are no longer used by dispensing systems.
		Section 6.5; supporting multiple ODS codes within a single system
		Section 6.10; requirement to display "PrescriptionType" to the user
		Section 6.11; the 'dispensing window' now relates to individual prescribed items not the entire prescription; new type of prescription for 'delayed prescribing'; requirement to process a positive acknowledgement following a dispense notification.
		Section 6.13; requirement to process a positive acknowledgement following a claim submission; requirement to alert the user if a default of "patient paid" is to be used.

		Section 6.15; clarification on handling expired prescriptions; updated guidance notes for Spine data cleansing rules; requirement to highlight prescriptions marked as "paid" by default within the view of un-endorsed Electronic Reimbursement Endorsement messages; requirement to notify the user of the number of un-endorsed Electronic Reimbursement Endorsement messages are various times leading up to the end of the claiming month.
		Section 6.17; updated guidance for update semantics; systems must support amended dispense notifications.
		Appendix A; updated 'PrescriptionType' vocabulary to remove references to PCT employed prescribers.
5.4	12/08/2015	Section 6.1 updated; change to the how the quantity in words is populated within the 'originalText' element for Schedule 2 or 3 controlled drug prescriptions.

Reviewers

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Glossary of Terms

Term / Abbreviation	What it stands for
Acute prescription	A "one-off" prescription generated following a consultation between a prescriber and a patient
Advanced Electronic Signature (AES)	An electronic digital signature standard referenced within DH legislation for signing prescriptions
Domain Message Specification (DMS)	The new name for the MIM. Separate versions are now published per domain.
Dispense or Dispensing	The verb to "dispense" or the act of "dispensing" for the EPS relates to the issue of medication to a patient, patient's representative or for processes like prescription delivery services, as close as business processes allow to the point the patient receives their medication. This term must not be confused with the act of labelling and bagging medication which the pharmacy industry often refers to as "dispensing".
Electronic prescription	The information transmitted electronically, with the inclusion of an Advanced Electronic Signature, from a prescriber to the Spine to allow dispensing via ETP
Electronic Prescription Service (EPS)	Electronic Prescription Service delivered by the ETP programme
Electronic Transmission of Prescriptions (ETP)	Electronic Transmission of Prescriptions programme, part of the HSCIC.
Prescription token	Paper token generated by a prescribing system that can be used using the dispensing process
FP10	The paper form that is used to create a prescription in the current prescribing process
Health & Social Care Information Centre (HSCIC)	The Health and Social Care Information Centre is the national data, information and technology organisation for the health and care systems in England.
Health Language 7 (HL7)	Organisation responsible for the production and communication of healthcare IT communications standards (http://www.hl7.org.uk)
Medication item	Any medication, appliance or device that can be prescribed
Message Implementation Manual (MIM)	Deprecated term - see 'Domain Message Specification'. A product from the NHS CFH that defines the HL7 messages implemented within the Spine.
Organisation Data Service (ODS)	The Organisation Data Service (ODS) is provided by the HSCIC. It is responsible for the national policy and standards with regard to organisation and practitioner codes.
NHS Dictionary of Medicines and Devices (dm+d)	Standard for exchange of information on drugs and devices between prescribers, dispensers and reimbursement agencies (http://www.dmd.nhs.uk)
Nomination of dispenser	Process by which a patient specifies a dispenser to manage their prescriptions
Personal administration	Medication administered directly by a healthcare professional to a patient
Prescribe	The act of authorising medication items on a prescription.
Repeat prescription	A prescriber-authorised repetition of a prescription
Repeatable prescription	A prescription valid for an authorised number of issues – also known as a repeat dispensing prescription
Spine	The national application infrastructure supported services including the EPS
The System	The system seeking compliance as an ETP prescribing system
TRUD	Technology Reference data Update Distribution (TRUD) service
Universal Unique Identifier	An information technology term for a unique identifier, also known as a Globally

(UUID) Unique Identifier (GUID)

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Related documents

NPFIT-SHR-QMS-PRP-0015 Glossary of Terms Consolidated NPFIT-FNT-TO-TIN-0377 Compliance Module for ETP v2 Prescribing and Dispensing Systems. NPFIT-ETP-EDB-0025 Prescribing Systems Compliance Specification NPFIT-FNT-TO-TIN-1383 IG v2 Foundation Module IG v3 Foundation Module NPFIT-ETP-EIM-0110 RBAC Implementation Guidance for the EPS R2 NPFIT-FNT-TO-TIN-1023 PDS Compliance Module v2 - Baseline Index NPFIT-ETP-EDB-0280 Nomination Web Services Requirements Specification for System Suppliers NPFIT-ETP-EDB-0080 EPS Dispensing Token Specification NPFIT-ETP-EDB-0064 EFP Message Signing Requirements NPFIT-ETP-EDB-0064 ETP Message Signing Requirements NPFIT-FNT-TO-IG-0019 Digital Signing and Non Repudiations

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1 Purpose

This document specifies the functionality required to support the EPS for dispensing systems in England.

In the main this document only details interoperability with EPS and new business process concerned with EPS which will be tested to assure EPS compliance is achieved, however suppliers may wish to work with their users to consider reconfiguration of existing business process in light of EPS. This will be outside of the scope of EPS compliance and will not be tested.

It is recognised that dispensing doctors, as well as pharmacists authorised to act as supplementary prescribers, may have one combined system. A dispensing system used by a dispensing doctor must adhere to the requirements defined within the "Prescribing Systems Compliance Specification" (ref: NPFIT-ETP-EDB-0025).

1.1 Audience

This document has been written for system suppliers.

1.2 Content

This document comprises this following sections / topics:

- Background
- EPS Objectives
- Compliance Overview
- Spine Core Functionality Compliance
- Electronic Prescription Service Compliance
- Business Continuity

This document <u>does not</u> cover the functionality required to support the following pharmacy processes:

- Prescribing queries
- Stock maintenance & reconciliation
- Local patient medical records
- Medication label printing
- Financial accounting
- Commercial business management.

Within this document, system requirements are explicitly listed within tables. Additional documentation, guidance and illustrations are contained within each document section to support the understanding of the requirements.

Previous versions of this specification document classified each requirement as either "Mandatory" or "Optional". This has been removed as the vast majority of requirements are mandatory.

The following use of terminology denotes the optionality of each requirement;

- Where the term '**must**' is used the requirement is mandatory
- Where the term '**should**' is used the requirement is optional but recommended
- Where the term 'could' is used the requirement is optional.

2 Background

The Electronic Transmission of Prescriptions (ETP) programme has its origins in a number of Government policy initiatives stemming from *The NHS Plan* (7/2000). In particular, *Pharmacy in the Future* (9/2000) said:

'By 2004 electronic prescriptions will be routine in the community as well as hospitals. Transfer of prescription data between GPs, pharmacies and the Prescription Pricing Authority will be carried out electronically, using the NHS net, in the large majority of cases by 2008, or even earlier.'

2.1 Pharmacy Policy

In response to the commitments made in **Pharmacy in the Future**, three ETP pilots commenced in mid-2002 and ended in June 2003. The pilots were independently evaluated by the Sowerby Centre for Health Informatics (SCHIN) at the University of Newcastle. The key findings of the evaluation included the following:

- The pilots have shown that ETP is technically viable. By the end of 2002, over 92,000 ETP messages had been transmitted by 51 GP practices and 40 pharmacies;
- Theoretical analysis indicates that ETP has the potential overall to reduce prescription fraud or irregularity, although some types may become more difficult to detect, and some easier to commit;
- There are no major concerns with the security of ETP, although there were minor security issues with the pilot solutions which must be taken into account in implementing and maintaining a secure national system;
- Patients, GPs and pharmacists are on the whole likely to find ETP acceptable, and may come to appreciate the benefits in time;
- When the majority of prescriptions are issued electronically, pharmacies operating prescription collection services expect to make time savings. This may release pharmacy staff to spend more time with customers providing health care advice.

A Vision for Pharmacy in the New NHS, published in June 2003, made clear the Government's intention to include community pharmacy within an integrated NHS. This is an important part of plans for developing the quality and range of community pharmacy services, supporting the development of professional working relationships across all health sectors – hospital, community and other primary care settings.

At the same time the Government also published the document **Framework for a New Community Pharmacy Contract** setting out the range of services that a community pharmacist might provide. These were grouped into three categories:

• **Essential** - including dispensing, repeat dispensing and reporting to the National Patient Safety Agency on incidents;

- Advanced including medication use review, and;
- **Enhanced** including the supply of medicines under minor ailment schemes and patient group directions and supplementary prescribing.

In taking on these extended roles and in working with other healthcare professionals to deliver new integrated services, the community pharmacist needs better access to medical and patient information to carry out these responsibilities. This will help ensure that the services they provide are delivered safely and effectively in a way that meets individual patient needs.

Community pharmacists need access to shared information on interventions and supplies made by other healthcare professionals and the ability to generate information that they need to contribute to the patient record. Systems are needed to ensure that essential information is safely recorded, stored, shared and communicated between all professional staff that provide care and treatment for a patient - in hospitals, GP surgeries and community pharmacies.

Community pharmacists also need access to the Internet and email to improve communications (for example, to be able to receive public health alerts and improve access to information such as the National Electronic Library for Health and to enable them to contribute to the work of agencies such as the National Patient Safety Agency (NPSA) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

2.2 NHS Business Services Authority Prescription Service

The NHS Business Services Authority (BSA) Prescription Services, previously known as the Prescription Pricing Division (PPD), is responsible, amongst other things, for the payment of community dispensers for the drugs, medicines, appliances and services they provide and for the provision of management information relating to the dispensing and supply of drugs.

The **NHS BSA Business Strategy** summarises the challenges currently facing the organisation as follows;

'We are entering a crucial period in which the interaction between growth and increasing complexity, on one hand, and our ability to reengineer our processes to increase automation, on the other, must be managed to enable us to contain projected growth within our current processing capacity. We must respond flexibly to these changing demands if we are to maintain the value and the effectiveness of our services to the NHS.'

The rules governing the reimbursement of prescriptions are complex and this, combined with the significant growth in prescription volumes, means that the BSA needs to increase processing capacity. BSA internal processes have been reengineered to automate as much as possible. However, the potential to receive prescriptions electronically offers the opportunity to fully automate the data capture process and reduce the dependence on manual processing. The timing of this capacity increase is critical.

2.3 The National Programme for Information technology in the NHS

Delivering 21st Century IT Support for the NHS (2002) announced the creation of the National Programme for Information Technology in the NHS. This national strategic programme is concerned with major developments in the deployment and use of Information Technology (IT) in the NHS. It aims to connect delivery of the NHS Plan with the capabilities of modern information technologies to:

- support the patient and the delivery of services designed around the patient, quickly, conveniently and seamlessly;
- support staff through effective electronic communications, better learning and knowledge management, cut the time to find essential information (notes, test results) and make specialised expertise more accessible;
- improve management and delivery of services by providing good quality data to support National Service Frameworks, clinical audit, governance and management information.

Delivering 21st Century IT Support for the NHS (2002) said:

'It is anticipated that the [ETP] trials will continue to grow and involve a sizeable number of GPs and Pharmacists with a natural migration into rollout. This project will create greater connectivity to NHSnet for Pharmacists allowing the access to the benefits that this service provides. In parallel the Prescription Pricing Authority will have re-engineered their systems to ensure that they process prescriptions electronically. The National Prescriptions Service will be 50% implemented by 2005 and fully implemented by 2006/7.'

The EPS programme therefore exists to carry forward both the commitments to delivering the Electronic Transmission of Prescriptions and to providing enhanced IT support to community pharmacists to enable them to play an expanded role in primary healthcare.

3 EPS Objectives

The principal objectives of the EPS programme are:

- 1. To enable the Electronic Prescription Service (EPS) in England between:
 - Prescribers
 - Dispensers
 - The NHS Care Record
 - Reimbursement Agencies (e.g. the NHS BSA)
- 2. To facilitate the provision of enhanced patient centred services by community pharmacists which require access to the NHS Care Record
- 3. To enable the BSA Prescription Services to re-engineer their processes to increase capacity and reduce the unit cost of processing prescriptions.

3.1 EPS Scope

EPS starts at the point where a decision to prescribe has been taken and ends when medication is dispensed and reimbursed (or prescription is cancelled, expires etc.).

EPS covers all primary care prescribing and dispensing (including repeat dispensing) and supply of medicines, drugs, appliances and chemical reagents by NHS dispensing contractors. Also within scope are prescriptions written within secondary care issued for dispensing in the community.

The EPS can be used for any patient with a known and valid NHS number.

The following are explicitly **out of scope**.

- Bulk prescriptions
- Prescribing of non dm+d medication items
- Handwritten medication items or amendments on prescription tokens that relate to electronically signed prescriptions
- Automated non-age exemption verification
- Schedule 1 controlled drugs
- Prescribing of extemporaneous preparations not already defined within dm+d as 'extemp orders' ¹
- Personal administration
- Private prescriptions

¹ Until such a time when supported within the HL7 messaging with clear implementation guidance available.

4 Compliance Overview

4.1 EPS National Model

The high level technical architecture for the EPS is shown in **Error! Reference** ource not found. below.

EPS Technical Architecture





Dispensing systems are required to interact with the Spine. Connectivity to Spine can be via the national communications infrastructure ('N3') or via commercial N3 aggregators. Transport layer security ensures that both connectivity models meet the security requirements of the HSCIC. All electronic interactions follow this model; no electronic interactions exist directly between a dispensing system and any other healthcare system.

Within the Spine are a number of sub-systems that an EPS compliant dispensing system will directly or indirectly communicate with:

- "Demographics" is the central store which holds all patient non-medical details.
- "Messaging" is a message router, which will direct a message to the required.
- "CIS Authentication" controls end-user authentication and access control.
- Various "Directories" for people, organisations and systems.

 "Prescriptions" is the subsystem that implements the necessary workflows and rules for EPS processes.

4.1.1 EPS Phased Implementation

The enduring strategy for the implementation of the EPS will consist of four main phases, underpinned by two releases of software. In summary these are:

Implementation Phase	EPS Software
1 – Initial Implementers	EPS Release 1
2 – Nationwide Deployment	EPS Release 1
3 – Transition	EPS Release 2
4 – Full EPS	EPS Release 2

The terms "Phase" (1 to 4) and "Release" (1 or 2) will be used within this specification.

5 Spine Core Functionality Compliance

A system wishing to use any of the services provided by the Spine must first be compliant with the core services and all appropriate legislation, regulations, national and international laws related to healthcare systems. The two core Spine services applicable to the EPS are Information Governance (IG) and Demographics.

It is the supplier's responsibility to ensure their system complies with all appropriate legislation, regulations, national and international laws related to healthcare systems. This specification was legally compliant at the time of issue however the overarching requirement to remain within the law has precedence over this document.

Where a supplier identifies conflicts between this specification and legal requirements (e.g. due to changes in the law) they are to contact HSCIC to ensure the specification is revised and to seek advice on how they should comply with the change in legislation.

5.1 Information Governance

The document "IG v3 Foundation Module" (ref: NPFIT-FNT-TO-TIN-1383) defines the baseline for documents related to the Information Governance (IG).

The following sections provide clarifications to common IG requirements within the context of EPS solutions.

5.1.1 Patient Consent

There is no requirement for a dispenser, or the dispensing system, to establish or record a patient's consent to use the EPS.

Prescribing systems will hold a local consent flag against each patient record, when not populated, consent is assumed as the EPS uses an 'implied consent' model.

Therefore patient consent is implied by them either;

- Nominating the dispenser for their electronic prescriptions
- Presenting a barcoded prescription or dispensing token to the dispenser
- Using any other method of communicating a Prescription ID to the dispenser that may become available over time, e.g. via a printed email or mobile device.

5.1.2 User Authentication

All pharmacists and necessary staff who support the dispensing process, who require access to the EPS, must first be sponsored, registered and issued with an NHS smartcard by their local Registration Authority.

User registration includes the creation of a User Role Profile (URP), stored in one of the Spine Directories. The URP contains the user's roles and associated attributes to implement Role Based Access Control (RBAC). Each URP is also associated with an organisation ODS code. For users who work in different organisations (i.e. which operate using a different ODS code), they will require a separate URP for each location in which they work.

An exception to requiring a URP for each organisation in which the user works is for locum pharmacists who may work in many organisations, possibly at short notice. A

locum pharmacist can be registered with a single URP associated with a virtual 'National Locum Pharmacy' organisation ODS code (code = FFFFF).

As part of the user authentication process, the System must check that the organisation ODS code within the URP matches the organisation ODS code configured for the local system. If this does not match, then the System must then check if the URP organisation is the virtual 'National Locum Pharmacy'. If neither of these checks is successful then the user must be denied access to Spine services.

If a user is authenticated with the virtual 'National Locum Pharmacy' organisation then the System must display this message to the user successful authentication.

"You are accountable to the pharmacy organisation in which you are currently working for all the actions you take on the system; you may not use the system to act in any other capacity".

It is recommended that the System provides a means where the user can identify when they are logged on to the Spine. For example, icons within an application status bar.

5.1.3 Role Based Access Control (RBAC)

The HSCIC NHS facing website contains RBAC documentation and guidance and is the primary source for the National RBAC Database (NRD) that defines all the roles, activities, areas of work and baselines for the NHS. This will include the relevant baseline for the EPS. See http://nww.hscic.gov.uk/iim/documents/index_html.

An RBAC baseline is a set of activities defined for a role/area of work combination. These baseline activities are the minimum set of activities that can be undertaken by someone with that role & area of work. In addition to the baseline activities, Sponsors can approve additional optional activities for a user. Therefore baseline activities will not need to be specified by the user's sponsor. The optional, additional activities will always need to be specified by the sponsor and entered into users' role profiles.

RBAC should be linked to application functionality and not directly with messaging interactions with the Spine. Also note that some activities do not directly relate to Spine functionality but are instead associated with existing local system functionality.

Guidance for how to interpret the activities listed within the EPS Baseline will be published within the document "RBAC Implementation Guidance for the EPS R2" (ref: NPFIT-ETP-EIM-0110).

5.1.4 Legitimate Relationships

The legitimate relationship requirements defined within the Spine Core Requirements are not applicable to the EPS service. For EPS, the existence of a legitimate relationship *does not* need to be checked by the System.

Ref	Requirement
5.1.1	The System <u>must</u> implement smartcard-based Spine user authentication as defined by the HSCIC Information Governance requirements.

Ref	Requirement
5.1.2	The System <u>should</u> provide a means where the user can identify when they are logged on to the Spine.
5.1.3	The System <u>should</u> allow users to access system functionality outside the EPS or other Spine Services without smartcard authentication. Access to such non-Spine functionality must be governed by existing IG procedures within the System.
5.1.4	The System <u>should</u> access non-Spine web services, such as the NHS Choices web services without Spine user authentication.
5.1.5	The System <u>must</u> adhere to the RBAC requirements defined within "IG Requirements for ESP".
5.1.6	The System <u>must</u> implement the EPS Baseline defined within the National RBAC Database (NRD) including subsequent updates and amendments to the baseline.
5.1.7	The System <u>must</u> check that the organisation ODS code within the URP matches the organisation ODS code configured for the local system. If this does not match, then the System <u>must</u> then check if the URP organisation is the virtual 'National Locum Pharmacy' (code = FFFFF). If neither of these checks is successful then the user <u>must</u> be denied access to Spine services.
5.1.8	If a user is authenticated with the virtual 'National Locum Pharmacy' organisation (code = FFFFF) then the System <u>must</u> display this message to the user successful authentication.
	"You are accountable to the pharmacy organisation in which you are currently working for all the actions you take on the system; you may not use the system to act in any other capacity".

5.2 Spine Demographics Service

The document "PDS Compliance Module V2 - Baseline Index" (ref: NPFIT-FNT-TO-TIN-1023) defines the baseline for documents related to the Demographics Service.

Dispensing systems are required to integrate with the Spine Demographics Service for the process of setting a patient's nominated dispenser. The Demographics Service baseline references the various documents that define these requirements and provide implementation guidance.

In all cases, the EPS is available to patients with a known NHS Number obtained from the Demographics Service.

5.2.1 Relevant Demographics Service MIM Interactions for Dispensers

The following table lists the Demographics Service interactions defined within MIM 4.2.00 together with whether these are relevant to dispensing systems. The relevancy is based on the need for the dispensing system to trace and update patient demographics (e.g. nominated dispenser), but not to allocate NHS numbers or update consent or death status.

MIM Interaction	Relevant	Notes
PDS Trace Query Started	Yes	
PDS Advanced Trace Query Started	No	See Note 1
PDS Trace Query Successful	Yes	
PDS Retrieval Query Started	Yes	
PDS Retrieval Query Successful	Yes	
PDS Confirm NHS Number Query Started	Optional	See Note 2
PDS NHS Number Confirmed	Optional	See Note 2
PDS NHS Number Allocation Request Started	No	
PDS NHS Number Allocation Request Completed	No	
PDS General Update Started	Yes	
PDS Successful Update Response	Yes	

Refer to MIM and Demographics Service documentation for more information regarding these interactions.

Notes

- The Advanced Trace interaction is excluded as the (simple) Trace interactions can be used with the demographic information available to dispensers (i.e. name, sex, DoB & postcode). The Advanced Trace interaction may be implemented but additional PDS requirements apply.
- 2. The process of confirming an NHS number can be performed using the 'PDS Retrieval Query Started/Successful' interactions.

5.2.2 Patient Nomination of Dispensing Contractor

The EPS requires the System to be able to nominate or de-nominate a dispensing contractor for a patient.

A patient can choose up to three nominated dispensers to cover the different contractor types;

- Community Pharmacy
- Appliance Contractor
- Dispensing Doctor

The MIM contains two vocabularies for contractor types. The "DispensingSitePreference" vocabulary is used within the Medication Management domain and the "PatientCareProvisionType" vocabulary is used within the Demographics domain. The vocabularies are aligned as some previous codes have been deprecated.

Nomination information is stored in the Demographics Service and is updated using the same update semantics as other aspects of the patient's demographic record. The "PatientCareProvisionType" vocabulary must be used when updating a patient's nomination information using PDS messaging. The ODS code of the nominated dispenser is populated within the "HealthCareProvider" entity of the PDS update message.

5.2.3 Identification of a Dispenser ODS Code

To set a patient's nominated dispenser, the ODS code of the dispensing location must be known. Details of pharmacies operating the EPS and their ODS codes will be recorded on the NHS Choices web site (http://www.nhs.uk).

NHS Choices web services will be available to allow an end system to integrate with the NHS Choices database. Dispensers operating the EPS can be located by various search criteria.

Where the System is not nominating its own site then the NHS Choices web services must be used to validate that the dispensing location exists and is operating an EPS nomination service. If the System permits the manual entry of a ODS code of a dispensing site then the NHS Choices web services must be used to validate this site.

Where the System is nominating its own site then the ODS code of the site needs to be known and held as a secure parameter, configurable only by authorised system administrators. The contractor type of the site (e.g. Community Pharmacy, Dispensing Appliance Contractor or Dispensing Doctor) must also be a secure parameter to avoid an invalid nomination being configured.

ODS codes are case sensitive. All ODS codes therefore must be formatted using UPPER case characters and numbers.

The System must ensure that a chosen ODS code represents a dispensing contractor 'site'. The nomination of dispensing contractor organisations or groups shall not be permitted.

The ODS codes of dispensing doctors will not be available via the NHS Choices service. A nomination to a dispensing doctor must only be possible from that dispensing doctor's location. Nomination to a dispensing doctor must not be possible remotely. A dispensing doctor must have access to an EPS R2 compliant dispensing system before nominating any patients to the practice.

5.2.4 Identification of the Patient's Nominated Dispensers

The System must display all of the current nominated dispensing organisation details for a patient. This must include the following;

- Contractor type
- Organisation name
- Organisation address
- Organisation postcode.

The dispenser's address displayed must be at least as many address lines as required to distinguish between dispensers of the same chain within the same location. For example to distinguish between; "Acme Chemist, 1 High Street, Anytown" and "Acme Chemist, 123a Lower High Street, Anytown".

The patient's national demographics record only contains the ODS code for a nominated dispenser therefore Spine organisational directory must be queried for this additional information. Table 1 below lists the Spine SDS attributes relevant for the LDAP query.

Data Item	Spine SDS Attribute
Contractor type	organisation.nhsOrgType
Organisation name	organisation.o
Organisation address	organisation.postalAddress
Organisation postcode	organisation.postalCode

Table 1 - Spine Directory Attributes for Nominated Dispenser Organisation Details

Refer to the External Interface Specification, section 5.1.1 for Directory security requirements and note that LDAPS (LDAP over TLS) using Spine certificate authority credentials is required.

5.2.5 Source of NHS Number Flag

The "PDS Retrieval Query Started" interaction uses the patient's NHS number as an input parameter. Demographics requirements state that if the NHS number held locally is not derived from Spine Demographics then the System must first use the "PDS Trace Query Started" interaction to find the patient's record using their demographic details.

In order for the System to implement the necessary logic to decide whether a PDS Trace is required before a PDS Retrieval, the System should associate a flag against each local demographic record to identify whether the patient's NHS number has been derived from Spine Demographics. An NHS number derived from Spine Demographics will be either that returned directly from a PDS Trace or returned indirectly from the content of an HL7 Prescription Release Response message.

Ref	Requirement
5.2.1	The System <u>must</u> include the functionality to add, update or remove a patient's nominated dispensing contractor information recorded within the Spine Demographics Service. This includes the ability to remove a dispensing doctor nomination.
	The System <u>must</u> populate the Spine Demographics Service with the contractor type and ODS code of that nominated contractors site.
	To delete a nomination, the Demographics object <u>must</u> be removed. Refer to the MIM for details of how to remove a Demographics object.

Ref	Requirement
5.2.2	The System <u>must</u> allow the nomination of other dispensing sites (other than its own dispensing site). The NHS Choices web services must be used to locate other dispensing sites operating the EPS.
	Additional requirements are defined within the document "Nomination Web Services Requirements Specification for System Suppliers" (NPFIT-ETP-EDB-0280).
5.2.3	The ODS code for a dispensing site, where this is not the code for the local site (where the nomination is taking place) <u>must</u> be validated using the NHS Choices web services to ensure the site is valid and operating the EPS Release 2.
5.2.4	If the System permits the manual entry of a ODS code for a dispensing site then the NHS Choices web services <u>must</u> be used to validate that this site is valid and operating the EPS Release 2.
	Note . Any manually entered ODS codes must be restricted to UPPER case characters (and numbers) either at the point of data capture or before data is stored.
	Note . The functionality to permit a manual entry of a ODS code is optional. If implemented, the use of NHS Choices web services to validate the code is mandatory.
5.2.5	The ODS codes of dispensing doctors will be not available via the NHS Choices service. A nomination to a dispensing doctor <u>must</u> only be possible from that dispensing doctor's location. Nomination to a dispensing doctor must not be possible remotely.
5.2.6	The System <u>must</u> ensure that the chosen ODS code is a dispensing contractor 'site'. The nomination of dispensing contractor organisations or groups must not be permitted.
5.2.7	The System <u>must</u> be able to display the current nominated dispensing organisation details for a patient. This must include the following;
	 Contractor type (e.g. community pharmacy, appliance contractor or dispensing doctor)
	Organisation name
	Organisation address
	Organisation postcode
	The patients national demographics record only contains the ODS code for a nominated dispenser therefore Spine Organisational Directory must be queried for this additional information.

Ref	Requirement
5.2.8	Where the System is nominating its own site then the ODS code of the site needs to be known and held as a secure parameter, configurable only be authorised system administrators.
	The contractor type of the site (e.g. Community Pharmacy, Dispensing Appliance Contractor or Dispensing Doctor) <u>must</u> also be a secure parameter, configurable only be authorised system administrators.
5.2.9	The System <u>should</u> associate a flag against each local demographic record to identify whether the patient's NHS number has been derived from Spine Demographics, either directly from a PDS Trace or indirectly from the content of an HL7 Prescription Release Response message.
5.2.10	The ODS code for a patient's nominated dispenser <u>must</u> be formatted in UPPER case within a "PDS Update" interaction.

6 Electronic Prescription Service Compliance

The remainder of this document relates to the specific compliance requirements for dispensing systems that are seeking HSCIC EPS dispensing systems compliance.

Dispensing and additional pharmacy processes not covered in this document are not subject to HSCIC compliance testing. For example;

- Prescribing queries
- Stock maintenance & reconciliation
- Local patient medical records
- Medication label printing
- Financial accounting
- Commercial business management.

All requirements defined within this section are in addition to existing pharmacy requirements from the DH and/or NHS England.

6.1 Prescribing Models

The EPS supports three prescribing models in addition to existing paper-based FP10 prescribing. The three prescribing models, depicted in Figure 2, are;

- Electronic Acute Prescribing
- Electronic Repeat Prescribing
- Electronic Repeat Dispensing (Repeatable Prescriptions)

However in certain circumstances the prescriber shall still be available to provide an FP10 prescription to the patient.

6.1.1 Electronic Acute Prescribing

An acute prescription is generated following a consultation between a prescriber and a patient and is a "one-off" prescription.

An electronic "Parent Prescription" message is created by the System and sent to the Spine, to be made available for "pull-down" by a dispenser. The prescribed medication is dispensed and this is recorded within an electronic "Dispense Notification" message sent back to the Spine. If an electronic reimbursement claim is applicable, this can also be sent to the Spine.

A variant on an acute prescription is a "Delayed Prescription". See section 6.11.2.

6.1.2 Electronic Repeat Prescribing

An electronic repeat prescribing prescription is treated by the EPS Spine component in the same way as an acute prescription and therefore is processed the same way as an acute by the dispensing system.



Figure 2 – EPS Prescribing and Dispensing Models

6.1.3 Electronic Repeat Dispensing

The EPS "repeat dispensing" model is designed to work alongside the paper-based repeat dispensing model, thus allowing either model to be adopted by dispensers with minimal change. For the purposes of this specification, it is assumed that the reader has knowledge of the paper-based repeat dispensing model.

One of the key aspects of repeat dispensing is that the Spine manages the re-issue of subsequent authorised issues of the repeat dispensing prescription. Electronic repeat dispensing prescriptions must be electronic prescriptions, electronically signed with an Advanced Electronic Signature (AES) by the prescriber.

The technical model² for repeat dispensing works in the following way;

- The prescriber authorises a prescription with a specified number of issues for which it is valid.
- Each issue is for the same prescribed medication items.
- The prescriber optionally prints a "Repeatable Prescription Authorising Token" to give to the patient. Refer to the document "EPS Prescription Token Specification" (ref. NPFIT-ETP-EDB-0027) for detailed token printing requirements.

² The model description for repeat dispensing has been simplified for the purposes of this specification as the details do not impact the technical functionality required by a prescribing system.

- When the Spine ETP component receives the electronic repeatable prescription it makes this available as the 1st issue of the prescription for dispensing.
- The next issue of the prescription is created on the Spine once the previous issue is deemed "complete" (i.e. all medication items either dispensed or not dispensed) so it can be requested and download by the dispenser. The Spine will send nominated repeat dispensing subsequent issues to the nominated dispenser at a time a few days before the next issue is due based on the date of the last dispensing event and the 'DaysSupply' attribute from the prescription.
- Once all authorised issues of the prescription have been dispensed, or if the prescription has expired, the repeatable prescription is completed. For more medication, the patient must re-visit their GP and obtain a new Repeatable Prescription Authorising Token for another repeat cycle.
- At any time, the prescriber may submit a prescription cancellation request on the prescription or an item within the prescription. This will cancel the repeat dispensing authorisation, or prescribed item, and prevent any further issues of the prescription, or prescribed item, from being dispensed.

6.1.4 Controlled Drugs

Changes in legislation in 2015 permitted the prescribing of Schedule 2 and 3 controlled drugs using an Advanced Electronic Signature (AES), thus such prescriptions could be prescribed via the EPS.

A prescription may contain a mix of controlled and non-controlled drugs. The System must calculate the expiry period for each prescribed item, see Section 6.15.3.

When a Schedule 2 or 3 controlled drug is prescribed, the quantity of medication will be expressed in both words and figures. The representation in words will be contained within an 'originalText' element as per the example below;

There is no requirement for the system to determine the equivalence between the quantity expressed in words and figures. If the user identifies a mismatch then he/she should contact the prescriber to determine the intention for the prescription. The System should process the quantity based on the representation in figures.

6.1.5 NHS Private Prescriptions

Electronic NHS private prescriptions <u>must not</u> be prescribed via the EPS until they are brought into scope and this is communicated by HSCIC.

This section has been removed pending confirmation of the requirements.

Ref	Requirement
6.1.1	Requirement Removed If a prescription signed with an Advanced Electronic Signature (AES) containing schedule 2 and 3 controlled drugs is received by the System before necessary DH legislation is changed, then the prescription is not a legal NHS prescription. The prescribed items <u>must</u> be marked as "Not Dispensed" within a Dispense Notification, using the reason code 0006 "Illegal NHS prescription".
6.1.2	Out of Scope If an NHS private prescription signed with an Advanced Electronic Signature (AES) is received by the System before they are brought into scope, then the prescribed items <u>must</u> be marked as "Not Dispensed" within a Dispense Notification, using the "Not Dispensed Reason" code of 0007 "Prescribed out of scope item".
6.1.3	Out of Scope Electronic NHS private prescriptions are not submitted to the BSA for reimbursement therefore electronic endorsement messages <u>must not</u> be submitted to the Spine.
6.1.4	The quantity of medication prescribed for a schedule 2 or 3 controlled drug will be expressed in both words and figures using an <originaltext> element inside the quantity expressed in figures using the "alternative units" HL7 flavour.</originaltext>
	<pre>For example; <quantity unit="capsule" value="28"></quantity></pre>
6.1.5	The System <u>should</u> process the quantity of a schedule 2 or 3 controlled drug based on the representation in figures, not words.
6.1.6	Schedule 2, 3, 4 or 5 controlled drugs, together with non-controlled drugs, can be prescribed on the same prescription. The System <u>must</u> handle the differing expiry periods for such medication.

6.2 Electronic Patient Medical Records

The electronic Patient Medical Record (PMR) that dispensers are required to maintain locally still applies for EPS. If not already used, the patient NHS Number must be recorded as this is the primary identifier for all Spine patient services such as EPS.

The EPS introduces more emphasis on electronic records, particularly with the introduction of electronically signed prescriptions. Therefore the System must demonstrate an effective back up and disaster recovery process.

Ref	Requirement
6.2.1	The System <u>must</u> maintain a local database of electronic prescriptions received from the Spine.
6.2.2	As per current pharmacy arrangements, the System <u>must</u> maintain a local database of patient demographic information.
6.2.3	The System <u>must</u> use the NHS Number, contained within an electronic prescription or from the Spine Demographics, as the patient identifier.
6.2.4	The System <u>must</u> demonstrate an effective back up and disaster recovery process.

6.3 Messaging Requirements

The mechanism of communication with the Spine Messaging Service is defined within the External Interface Specification (ref: CDT D0002).

All system-to-system communication for EPS is implemented using messaging. The standard for messaging is ebXML based on the HL7 Transport Specification - ebXML, Release 1.

Messages received and sent by a dispensing system will be as defined by the Standard Message Set. These are HL7 Version 3 compliant and will be validated using schemas. The only messages that may be utilised for EPS are those specified for EPS and published under the auspices of HL7. Systems will be required to remain current as revisions to the message specification are published.

Health Level 7 (HL7) is an organisation responsible for the production and promotion of the HL7 series of healthcare IT communications standards. In 2002 the NHS Information Standards Board (ISB) approved HL7 Version 3 as the strategic standard for NHS clinical messaging within the National Programme.

HL7 Version 3 ensures consistency in the definition of different information objects and their representation in messages, thus allowing for easier implementation and the definition of clearer conformance requirements. HL7 V3 standards are developed using XML schema to define the information model.

6.3.1 Message Implementation Manual

The relevant versions of the historic Message Implementation Manual (MIM), and the replacements for MIMs, the Domain Message Specification (DMS), at the time of writing, for EPS is as follows:

MIM Domain	EPS Release 1	EPS Release 2	EPS Release 2.1
Medication Management	MIM 3.1.07	MIM 4.2.00	DMS 3.3.0
Infrastructure	MIM 3.1.07	MIM 4.2.00	DMS 3.3.0
PDS	MIM 2.3	MIM 4.2.00	MIM 4.2.00

(*) The term "Release 2.1" is an internal name for this release. It is not planned to use this term for external or end-user communications.

Suppliers are reminded that a mandatory requirement for all message handling services that implement EPS messages is that all outbound messages (i.e. to the Spine) **must** be schema validated against the relevant XML schemas published within the MIM. Messages failing schema validation **must not** be sent to the Spine.

6.3.2 Use of Spine Directory Service for Messaging

The System is required to obtain messaging parameters (i.e. ASIDs and CPA IDs) from the Spine Directories via LDAP. The System is required to obtain these parameters on a regular basis as these values could be subject to change. Suppliers are recommended to check messaging attributes returned from the Spine Directories to ensure they are valid, for example to ensure they are non-blank.

6.3.3 Character Encoding

Within the W3C XML recommendation (http://www.w3.org/TR/2006/REC-xml11-20060816/) there are sections related to the use of encoding.

Section 4.3.3 of the recommendation states that the encoding implemented must be that which is declared at the start of the XML document. Further if encoding is not explicitly declared then only certain entities can be used. It is deemed an XML fatal error is either of these recommendations is not adhered to.

A specific example where incorrect encoding has caused interoperability issues for the EPS is with the '£' character. The UTF-8 encoding of this character is (in HEX) 0xC2 0xA3. See http://www.fileformat.info/info/unicode/char/00a3/index.htm

6.3.4 Timestamps

Suppliers are reminded of the CFH Standards Consulting Group clarification for timestamp representation, "NPFIT-FNT-TO-SCG-0005 SCG clarification on time zone v1.0". The System must adhere to this guidance for Spine 2 compliance.

6.3.5 Population of CMETs

A CMET is a common component used across MIM domains.

From an XML schema perspective, a CMET schema is quite loose each must support the lowest common dominator of use. For example when referring to a patient in care settings outside the EPS, the minimum data requirement is just the patient's NHS Number. Hence within the CMET "R_Patient" the only mandatory attribute is "id" that holds the NHS Number.

Guidance is provided for the following CMETs and common data types within a CMET.

- R_Patient
- R_AgentNPFITPerson
- R_AgentNPFITOrgSDS
- Person Name data type
- Postal Address data type
- Telecommuncations Address data type
- Physical Quantity data type
- Implementation of SET data types

6.3.5.1 R_Patient

The "R_Patient" CMET contains data related to a single patient.



Figure 3 - R_Patient CMET (extract from MIM)

The population of this CMET is defined within the MIM within the tabular view for the "recordTarget" entity.

The required fields are;

• id

NHS Number of the patient.

• name

Patient name

addr
 Address of the patient

- administrativeGenderCode
- The gender of the patient
 - birthTime

The date of birth in the format YYYYMMDD, see note below.

• healthCareProvider.id

The ODS code for the patient's registered GP practice organisation.

6.3.5.2 R_AgentNPFITPerson

The "R_AgentNPFITPerson" CMET is used when recording details of Spine user who is acting as the author or responsible party. This CMET supports two variants of such details; PersonSDS / OrganisationSDS and Person / Organisation. The SDS variants only capture the ID of the person or organisation. The details could be queried from the SDS. However for legal reasons, additional information such as name and address must be contained within a prescription.

Therefore **in all cases**, the non-SDS variant within this CMET must be used (e.g. "Organization" and "Person").



Figure 4 – R_AgentNPFITPerson CMET (extract from MIM)

The population of this CMET is defined within the MIM within the tabular views.

Within "AgentPerson"

The required fields are;

• id

The role profile code for the dispenser for the current role in which they are working (OID = 1.2.826.0.1285.0.2.0.67).

• code

The SDS job role code (returned in the SAML assertion following successful enduser authentication) for example "S8000:G8000:R8003".

telecom

A valid telephone number for the user for the role in which they are playing. Where a specific individuals telephone number is not available use the same telephone number as provided within the Organization entity.

Within "Person"

The required fields are;

• id

The user's unique identifier defined within Spine SDS (OID = 1.2.826.0.1285.0.2.1.54).

• name

The name of the person.

Within "Organization"

The required fields are;

• id

The ODS site code for the dispensers organisation (OID = 1.2.826.0.1285.0.1.10).

• code

The organization type from the pre-defined vocabulary within the MIM.

• name

The name of dispensing organisation.

• telecom

A valid telephone number for the dispensing organisation.

• addr

The postal address of the dispensing organisation.

6.3.5.3 R_AgentNPFITOrgSDS

This CMET is used to capture the patient's nominated dispensing site.



Figure 5 - R_AgentNPFITOrgSDS CMET (extract from MIM)

The only required attribute is the OrganizationSDS 'id' containing the ODS code of the dispensing site (OID = 1.2.826.0.1285.0.1.10).

6.3.5.4 Person Name (PN)

Within HL7 a name can be represented by either a structured or unstructured name format. Within the EPS domain, there are two implementations of this data type; for a patient name and for a registered Spine user name.

Patient Name

Patient names must always be formatted using the "Person name structured" flavour. This CMET supports multiple names however for the EPS only a single name shall be populated (the patient name printed on the prescription token). The HL7 elements of "use" and "valid time" can be ignored.

Registered Spine User Name

The name of the registered Spine user may be formatted using either the "Person name structured" or "Person name unstructured" flavours. Two flavours are required because the Spine SDS, the repository for registered users, only mandates "full name" and "family name" attributes. Thus if the other optional attributes of a name are not populated, a structured name cannot be formed. Where possible, structured names should be used when data is available from Spine SDS and unstructured names used only when just the "full name" and "family name" exist. The HL7 elements of "use" and "valid time" can be ignored.

6.3.5.5 Postal Address (AD)

All postal addresses must use the "Unstructured address plus postal code" flavour. The minimum dataset as defined by the Spine PDS is the population of address lines 1, 2 and 4, therefore some elements of the flavour may be blank, but not omitted.

Multiple addresses are supported by the HL7 messages however for the EPS, only a single address is required (the address printed on the prescription token).

For all addresses, if additional HL7 elements such as "use" and "valid time" are included, these can be ignored.

6.3.5.6 Telecommunication Address (TEL)

All flavours of the "Telecommunication address" data type must be supported for the EPS so that the user has access to all known means to contact the patient or clinician. Suppliers can choose how they present telecommunications numbers when the "use" attribute and/or "useable period" elements are populated.

All telephone numbers within HL7 messages must be formatted <u>without</u> whitespace characters, e.g. "tel:01392206060". Note that telephone numbers obtained from Spine SDS may contain whitespace therefore such characters must be removed before population within HL7 messages.

6.3.5.7 Physical Quantity (PQ)

When representing the quantity of a medication item, the Physical Quantity data type must be formatted using the "Quantity in Alternative Units" flavour when using a dm+d unit of measure.

Where the quantity value is an integer, the system must format the PQ data type as an integer value, i.e. "28". The system must not format PQ data type as a decimal value, i.e. "28.0".

See Section 6.4 for more information.

6.3.5.8 Implementation of SET data types

The CMETs "R_Patient" and "R_AgentNPFITPerson" convey personal demographic information relating to the patient and clinicians for the prescription. Within these CMET structures some data attributes can be recorded in "sets", thus recording multiple values for the same data item. This specifically relates to the following demographic data;

- Name e.g. "name (SET<PN>)"
- Address e.g. "addr (SET<AD>)"
- Telecommunication address e.g. "telecom (SET<TEL>)"

The legal requirement for such patient demographics on a prescription is a single patient name and address, therefore the System must populate the HL7 message with a single patient name and a single patient address. These details must be the same as that printed on the FP10/prescription token.

Spine Demographics supports multiple patient names and addresses. Refer to Spine Demographics guidance documentation for handling multiple patient demographic data, but note that in most circumstances, the patient name marked within Spine Demographics as the "Usual (current) name" and the patient address marked as the "Usual address" will be relevant for use when creating a prescription.

All available, and valid for the current date/time, patient telecommunication addresses recorded within the Spine Demographics must be recorded within the prescription.

The "R_AgentNPFITPerson" CMET support multiple address and telecommunication address elements for the "AgentPerson" entity that aligns with the user's selected role profile. The Spine User Directory does not record a specific address or telecommunication address against each role profile therefore for EPS interactions

these optional elements must not be populated. The "Organization" entity within this CMET is used to capture these demographic details.

Ref	Requirement
6.3.1	The System <u>must</u> implement the interactions identified for "Dispensing Systems" within the "Medication Management" domain as defined within the relevant Message Implementation Manual (MIM).
6.3.2	The System <u>must</u> populate all mandatory fields as defined by the XML schema and all required fields as defined within the MIM tabular views.
6.3.3	The System <u>must</u> validate outbound messages against the relevant XML/HL7 schemas published within the MIM.
	Messages failing schema validation must not be sent to the Spine.
6.3.4	The System <u>should</u> validate inbound messages against the relevant XML/HL7 schemas.
6.3.5	The System <u>must</u> receive and handle HTTP transport layer acknowledgements sent from the Spine TMS together with the relevant interactions from the 'Infrastructure' domain of the MIM.
6.3.6	The System <u>must</u> obtain messaging parameters (i.e. ASIDs and CPA IDs) from the Spine Directories via LDAP.
	The System <u>must</u> obtain these parameters on a regular basis as these values could be subject to change.
	The System is required to obtain messaging parameters (i.e. ASIDs and CPA IDs) from the Spine Directories via LDAP. The System is required to obtain these parameters on a regular basis as these values could be subject to change. Suppliers are recommended to check messaging attributes returned from Spine Directories to ensure they are valid, for example to ensure they are non-blank.
6.3.7	The System <u>must</u> correctly UTF-8 encode characters within HL7 messages.
6.3.8	The System <u>must</u> format timestamp data as per the "NPFIT-FNT-TO-SCG-0005 SCG clarification on time zone" guidance paper.
6.3.9	The non-SDS variants ("Person" and "Organisation") of the HL7 CMET "R_AgentNPFITPerson" <u>must</u> be used when populating author details.

Ref	Requirement
6.3.10	Within "R_AgentNPFITPerson", the 'id' attribute of 'AgentPerson' <u>must</u> be the Role Profile Code for the user for the current role in which they are working.
6.3.11	Within "R_AgentNPFITPerson", the 'id' attribute of 'Organization' <u>must</u> be the ODS site code of the dispensers organisation.
6.3.12	Within "R_AgentNPFITPerson", the 'id' attribute of the 'Person' <u>must</u> be the user's unique identifier defined within Spine SDS.
6.3.13	The System <u>must not</u> populate the "AgentPerson" address or telecom elements within the "R_AgentNPFITPerson" CMET. The "Organization" entity within this CMET is used to capture these demographic details.
6.3.14	Within "R_Patient", the patient name <u>must</u> be formatted using the "Person name structured" HL7 flavour.
6.3.15	The System <u>must</u> populate the "R_Patient" CMET with a single patient name and a single patient address. The patient name and address must be the same as that printed on the FP10/prescription token.
6.3.16	The System <u>must</u> populate the "R_Patient" CMET with all available telecommunication addresses recorded within Spine Demographics that are valid for the current date/time.
6.3.17	Within "R_AgentNPFITPerson", the name of a registered Spine user <u>may</u> be formatted using either the "Person name structured" or "Person name unstructured" HL7 flavours.
6.3.18	The Postal Address (AD) data type <u>must</u> be formatted using the "Unstructured address plus postal code" HL7 flavour.
6.3.19	All defined HL7 flavours for a Telecommunication Address (TEL) data type <u>must</u> be supported.
6.3.20	The PQ (Physical Quantity) data type <u>must</u> be formatted using the 'alternative units' HL7 flavour.
6.3.21	The PQ (Physical Quantity) data type <u>must</u> be formatted as a integer value if an integer, or as a decimal value if a decimal. The system <u>must not</u> populate an integer value with trailing zeros, e.g. "28.0" must be formatted as "28".

6.4 Medication Management (dm+d)

The ETP programme is dependent on a standard for exchange of information on drugs and devices between prescribers, dispensers and reimbursement agencies.

The NHS Dictionary of Medicines and Devices (dm+d, ref: http://www.dmd.nhs.uk) is the NHS standard for drug and device identification. It provides a stable, unique term (description) and identifier (code) for all drugs and devices used in the treatment of patients. It enables clinical system interoperability by ensuring safe and reliable exchange of information on drugs and devices. The dm+d uses the SNOMED coding scheme (ref: http://www.snomed.org).

6.4.1 Implementation of dm+d

Refer to the dm+d implementation guidance published on the dm+d web site (http://www.dmd.nhs.uk).

Where a medication item is not in the dm+d current FP10 processes will be followed. An electronic prescription will therefore never contain a medication item that is not in the dm+d.

A prescribed system medication item will be represented using either a VMP or AMP dm+d concept.

6.4.2 Dosage Instructions

A free-text medication item dosage instruction will always be provided on the prescription. Dosage instructions shall be provided by the prescription without abbreviation.

It is not recommended that dosage instructions are automatically used by the dispensing system for medication labelling as in some cases the pharmacist may choose to make amendments or use locally agreed patient instructions.

6.4.3 Quantity and Unit of Measure

A quantity of medication must be expressed in HL7 as a numeric value using the "Alternative Units" flavour of quantity with the dm+d unit of measure as defined in the above section. An example is shown below.

In the example above;

- 'quantity/@value' and 'translation/@value' represent the numeric quantity of the unit of measure. Always populate with the same value.
- 'unit' is the UCUM representation of the unit. If UCUM units are not available or the unit of measure is not known within UCUM the fixed value of "1" must be used
- 'codeSystem' is a fixed OID for SNOMED (dm+d)
- 'code' is the SNOMED (dm+d) code for the unit of measure
• 'displayName' is the dm+d text representation of the unit of measure.

Note. The example for "Alternative Units" within the DataTypes section of the MIM 4.2.00 is incorrect and should be ignored.

Medications recorded within dispense notifications or reimbursement claim messages must, where appropriate, be recorded using the dm+d Actual Medicinal Product Pack (AMPP) concept. Other dm+d concepts (VMP, AMP or VMPP) are permissible as defined within the "Guidance for Endorsement" (Ref: NPFIT-ETP-EIM-0015).

6.4.3.1 Guidance: Processing non dm+d units within EPS R1 prescriptions

EPS R1 prescriptions generated by EPS R1 prescribing systems may continue to represent medication quantities in standard units (i.e. non dm+d) or alternative units (i.e. dm+d). Only EPS R2 prescribing systems can be constrained to always use alternative units.

If an EPS R1 prescription is received containing quantity values formatted in standard units then the information must be made visible to the dispenser to support dispensing, then following the dispensing event, either;

- 1. No Dispense Notification interaction is sent, or
- 2. An EPS R1 (MIM 3.1.07) Dispense Notification is sent with the prescribed quantity represented in standard units and the dispensed quantity represented in either standard or alternative units.

Suppliers must ensure either method of handling non dm+d units are seamless to the users. For example, if option 1 is implemented, still present a button (or equivalent) to allow the user to send the Dispense Notification. This will encourage a consistent way of working while behind the scenes when no actual Dispense Notification is submitted.

It is recommend that option 1 above is implemented where no Dispense Notification is submitted so that the MIM 3.1.07 message set for dispensing systems can be deprecated by HSCIC.

6.4.4 Timeliness of Local dm+d Data

The dm+d terminology is updated weekly by the NHS BSA and is available to download from the HSCIC TRUD Service (https://isd.hscic.gov.uk).

It is important that local systems use an up-to-date version of the dm+d to ensure that new concepts or amendments within the dictionary are available. The system supplier must ensure that the version of dm+d installed at each site is no more than 2 months older than the current version of dm+d as published on the TRUD.

Suppliers can choose to implement dm+d directly or take a value-added terminology from a 3rd party supplier. To account for those suppliers who use a 3rd party terminology, a period of 2 months is sufficient for each supplier to process, manipulate and distribute the latest version of the dm+d.

6.4.5 Processing Unknown dm+d Concepts

It may be possible that a prescribed dm+d concept is not known to a dispensing system. This may arise if a prescribing and dispensing system are out of sync with the version of the dm+d.

The dm+d stores the last previous code for a concept so if an old code is used by the prescribing system then the dispensing system can look this up and identify the concept within the local implementation of dm+d.

If an inbound dm+d concept is not recognised then the concept description must be displayed to the user. Then there are four possible outcomes for dispensing.

- 1. An appropriate product is available for dispensing and is dm+d coded within the local system. The Dispense Notification interaction can transpose (copy) the unknown prescribed code and descriptor to record the prescribed item and use the known dm+d code and descriptor to record the dispensed item.
- 2. An appropriate product is available for dispensing but is not coded within the local system. The Dispense Notification interaction can transpose (copy) the unknown prescribed code and descriptor to record both the prescribed and dispensed items.
- 3. Dispensing is not possible as an appropriate product is not known or available to the pharmacist. Prescription token given back to the patient to take elsewhere. Electronic prescription returned to the EPS using the "Dispense Proposal Return" interaction.
- 4. Dispensing is not possible as an appropriate product is not known or available to any pharmacist (an unlikely scenario but possible). The prescription cannot be fulfilled and is marked as "Not Dispensed" within a Dispense Notification interaction. The unknown prescribed code and descriptor can be transposed (copied) into the message to record the prescribed item.

6.4.6 Processing Invalid dm+d Concepts

It may be possible that a prescribed dm+d concept, valid at the time of prescribing, is updated to "Invalid" by the time of dispensing.

Invalidation in dm+d is carried out for a number of reasons;

- 1. Moving AMPs from one VMP to a new parent
- 2. Authoring errors
- 3. Clinical Safety
- 4. Changes in Editorial Policy

The decision to dispense or not dispense a prescription for an invalid item is related to the reason why it was invalidated. An AMP moving parent VMP does not normally mean the original AMP is unsafe. But a change in editorial policy could mean that the old concept is no longer reimbursable. As such, the decision to dispense or not dispense has to be taken by the user, not the system.

The NHS BSA normally leaves a 1 month window for replacements in dm+d. The replacement concept is authored and for 1 month, duplicate concepts appear. The old concept is then invalidated after the month. This is to help support reimbursement processes.

Ref	Requirement
6.4.1	The System <u>must</u> use the NHS Dictionary of Medicines and Devices (dm+d) coding scheme for medication item information within HL7 messaging. Specifically, this must be the SNOMED CT code and the dm+d description for the medication item.
6.4.2	The System <u>must</u> ensure that all references within the dm+d can be handled without string truncation.
	Note. String wrapping onto an additional line is permitted.
6.4.3	The System <u>must</u> record dispensed medication items using the dm+d "Virtual Medicinal Product Name", "Actual Medicinal Product Description", "Virtual Medicinal Product Pack Description" or "Actual Medicinal Product Pack Description" and the associated SNOMED code. These data fields are described within the dm+d technical specification.
	Note . dm+d descriptors must be used within the correct case (i.e. uppercase/lowercase characters) as defined within dm+d.
6.4.4	The System <u>must</u> use dm+d descriptors (see requirement 6.4.3) within the application user interface (e.g. on-screen, picking lists etc.) and within patient medication records held locally.
6.4.5	The System <u>must</u> use dm+d descriptions on printed FP10 prescription/dispensing tokens and within electronic endorsements.
	Note . The use of the dm+d (full or abbreviated) names for medication labelling is not required with regard to EPS systems compliance.
6.4.6	If the System implements a mapped solution from another terminology service to dm+d then the System <u>must</u> adhere to the definition of 'Native dm+d' as defined by the HSCIC Terminology Services programme. See http://www.dmd.nhs.uk/implementation/native.pdf
6.4.7	The System <u>must</u> implement the dm+d requirements defined within this specification for phases 3 and 4 of the EPS Implementation Strategy regardless of which version of the Prescription Release Response HL7 message version is being processed.
6.4.8	The System <u>must</u> use the HL7 "Alternative Units" representation of quantity when expressing a quantity of medication. The unit of measure must be defined within dm+d. The HL7 attributes of 'value', 'unit', 'codeSystem', 'code' and 'displayName' <u>must</u> be populated.

Ref	Requirement
6.4.9	The System supplier <u>must</u> ensure that the version of dm+d installed at each site is no more than 2 months older than the current version of dm+d as published on the TRUD.
6.4.10	The System <u>must</u> be able to handle unknown dm+d concepts as per the guidance provided within this section.
6.4.11	The System <u>must</u> display the clinical information as normal if a prescribed dm+d concept is marked as invalid.
	The System <u>must</u> indicate to the user that the prescribed dm+d concept is marked as invalid.
	The System <u>must</u> allow any dm+d concept to be selected as the dispensed product when the prescribed concept is marked as invalid.
	The System must not prevent dispensing of an invalidated concept.

6.5 Prescription Request and Download

Prescriptions are held within the Spine until they are required for dispensing and downloaded by the dispensing system. This download can be triggered using two different mechanisms that use two separate MIM messages;

- 1. Patient Prescription Release Request
- 2. Nominated Prescription Release Request

Both messages result in a "Prescription Release Response" message if successful or a "Prescription Release Rejection" message if unsuccessful.

6.5.1 Patient Prescription Release Request

The MIM interaction "Patient Prescription Release Request" is used to request individual prescriptions from the Spine. To request a prescription, the prescription identifier for the prescription must be known and this is used within the request message. At the time of prescribing, if the patient is not using a nominated dispenser, the patient will be given a prescription token that includes the prescription identifier as a machine readable barcode and as a human readable character string.

Note. The EPS Release 2 interaction "Patient Prescription Release Request - PORX_IN132004UK30" must be used to request either an EPS Release 1 or Release 2 prescription. This version of the interaction supports both the 36-char prescription UUID and 18-char short-form prescription ID.

The specification for the prescription token is published separately (ref: NPFIT-ETP-EDB-0027). Shown in Figure 6 is an example of a prescription token for illustration purposes only.



Figure 6 - An example prescription token

The System should allow for multiple prescription requests to be sent to the Spine, handling the subsequent response messages as they are received.

Note. It is permissible for a bar-coded prescription/token to be scanned on a pharmacy terminal by a user who is not smartcard authenticated with the Spine. In this scenario, the Prescription ID (from the barcode) can be passed to a different pharmacy terminal where an authenticated user is present and this terminal would interact with the System to request and receive the prescription from the EPS.

6.5.2 Nominated Prescription Release Request

The MIM interaction "Nominated Prescription Release Request" (PORX_IN060102xxxx) is used to request currently available nominated prescriptions from the Spine for a given dispensing site ODS code.

This interaction operates in a similar way to the individual request of a prescription except that the prescription ID is replaced by a site ODS code and the response message, "Prescription Release Response" may contain multiple prescriptions.

The Spine will return a maximum number of prescriptions within a single response, currently set to twenty five (25). This prevents the risk of the Spine sending excessively large response messages which could result in dispensing system performance issues. The System should repeat the request/response process until no more prescriptions are returned, or until a maximum number of requests have been submitted (determined locally). When no more nominated prescriptions are

available, the Spine will respond with a "PrescriptionReleaseRejection" message using the "Prescription Release Rejection Reason" of 0006.

The System should only automatically request nominated prescriptions once a day, ideally as an out-of-hours process between the hours of midnight and early morning. During this time, as many request messages as needed can be sent to retrieve the sites nominated prescriptions. This is the optimum time for these requests to tie in with Spine overnight processing. It will not be acceptable for the System to automatically request nominated prescriptions at regular intervals during the working daytime hours. Requests initiated by the end user on an ad-hoc basis are permitted at any time.

Note. It is planned to remove the above restriction and allow the system to schedule nominated release request interactions at any time during the 24 hour day. The proposal is that scheduled requests are addressed to a different Spine service name to manually triggered requests. This will allow Spine to manage the potential large volumes of concurrent inbound requests. Suppliers will be notified when the new service name is available within the test environment. Spine transaction logs will be retrospectively checked to ensure systems are addressing the correct service name for manual and scheduled requests.

The System should have the ability to request nominated prescriptions for a different dispensing ODS code. This functionality could be needed for four, and in the future five, scenarios;

- To provide local contingency should a dispenser be unable to supply medication, for example, flooding or other unforeseen closure. A business arrangement must exist with another dispenser so that they request and download prescriptions on behalf of the dispenser unable to supply the medication.
- 2. To download prescriptions during a period where a dispensing organisation has changed their ODS code. During this period, some prescriptions may be nominated against the old or new ODS codes. **Note**: The EPS Programme team within HSCIC has the ability to 'migrate' nomination preferences from and old to new ODS code for a given list of patients by contacting epsimplementation@hscic.gov.uk.
- 3. To support dispensing within a dispensing doctor's organisation where some prescriptions may be processed against a GP ODS code while others may be processed against a pharmacy ODS code. Where two dispensing contracts exist, these could be supported within the same dispensing system, or could be supported by implementing two separate systems, i.e. one system per dispensing contract.
- 4. For dispensing sites that hold a local pharmaceutical services (LPS) contract.
- 5. When privately prescribed controlled drug prescriptions (Schedule 2 and 3) come into scope for the EPS, these must be submitted to the NHSBSA using the pharmacy's private controlled drug account number (ODS code).

The MIM 4.2.00 version of this interaction requires the credentials of a smartcard authenticated user to be available. When this interaction is submitted as an out-of-

hours process then the 'author' entity that uses the 'R_AgentNPFITPerson' CMET can be populated as follows;

- All schema mandatory fields need to be populated. These are all static attributes related to HL7 constructs.
- The 'person.id' attribute must be populated with a valid user's identifier defined within the Spine User Directory. As no user will be logged in at this time, this attribute should be a pre-configured value. The user whose user ID is to be used must be informed and agree for their credentials to be used for this purpose.
- The 'organization.id' attribute must be populated with the dispensing site ODS code.

6.5.3 Prescription Release Response

When prescriptions are requested from the Spine using the "Patient Prescription Release Request" or "Nominated Prescription Release Request" messages, if successful the Spine will respond with a "Prescription Release Response" HL7 message.

This is a container message that could contain prescriptions of multiple MIM versions (i.e. MIM 3.1.07, MIM 4.2.00 or EPS DMS 3.3.0 prescription release response messages).

When prescriptions are requested and received as part of an out-of-hours process then the prescriptions must be 'locked' within the system until a smartcard authenticated user chooses to 'unlock' them. A 'locked' prescription must only have the Prescription ID and prescription date/time attributes visible to the end-user. No further information from the prescription must be visible until the prescription is 'unlocked'.

Once an authenticated user, with the RBAC activity "Perform Pharmacy Activities (B0570)" is logged into the system, one or more 'locked' prescription can be 'unlocked'. After this time, all the prescription information can be viewed and processed as per any other prescription within the System.

6.5.4 Prescription Release Rejection

When prescriptions are requested from the Spine using the "Patient Prescription Release Request" or "Nominated Prescription Release Request" messages, if this is unsuccessful, the Spine will be responded with a "Prescription Release Rejection" HL7 message.

If no response is received after 60 seconds, then assume failure. The System should automatically re-request the prescription. If it fails the second time then the user must be informed of a possible system failure and that the issue needs to be reported to the local service help desk.

The following table lists the prescription release rejection reason codes and the appropriate action for the System or user to take.

Note. This list is based on the Spine (1) external interface specification. An equivalent document will be published for Spine 2 in due course.

Prescription Release Rejection Reasons

Code	Rejection Reason	Action to Take
0001	Prescription has been cancelled	Inform the dispenser to advise the patient that their prescription has been cancelled
0002	Prescription has expired	Inform the dispenser that the prescription has expired and it cannot be downloaded
0003	Prescription cannot be found. Contact prescriber	 Inform the dispenser that the prescription not be found. This may be because; There is no matching prescription. The prescription has been removed from the ETP component under the ETP housekeeping rules. In such cases, there has been a considerable time period between this request and the receipt of the prescription. The prescription has not arrived at the Spine. This may occur if the prescription is requested immediately after the prescriber has submitted it, or is a post-dated prescription.
0004	Prescription is with another dispenser	Inform the dispenser that the prescription has been downloaded by another dispenser. The rejection message will contain details of the dispensing site that has the prescription.
0005	Prescription has been dispensed/not dispensed	Inform the dispenser to advise the patient that this prescription has already been dispensed.
0006	No more nominated prescriptions available	No further request messages to pull down nominated prescriptions should be submitted at this time
0007	Nominated download functionality disabled in spine	The Spine nomination functionality has been disabled at the request of the Authority and the message is rejected. The request will not be processed. However, the prescription request by prescription unique identifier should be available.
0099	Incompatible version of Request. [Additional Information (if any)]	The user should inform their system supplier that an incompatible version of a prescription has been received. This scenario may occur when a new version of the EPS is deployed but any messaging incompatibles will be carefully managed by the EPS Programme.
5000	Unable to process message. [Additional Information (if any)]	The user should inform their system supplier that a request message was rejected by the Spine.
5888	Invalid message	The user should inform their system supplier that a message was rejected as invalid by the Spine.
9006	Format of date passed is invalid	The format of a date/time attribute with the prescription does not confirm with the format defined within the MIM. The System shall correct the date/time attribute and re-submit the prescription to the Spine.

For the rejection code '0004' listed above, the System should display details of the pharmacy that has the prescription to the end user. Within the rejection will be the HL7 CMET "R_AgentNPFITPerson" containing both person and organisation details.

The System must only display organisation details to the end user. These details will be the name, address and telephone number of the dispensing site that has the prescription. The person details of the dispenser must not be displayed as the prescription is with the dispensing site and not the individual dispenser.

Ref	Requirement
6.5.1	The System <u>must</u> implement the "Patient Prescription Release Request" interaction.
6.5.2	The System <u>must</u> support keyboard entry a Short Form Prescription ID to request an EPS R2 prescription or a UUID to request an EPS R1 prescription.
6.5.3	The System <u>should</u> allow for multiple prescription requests to be sent to the Spine, handling the subsequent response messages as they are received.
6.5.4	The System <u>must</u> be capable of reading and interpreting the barcode on a prescription token. The barcode will use the Code 128 standard.
6.5.5	The System <u>must</u> implement the "Nominated Prescription Release Request" interaction.
6.5.6	The System <u>should</u> have the ability to request nominated prescriptions for a different dispensing ODS codes.
6.5.7	When requesting nominated prescriptions, the System <u>must</u> extract and process the multiple prescriptions contained within the received "Nominated Prescription Release Response" HL7 message.
6.5.8	The System <u>should</u> automatically request nominated prescriptions as an out-of-hours process. If the System does not operate a 24x7 service then nominated prescriptions can be requested as a system start-up process.
6.5.9	The System <u>must not</u> automatically request nominated prescriptions at regular intervals during working daytime hours. Requests initiated by the end user on an ad-hoc basis are permitted at any time.

Ref	Requirement
6.5.10	The System <u>must not</u> amend the prescription information that has been pulled down from the Spine.
	This requirement does not prevent different dm+d concepts from being dispensed to those prescribed. For example if a sugar-free dm+d concept is dispensed for a non-sugar free prescribed dm+d concept.
6.5.11	The System <u>must not</u> display the details within the "Person" entity of the "R_AgentNPFITPerson" CMET when informing the user that a prescription is with another dispenser. Only the "Organization" details <u>must</u> be displayed.
6.5.12	The System <u>must</u> 'lock' prescriptions that have been requested when no end-user Spine smartcard authenticated session exists. A 'locked' prescription must only have the prescription ID and prescription date/time attributes visible to end-users.
6.5.13	The System <u>must</u> allow a Spine smartcard authenticated user, with the RBAC activity "Perform Pharmacy Activities (B0570)", to be able to 'unlock' a locked prescription. An unlocked prescription can then be viewed and processed as per any other prescription within the System.
6.5.14	The System <u>must</u> handle receipt of the "Prescription Release Rejection" and inform the user of the reason for rejection.
6.5.15	The System <u>must</u> inform the user of a possible system failure, in order to report this to the local service help desk, if no response to a "Patient Prescription Release Request" or "Nominated Prescription Release Request" interaction has been received after 60 seconds, and an automated second attempt, after 60 seconds.

6.6 Prescription and Medication Item Identifiers

Each prescription and medication item within a prescription is uniquely identified by a locally generated Universal Unique Identifier (UUID).

From MIM 4.2.00 onwards, prescriptions have two identifiers.

- Short Form "Prescription ID"
- Prescription UUID

MIM 3.1.07 prescriptions are only identified by their Prescription UUID.

Each prescribed medication item is identified by a medication item UUID.

6.6.1 Short Form "Prescription ID"

The purpose of the Short Form Prescription ID is to identify the prescription during its lifecycle within the Spine (i.e. prescribe, dispense, claim) and to provide an ID that can be more easily conveyed between users or support staff.

The format of the Short Form Prescription ID is as follows;

<RandomNumber>-<PracticeODSCode>-<PracticeSequence><CheckDigit>

Where;

<*RandomNumber>* is a locally generated random number of length 6 hexadecimal characters.

<*PracticeODSC*ode> is the unique ODS code for the practice as defined within the Spine SDS of length 6 characters.

<*PracticeSequence>* is an incremental sequence number starting from 00000 that is reset after FFFFF back to zero of length 5 hexadecimal characters. For systems that support multiple practices, a sequence number per practice is required. This is to ensure uniqueness of prescriptions within the Spine ETP component during the prescription lifecycle.

<*CheckDigit*> is calculated on the entire ID using the ISO/IEC 7064:2003 MOD 37-2 standard.

Note. Hyphens are always included to separate the ID into 3 blocks of 6 characters.

Note. The implementation of the MOD 37-2 standard uses a "+" character for char 36 opposed to a "*" character.

Short Form Prescription ID example (for illustration purposes only);

83C40E-A23856-00123W

6.6.2 Prescription UUID

The Prescription UUID is retained to provide a universally unique reference for the prescription. When UUIDs are used within HL7 messages they must be represented in an upper case human-readable hexadecimal format where hyphen separators are used as per the example below and as defined by the 'datatype' schema within the MIM.

Prescription UUID example (for illustration purposes only);

34026084-A445-84AD-2D01-97D69ED25865

Ref	Requirement
6.6.1	The System <u>must</u> support the request and receipt of both Release 1 (UUID) and Release 2 (Short Form Prescription ID) prescriptions.
6.6.2	The representation of UUIDs and the Short Form Prescription ID within HL7 messages <u>must</u> be in upper case characters and include hyphen separators where required.

6.7 Guidance for receipt of Repeat Dispensing Prescriptions

If the patient is using the dispensary as a nominated dispenser for their repeat medication then a repeat dispensing prescription will be received within nominated batch response messages.

The 'DaysSupply' entity within the prescription is set by the prescriber and defines the expected course, in days, for the medication prescribed. If the 'DaysSupply' entity is omitted, the Spine will assume a value of 28 days for repeat dispensing prescriptions. The 'DaysSupply' entity is not populated for acute or repeat prescribing prescriptions.

The Spine will send the nominated dispenser their repeat dispensing prescriptions seven (7) elapsed days³ before the expected end date of the previous issue of each prescription based on the date the previous issue was completed and the 'DaysSupply' value.

For example, if 6 x 28 day's supply of repeatable medication was prescribed to a patient who is using their nominated dispenser, if the 1st issue was completed on March 23rd, the 2nd issue would be sent within a nominated batch to the dispenser on April 13th (i.e. 23/03 + 28 days = 20/04 - 7 days = 13/04).

If the dispenser wishes to receive the next issue before this time, the System can request the prescription by Prescription ID using the "Patient Prescription Release Request" interaction. Therefore the System must store the Prescription ID so it can be used to request subsequent issues of the prescription.

The System may also implement scheduling functionality to request and receive subsequent issues of repeat dispensing prescriptions ahead of the time that the Spine will automatically send them to the System via a nominated batch download.

Ref	Requirement
6.7.1	When processing repeat dispensing prescriptions, the System <u>must</u> store the Prescription ID so this can be used to request subsequent issues of the prescription.
6.7.2	The System <u>may</u> implement scheduling functionality to request and receive subsequent issues of repeat dispensing prescriptions ahead of that time that the Spine will automatically send them to the System via a nominated batch download, i.e. by retrieval by Prescription ID.

³ The period of 7 days is a configurable parameter within the Spine, therefore can be changed if deemed necessary by HSCIC

6.8 Electronic Prescription to Local PMR Matching Requirements

Once a prescription release response has been downloaded from the Spine, the prescription must be matched against the local patient record to identify if the patient is already known within the local record or if not, to create a new local patient record.

During EPS Release 1, each supplier implemented proprietary rules for matching an incoming release response to the patient's medical record. In a small number of circumstances, the matching rule sets were not sufficiently robust to ensure the response was always matched to the correct patient's record. Moving forward in EPS Release 2, it is imperative that the release responses downloaded by a dispensing system are accurately matched to the patient's medical record.

The following requirements represent the minimum matching levels that must be implemented in a dispensing system on receipt of either an EPS R1 or EPS R2 prescription.

The matching process is tiered into four stages. If the local patient record is not found after Stage 1, the system must use the matching algorithm described in Stage 2. This process continues until Stage 4 when a new patient record needs to be created as no local record exists. See Figure 7 - Local PMR Matching.





6.8.1.1 Stage 1 – Full Automatic Match

For a full automatic match to occur all demographic attributes from the prescription release response message listed in requirement 6.8.1 must be matched against the local record. Case and whitespace can be ignored in the matching algorithm.

If the demographic attribute is not populated within the prescription release response message then it can be excluded from the matching algorithm.

Only when a single matching record is found is the full automatic match deemed successful.

It is acknowledged that when the first electronic prescription is received for a patient, it is likely that this full automatic match will fail. However once the patient's local demographic record is synchronised with the demographics derived from the Spine PDS (via a prescription), then all subsequent prescriptions for the patient will match, until such a time as when the patients demographic details change.

6.8.1.2 Stage 2- Partial Match with User Confirmation

A partial match requires the demographic attributes from the prescription release response message listed in requirement 6.8.2 must be matched against the local record. Case and whitespace can be ignored in the matching algorithm.

If multiple local records match these attributes then the system must display the matching records to allow the user to select the correct patient or continue to manually search for the patient (i.e. Stage 3).

6.8.1.3 Stage 3 – Manual Match

A manual match requires the user to use local search functionality to locate the patient's record within the local PMR. If the appropriate patient record is not found then the user must be given the option to create a new patient record (i.e. Stage 4).

6.8.1.4 Stage 4 – Creation of New Patient Record

The System must allow a new patient record to be created if a matching existing patient record cannot be found following stages 1, 2 and 3 of the patient matching process described within this section.

6.8.1.5 Grouping Prescription / Medication Records by Patient

Once an existing local patient record is found, or a new patient record is created, the system must allow the user to easily see other prescriptions, both new, currently inprogress and recently dispensed, for the same patient. A list of prescribed medication, grouped by patient, must have a default sort order of chronological, newest first, based on the date/time of receipt or download. The list may be grouped by prescription/workflow status, for example, showing new prescriptions yet to be dispensed chronologically first. The system should allow the user to specify how far back in the patient's medication history to go for 'recent' prescriptions, for example 30 days or 90 days.

Ref	Requirement	
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Ref	Requirement
6.8.1	A Full match requires the following demographic attributes in the prescription release response message to be matched exactly to the details in the patient's medical record. Case and whitespace can be ignored in the matching algorithm.
	NHS Number
	• Prefix (e.g. Mr, Mrs, Dr)
	Given Name (if more than one, a match on all is required)
	Family Name
	• Suffix
	First Address line / House Name
	Second Address line / House Number and Thoroughfare
	Third Address line / Locality
	Fourth Address line / Post Town
	Fifth Address line / County
	Postcode
	Date of Birth
	Gender
	If the demographic attribute is not populated within the prescription release response message then it can be excluded from the matching algorithm.
	Only when a single matching record is found is the full automatic match deemed successful.
6.8.2	A Partial match requires the following details in the prescription release response message to be matched exactly to the details in the patient's medical record. Case and whitespace can be ignored in the matching algorithm.
	NHS Number
	Postcode
	Date of Birth
	Gender
	If multiple local records match these attributes then the system <u>must</u> display the matching records to allow the user to select the correct patient or manually search for the patient.
6.8.3	A Manual match requires the user to use local search functionality to locate the patient's record within the local PMR. If the appropriate patient record is not found then the user <u>must</u> be given the option to create a new patient record.

Ref	Requirement
6.8.4	The System <u>must</u> allow a new patient record to be created if a match to an existing patient record cannot be found following stages 1, 2 and 3 of the patient matching process.
6.8.5	The System <u>must</u> provide a view of prescribed medication records grouped by patient NHS number, including new, in-progress and completed prescriptions.
6.8.6	The System <u>must</u> use a default sort order for the view of prescribed medication grouped by patient NHS number as chronological, newest first, based on the date/time of prescription receipt or download.
6.8.7	The System <u>should</u> allow the user to specify how far back in the patient's medication history the System should go when presenting the view of prescribed medication grouped by patient NHS number.
6.8.8	The System <u>may</u> additionally group the list of prescribed medication by prescription/workflow status, for example, showing new prescriptions yet to be dispensed chronologically first.

6.9 FP10, Unsigned and Digitally Signed Electronic Prescriptions

During the EPS transitional phase, dispensers will be receiving FP10 and both unsigned/signed electronic prescriptions.

6.9.1 FP10 Prescriptions

Some prescriptions will remain paper-based using the current FP10. These will be hand signed in ink by the prescriber and the FP10 will be used for dispensing and reimbursement purposes.

Examples of when an FP10 will be used are;

- Prescriptions for medication items not contained within the dm+d
- Prescriptions written out of hours or otherwise when an electronic prescribing system is unavailable.

When an FP10 is presented it must be dispensed and reimbursed using existing FP10 process. No electronic communication with the Spine is required.

6.9.2 FP10 + Unsigned Prescription Message (EPS Release 1)

For EPS Release 1, all prescription messages using the EPS are not electronically signed. The prescriber prints an FP10 and signs this in ink. The paper prescription is the legal prescription. The electronic message that accompanies the FP10 is to support dispensing processes but has no legal standing.

During the EPS transitional phase, the same model applies with prescriptions for patients not using a nominated pharmacy (otherwise known as 'non-nominated prescriptions). These will be EPS Release 1 messages and will not be electronically signed by the prescriber. The prescriber will print and hand-sign the FP10.

Hand-written and counter signed amendments to the prescription by the prescriber may be present but note that such amendments will not be reflected within the electronic message that accompanies the FP10.

Note. For unsigned electronic prescriptions, the signature block within the message will be coded as;

<signatureText nullFlavor="NA"/>

The System can request and download the electronic prescription message and use the data to support the dispensing process. Dispense notification messages must be submitted to the Spine to manage the status of the prescription.

Reimbursement of these prescriptions will be through existing FP10 processes. No electronic reimbursement interactions are required and will be rejected by the BSA.

6.9.3 Electronically Signed Prescriptions (EPS Release 2)

During the EPS transitional phase, prescriptions for patients using a nominated pharmacy will be electronically signed with an Advanced Electronic Signature (AES) which will make them legal NHS prescriptions. Dispensing and reimbursement of such prescriptions will be fully electronic.

Hand-written amendments on a prescription token must be ignored as these will not be reflected within the electronically signed prescription. Prescribers have been informed that hand-written amendments in this case are not valid and must not be added.

6.9.3.1 Electronic Signature Validation

The System is required to check that the integrity of electronically signed data within the message is valid (i.e. has not been changed and was signed by an authorised signer).

The process for electronic signature validation is described within the document "Digital Signing and Non Repudiation" (Ref: NPFIT-FNT-TO-IG-0019). Additional requirements for the validation process are defined within the document "ETP Message Signing Requirements" (Ref: NPFIT-ETP-EDB-0064).

If electronically signed data is found to be invalid or if the prescribers AES is invalid then this must be reported to the National Help Desk quoting the Prescription ID of the invalid prescription. The prescription must then be returned to the Spine using the "Dispense Proposal Return" HL7 message using the "Invalid digital signature" reason code as defined within the MIM. Once returned, the prescription should be removed from the System.

Details of the prescription must be retained within the system so that users are aware that an invalid prescription was received. These details must include the ability to identify the patient, the prescriber and the prescriber's organisation.

If successfully validated, dispensing activities can commence.

Ref	Requirement
6.9.1	The System <u>must</u> be capable of handling FP10 prescriptions where no electronic messages exist, as per current FP10 processes.
	Note . Dispensing information for FP10 prescriptions where no electronic messages exist must not be submitted to the Spine. Current FP10 processes apply in this case.
6.9.2	The System <u>must</u> validate the Advanced Electronic Signature (AES) within the "Patient Prescription Release Response" HL7 message.
6.9.3	Prescriptions with an invalid AES <u>must</u> be reported to the National Help Desk quoting the Prescription ID of the invalid prescription. The prescription must be returned to the Spine using the "Dispense Proposal Return" HL7 message using the "Invalid digital signature" reason code. Once returned, the prescription should be removed from the System.
	Details of the prescription must be retained within the system so that users are aware that an invalid prescription was received. These details must include the ability to identify the patient, the prescriber and the prescriber's organisation.
6.9.4	The System <u>must</u> implement the requirements defined within the "ETP Message Signing Requirements" (Ref: NPFIT-ETP-EDB-0064).
6.9.5	From time to time new Root and Intermediate authentication certificates will be issued by the Authority and will be used in validating signatures created using them. Suppliers <u>must</u> ensure that systems have copies of all certificates in current use installed in an appropriate certificate store.

6.10 Prescription Processing

Once a prescription is identified, downloaded from the Spine and has the Advanced Electronic Signature validated, where applicable, the prescription can be processed ready for dispensing activities to commence.

6.10.1 Content of an Electronic Prescription

An electronic prescription contains all the information printed on the prescription token together with supplementary information required for EPS and by the HL7 standard.

The "ParentPrescription/effectiveTime" attribute relates to the date of the prescription, akin to the date printed on an FP10.

The "Author/time" attribute relates to the date of electronic signing by the prescriber. This attribute is used during the process of electronic signature validation. The date of signing must be within the validity period for the certificate used to create the electronic signature. The signature validation process is documented within the electronic signature guidance available within the EPS R2 document baseline.

At this time, an electronic prescription may contain up to four medication items. This is a restriction as the Spine has been designed to cater for up to 32 items per prescription. At some point in the future, and under certain circumstances, it is expected that the restriction of four items per prescription will be lifted.

All medication items are recorded using the NHS Dictionary of Medicines and Devices (dm+d) coding scheme and must be recorded within the System.

The electronic prescription will contain all the necessary patient demographic information to allow dispensing. The System may choose to update the local patient demographic record with the information from the electronic prescription if this is deemed more accurate by either the dispenser or the patient.

The prescription may contain a review date within the "Review Date" HL7 entity. Whilst the MIM constraint states that a review date will only be populated for repeat dispensing prescriptions, it may be populated, or omitted for ANY prescription.

The System must alert the user if the review date is within four (4) weeks so that this information can be communicated to the patient.

The prescription will contain a "PrescriptionType" HL7 entity which identifies the type of prescriber and prescribing care setting. This supports prescription regulations that state a prescription must have "*an indication of the kind of appropriate practitioner giving it*", and any associated prescribing formulary.

6.10.2 Prescription or Item Cancellation

Individual medication items on a prescription may be cancelled by the prescriber. A prescriber may cancel any item up until the time the prescription is requested and downloaded into a dispensing system. An entire prescription may also be cancelled and in this scenario the download request will be unsuccessful.

Cancelled items will be identified within the prescription via an item status code of "0005". The textual reason for cancellation is not provided within the 'Prescription Release Rejection' message therefore this cannot be displayed within the dispensing system. Only the status that the prescription has been cancelled is available to the dispensing system.

No dispensing activities against a cancelled item will be accepted by the Spine.

Note. Dispensing systems are not able to cancel a prescription, or items on a prescription. The MIM interaction for cancellation is only applicable for prescribing systems.

6.10.3 Prescribed Medication Item "Additional Instructions"

The 'Additional Instructions' entity has two purposes and can contain a large amount of data, often in excess of 1000 characters, with no upper size limit defined. Systems must handle variable lengths without truncation.

6.10.3.1 Additional Medication Specific Clinical Information

The first use is for additional clinical information relating to a prescribed medication item. Typically this would be for clinical information that cannot be conveyed within dosage instructions.

Examples of medication specific additional instructions are;

- For certain drugs which require monitoring, such as Lithium or Amiodarone, additional instructions to inform patients how often they need to have a blood test or a review check-up.
- To explain changes in dosage, for example, "Dosage has been increased on advice of the hospital".
- To communicate that this is the last authorised repeat of a medication line item, for example, "Last authorised repeat".

Additional clinical information relating to a prescribed medication item must be made available to the dispenser.

6.10.3.2 Additional Patient Specific Information

The second use is for patient specific clinical information.

Until such a time when a specific HL7 entity is available for this purpose, patient specific information will be conveyed within the "Additional Instructions" entity of the **FIRST** medication line item.

To separate this from additional medication specific information, patient information shall be semi-structured and contained within XML CDATA tags to maintain schema integrity.

A *<medication>* tag will be used to communicate a current repeat medication statement. Such a medication statement is free text but must contain the dm+d medication item name/description. Where applicable the statement will also contain the current issue number and maximum number of issues authorised, e.g. "Bendroflumethiazide 2.5 mg Tablets (3/6)". It may also contain dosage instructions or other relevant information.

A <patientInfo> tags will be used to communicate a single information statement for the patient. Examples include "Please make an appointment to see your GP" or "Review date due".

Patient specific clinical information must be made available to the patient.

W3C compliant XML processing within Spine performs HTML encoding on the data contained within the CDATA block.

An example is given below for the <value> element as populated by an EPS R2 prescribing system;

```
<value>
<![CDATA[
<medication>Bendroflumethiazide 2.5 mg Tablets (3/6)</medication>
<medication>Salbutamol 100micrograms/dose inhaler CFC free 200 dose
(2/6)</medication>
<patientInfo>Please make an appointment to see your GP</patientInfo>
<patientInfo>Review date due</patientInfo>
]]>
```

Dosage has been increased on advice of the hospital </value>

Following Spine XML processing, this element will be received by EPS R2 dispensing systems as;

```
<value>
<medication&gt;Bendroflumethiazide 2.5 mg Tablets (3/6)&lt;/medication&gt;
<medication&gt;Salbutamol 100micrograms/dose inhaler CFC free 200 dose
(2/6)</medication&gt;
<patientInfo&gt;Please make an appointment to see your GP&lt;/patientInfo&gt;
<patientInfo&gt;Review date due&lt;/patientInfo&gt;
Dosage has been increased on advice of the hospital
</value>
```

Additionally be aware that any reserved XML characters that are included within the CDATA block will also be encoded. For example;

Sent from the prescribing system;

```
<value>
<![CDATA[
<patientInfo>Remember to take both the red & green
tablets</patientInfo>
]]></value>
```

Received by the dispensing system;

```
<value>
<patientInfo&gt;Remember to take both the red &amp; green
tablets</patientInfo&gt;
</value>
```

6.10.4 Guidance: Use of 'repeatNumber' Attribute

This section details how the 'repeatNumber' attribute will be populated by prescribing systems and how this attribute should be populated within Dispense Notification messages. The 'repeatNumber' attribute exists at both the prescription and item level.

Note. This guidance supersedes that defined within MIM 4.2.00

6.10.4.1 Use within "Prescription Response" - PORX_MT122003UK30

The PORX_MT122003UK30 message will contain an EPS Release 1 prescription.

For an acute prescription the 'repeatNumber' attribute will be omitted.

For a repeat prescribing prescription the 'repeatNumber' attribute at both the prescription and item level will have a 'low.value' of 1 and a 'high.value' of 1.

Repeat dispensing prescriptions are out of scope for EPS R1 prescriptions.

6.10.4.2 Use within "Prescription Response" - PORX_MT122003UK32

The PORX_MT122003UK32 message will contain an EPS Release 2 prescription.

For an acute prescription the 'repeatNumber' attribute will be omitted.

For a repeat prescribing prescription the 'repeatNumber' attribute at both the prescription and item level will have a 'low.value' of 1 and a 'high.value' of 1.

For a repeat dispensing prescription the 'repeatNumber' attribute at both the prescription and item level will have a 'low.value' relating to the current issue, where the value of 1 denotes the first issue. The 'high.value' at the item level will be the total

number of authorised repeats for that medication item. The 'high.value' at the prescription level will be the number of authorised repeats for the prescription and will equal the high value for the medication item will be greatest number of authorised repeats.

6.10.4.3 Use within "Dispense Notification" - PORX_MT024001UK31

For an acute prescription the 'repeatNumber' attribute will be omitted.

For a repeat prescribing and repeat dispensing prescriptions the 'repeatNumber' is populated in the same way as a prescription message so values can be directly taken from the related prescription.

Ref	Requirement
6.10.1	The System <u>must</u> be capable of handling an electronic prescription containing up to four medication items.
6.10.2	The System <u>must</u> record all prescribed medication items within the local PMR.
6.10.3	The System <u>must</u> alert the user if the "Review Date" contained within the prescription is within four (4) weeks of the current date.
6.10.4	Patient demographic information received within a "Patient Prescription Release Response" message <u>should</u> be synchronised with the System's local patient demographic records.
6.10.5	The System <u>must</u> handle cancelled medication items. Cancelled medication items will be identified within the "Patient Prescription Release Response" message and should be visible to the dispenser.
6.10.6	The System <u>must</u> prevent dispensing activities against cancelled items.
6.10.7	The system <u>must</u> handle variable lengths of the "Additional Instructions" entity without data truncation.
6.10.8	Additional clinical information relating to a prescribed medication item within the "Additional Instructions" entity <u>must</u> be made available to the dispenser.
6.10.9	Patient specific clinical information represented as semi-structured text within the "Additional Instructions" entity of the first medication line item <u>must</u> be made available to the patient.
6.10.10	The System <u>could</u> display the "PrescriptionType" on the same screen as the prescribed medication so that the dispenser can identify the type of prescriber and any associated prescribing formulary.

6.11 Dispensing Activities

This section covers the activities for dispensing, particularly the use of the 'Dispense Notification' HL7 message that informs the Spine of dispensed medication. It also details concepts like the 'Dispensing Window' that supports the pharmacist with decision making.

6.11.1 The "Dispensing Window"

A prescribed medication item has a logical "dispensing window"; the timeframe during which the medication should be dispensed. Such rules are not enforced by the EPS but the information to calculate the dispensing window is contained within the prescription message to allow the System to alert the pharmacist so he/she can act accordingly.

The dispensing window is applicable to all prescribed items but is primarily designed to support EPS repeat dispensing.

For acute prescriptions, repeat prescribing prescriptions and the first issue of repeat dispensing prescriptions, the dispensing window for each prescribed item can be calculated as follows;

```
Window start date = Date of prescription OR Issue start date
(whichever is later)
Window end date = Expiry date
Date of prescription = ParentPrescription/effectiveTime
Issue start date = DaysSupply/effectiveTime/low
Expiry date = Date of prescription + item expiry period
```

For subsequent issues of repeat dispensing prescriptions, the dispensing window for each item can be calculated as follows;

```
Window start date = Date of previous issue + Expected use time - 7
days
Window end date = Issue end date OR Expiry date (whichever is sooner)
Date of previous issue = PreviousIssueDate/value<sup>4</sup>
Expected use time = DaysSupply/expectedUseTime/width
Issue end date = DaysSupply/effectiveTime/high
Expiry date = Date of prescription + 12 months
Date of prescription = ParentPrescription/effectiveTime
```

⁴ The Spine will always populate the "PreviousIssueDate" entity for subsequent issues of a repeat dispensing prescription

The dispenser must be alerted if the current date (the date the patient requires their medication) is outside the dispensing window. The dispenser can then use their clinical judgement to determine whether the medication should be provided to the patient.

When alerting the dispenser the following texts are examples of what could be displayed. The actual text to use is at the discretion of the supplier.

"Warning - The course of medication from the previous issue of this repeat dispensing prescription is not due to be completed until dd/mm/yyyy (this would be the "End date"). Confirm with the patient that they require this issue of their prescription."

"Warning – The review date for this prescription has passed. The review date was dd/mm/yyyy. Confirm with the patient that this issue of medication is appropriate."

"Warning – This prescribed item has expired. The expiry date was dd/mm/yyyy."

Note. The System must prevent the dispensing of expired prescription items. See Section 6.15.3.

Note. A prescription may contain items that have different dispensing windows, for example a prescription containing a Schedule 4 controlled drug (expires after 28 days) and a non-controlled drug (expired after 6 months).

6.11.2 Delayed Prescribing

The EPS supports the NHS England Antimicrobial Resistance (AMR) agenda by allowing the prescriber to prescribe a "Delayed Prescription". A delayed prescription is akin to an acute prescription with an optional delayed start (akin to a post-dated prescription) and an optional constrained end date. The EPS enforces that no dispensing events can be recorded outside the start and end dates defined by the prescriber.

A delayed prescription is identified using a new vocabulary entry for the "PrescriptionTreatmentType"; 0004 "Delayed Prescribing".

The 'effectiveTime' attribute within the "DaysSupply" entity defines the valid dispensing period for the prescription. The start of the dispensing period shall be later of the 'DaysSupply/low/value' and the 'ParentPrescription/effectiveTime'. The end of the dispensing period shall be the sooner of the 'DaysSupply/high/value' and the legal expiry period for the prescribed item.

All delayed prescribing prescriptions will be created as non-nominated prescriptions, even if the patient has a nominated dispenser and wants to use it. This is because the purpose of a delayed prescription is only for use if the patient requires it.

6.11.3 The "Dispense Notification"

Each time medication is provided to a patient (or a patient's representative) a "Dispense Notification" HL7 interaction must be submitted to the Spine. The dispense notification interaction contains the information of the dispensed medication items for the prescription. It should be noted that no communication with the Spine is required during the medication preparation stage of the dispensing process. See Figure 8.



Figure 8 – Dispensing Processes HL7 Messaging (Simplified)

During the process of preparing the medication, the dispense notification interaction can be created and populated with medication information. The "Author" entity of this message must be the currently logged on user. The dispense notification should be submitted when the medication is supplied to the patient (or patient representative) as closely as business processes allow. Dispense Notification messages can be submitted after the supply event, and outside the "Dispensing Window", in which case the "effectiveTime" attribute within the message should record the date/time that the supply event occurred, rather than the date/time the Dispense Notification was submitted.

The "Author" entity contains a "signatureText" element but an electronic signature is not required and this element should be encoded with nullFlavor.

For Spine 2 compliance, dispensing system end-points can be optionally configured to receive a positive application acknowledgement for the "Dispense Notification" interaction. The system should be configured this way to simplify error handling.

6.11.4 Owings and Partial Dispensing

The prescribed medication items on a prescription may not be fulfilled in one dispensing event. Each time medication is supplied to a patient, a dispense notification message must be submitted.

For items that are owing, the medication item is recorded with an omitted 'SuppliedLineItemQuantity' entity, as nothing as being supplied, and an item status of "Item not dispensed – owing" (0004).

For items that are partially dispensed, the medication item is recorded with the quantity of medication dispensed and an item status of "Item dispensed - partial" (0003).

Note. The population of the "Running Total" entity within a Dispense Notification is optional and will not be used during any reimbursement calculations.

When further medication items are dispensed in a separate dispensing event, another dispense notification message is submitted. This process is repeated until all medication items are dispensed. See Figure 9.

Note. The coded medication information contained within the Dispense Notification should reflect the actual medication supplied to the patient. This information will, in time, form part of the patient's national medication record but is not used by the BSA as part of prescription reimbursement calculations. See section 6.13 and the "Guidance for Endorsement" document for information related to the population of the "Dispense Claim Information" message.

Note. When an item is marked with a status of "Item not dispensed – owing" within a Dispense Notification, the System is not required to populate a "NonDispensingReason" entity.



Figure 9 - Partial Dispensing and Owings Model

The following table details how a prescription for the quantity of 100 Paracetamol tablets and single Salbutamol inhaler would be recorded in dispense notification messages if the tablets were dispensed over three separate dispensing events and the inhaler dispensed during the first dispensing event

Prescribing Event			
Medication ID (SNOMED)	Medication Name	Prescribed Quantity	Unit of Measure
322237000	Paracetamol 500mg soluble tablets	100	Tablet
320176004	Salbutamol 100micrograms/dose inhaler	200	Dose

1 st Dispensing Event – Prescription Status: "With Dispenser – Active"				
Medication ID (SNOMED)	Medication Name	Dispensed Quantity	Item Status	
1858411000001101	Paracetamol 500mg soluble tablets (Unichem Plc) 60 tablets	60	0003 (Partial)	
3416211000001106	Salbutamol 100micrograms/dose inhaler (Sandoz Ltd) 200 dose	200	0001 (Dispensed)	

2 nd Dispensing Event – Prescription Status: "With Dispenser – Active"			
Medication ID (SNOMED)	Medication Name	Dispensed Quantity	Item Status
185541100000106	Paracetamol 500mg soluble tablets (AAH Pharmaceuticals Ltd) 24 tablets	24	0003 (Partial)
3416211000001106	Salbutamol 100micrograms/dose inhaler (Sandoz Ltd) 200 dose	0	0001 (Dispensed)

3 rd Dispensing Event – Prescription Status: "Dispensed"			
Medication ID (SNOMED)	Medication Name	Dispensed Quantity	Item Status
2274211000001101	Paracetamol 500mg soluble tablets (Kent Pharmaceuticals) 16 tablets	16	0001 (Dispensed)
3416211000001106	Salbutamol 100micrograms/dose inhaler (Sandoz Ltd) 200 dose	0	0001 (Dispensed)

Note. If the "Running Total" entity is populated, this reflects the total quantity of medication supplied in relation to the prescribed item. In the example above, two different brands of Paracetamol were dispensed to fulfil the prescribed quantity. Hence when fully dispensed, the "Running Total" would be 100 which is equal to the prescribed quantity.

The Dispense Notification must always contain the same number of "SuppliedLineItem" entities as the number of prescribed items. If two different brands of a drug were supplied during the same dispensing event then the "SuppliedLineItemQuantity" entity is repeated. A "SuppliedLineItemQuantity" entity is required when a quantity greater than zero has been supplied.

6.11.5 Non Dispensed Items

Any medication item that cannot, and will not in the future, be dispensed must be set to the item status "Item not dispensed" (0002) with a reason code from the "Not Dispensed Reason" list defined within the MIM. This includes prescribed items that have expired.

MIM 4.2.00 states that the data type for the 'value' element of the entity 'NonDispensingReason' is "Coded with Code System". Hence to be schema valid only a 'code' and 'codeSystem' attribute needs to be present. Suppliers are requested to use the "Coded Plain" data type instead so that the additional 'displayName' attribute is provided. The existence of the 'displayName' attribute will allow reporting functionality within the EPS to be interpreted without the need for a separate look-up to identify the description for the code

If all prescribed items on a prescription are not dispensed then the "SuppliedLineItem" entities still need to be populated to declare the non-dispensing reason for each item.

Note. Within the "Not Dispensed Reason" vocabulary, the reason code 0003 "Owings note issued to patient" <u>must</u> not be implemented.

When an owings note is issued to a patient and no medication has been dispensed for any of the prescribed medication items on the prescription then no EPS messaging is required as no dispensing event has occurred. If other prescribed items have been dispensed then a Dispense Notification message must be submitted. This will indicate the quantity of medication dispensed and an item status code of 0004 "Item not dispensed owing" for the owing item.

When an owings note is issued to a patient where a partial quantity of medication has been dispensed then a Dispense Notification must be submitted. This will indicate the quantity of medication dispensed and an item status code of 0003 "Item dispensed – partial".

Note. The "Not Dispensed Reason" vocabulary has been within DMS 3.3.0 to include;

- 0008 "Item or prescription expired"
- 0010 "Patient did not collect medication"
- 0011 "Patient purchased medication over the counter"

6.11.6 Returning Prescriptions to the Spine

A prescription may be downloaded, but never dispensed by the pharmacy, for example if the pharmacy cannot supply the prescribed medication items. To allow the patient to visit a different dispenser the prescription must be returned to the Spine using the 'Dispense Proposal Return' interaction. Once returned, the prescription should be removed from the local System.

Note. The 'Dispense Proposal Return' interaction can be submitted when no user's smartcard is present provided this is a system-triggered function rather than a user initiated one. An example would be when the system returns an invalid prescription without human intervention. See section 6.5.2 for guidance on populating the HL7 'Author' entity in this scenario.

If no response is received after 60 seconds, then assume failure. The System should automatically resubmit the 'Dispense Proposal Return' interaction. If it fails the second time then the user must be informed of a possible system failure and that the issue needs to be reported to the local service help desk.

6.11.7 Data Entry Validation

The local system should implement in-field validation on data entry fields to reduce the risk of data entry mistakes. This prevents both patient safety issues and possible reimbursement claim rejection.

This should include checking at least the following;

- Medication item quantity values against that prescribed are within acceptable bounds (e.g. prescription for 50 tablets, dispenser entered 500 tablets should be flagged as a possible data error to the user)
- All mandatory fields are populated with meaningful data.

6.11.8 Prescription/Item Status Management

A prescription and each prescribed medication item have a "status" attribute. Each system in the end-to-end EPS process (i.e. prescribing systems, the Spine, dispensing systems and BSA systems) are required to implement status management functionality.

At various stages during the prescribing or dispensing process, the status of a prescription or a medication item is required to change. A prescription or a medication item can only have one status value at any time.

Note. The Spine will reject any HL7 message that has an invalid prescription or medication item status as defined by the workflow defined in this section.

6.11.8.1 Prescription Status

The "PrescriptionStatus" vocabulary within the MIM defines the status values for a prescription. The diagram shown in Figure 10 and the supporting text shows the workflows affecting the status of a prescription.



Figure 10 - Prescription Status Workflow

Prescription Status Notes:

0.	Prior to above, prescri	p prescription creation, there is no status and this has been identified in the diagram as the "Start" state. Once prescribed (acute, repeat or repeat dispensing prescription) a iption is created on ETP with a status of "To be Dispensed".	
1.	Prescriptions are requested by a Dispensing Site either individually for a Patient or en masse for a specified Dispensing Site. When a prescription's details are sent to a Dispensing Site its status changes to "With Dispenser".		
2.	Patien dispen dispen	t chooses not to receive any of the medication items or dispenser chooses not to se on clinical grounds. Dispensing Site notifies that none of the items have been sed. Prescription status set to "Not Dispensed".	
3.	Disper Disper dispen if not d	nser fully dispenses the prescription for the Patient (at least one item dispensed). Insing Site notifies that the prescription has been completed and which items have been sed/not dispensed. Prescription status set to "Dispensed" (each item to "Dispensed" or lispensed, "Not Dispensed").	
4.	Disper release	nser unable to dispense all of the Items on a prescription, dispenses nothing, and es entire prescription for dispensing elsewhere.	
	4a	Dispensing Site notifies that the prescription is returned. Prescription status set to "To be Dispensed"	
	4b	Dispensing Site notifies that the prescription is returned. A Prescribing Site has in the interim requested cancellation of the prescription, thus prescription status set to "Cancelled" to prevent download elsewhere.	
	4c	Dispensing Site notifies that the prescription is returned. In the interim the prescription has past its expiry date, thus the prescription status set to "Expired" to prevent dispensing elsewhere.	

5.	Dispenser dispenses at least part of one item from the prescription. All items will have been fully dispensed, not dispensed, partially dispensed or owing. Dispensing Site notifies current state of all items. Prescription status set to "With Dispenser – Active". Once a prescription has become "With Dispenser – Active", it cannot be returned to ETP for dispensing by another dispensing site.
6.	Dispenser dispenses further from the prescription without completing it. Dispensing Site notifies current state of all items. Prescription status remains "With Dispenser – Active", (item statuses update accordingly).
7.	Dispenser completes the prescription for the Patient (all items will have been dispensed or not dispensed). Dispensing Site notifies the prescription has been completed and which items have been dispensed/not dispensed. Prescription status set to "Dispensed" (all items to "Dispensed" or if not dispensed, "Not Dispensed").
8.	Prescribing Site requests cancellation of an existing prescription. Prescription status set to "Cancelled".
9.	ETP Spine determines under expiry rules that a prescription still in a "To be Dispensed" status has expired. Prescription status set to "Expired".
10.	ETP determines under expiry rules that a prescription still in a "With Dispenser" status has expired. Prescription status set to "Expired".
11.	ETP determines under expiry rules that a prescription still in a "With Dispenser - Active" status has expired. As the prescription has been partially dispensed the prescription status is set to "Dispensed", (item statuses updated appropriately).
12.	A protocol supply or personal administration is a combined prescribing/dispensing event. Notification of such an event will cause a prescription to be created on ETP with a status of "Dispensed".
13.	A request to record a medication update will not result in a prescription being created on ETP. The Patient medical record only is updated and this requirement is satisfied by PSIS Provision of Care when available.

6.11.8.2 Prescription Item Status

The "ItemStatus" vocabulary within the MIM defines the status values for a medication item. The diagram shown in Figure 11 and the supporting text shows where dispensing system workflows affect the status of a medication item.





Prescription Item Status Notes:

0.	Prior to prescription creation, there is no status and this has been identified in the diagram above, as the "Start" state. Once prescribed (acute, repeat or repeat dispensing prescription) all items on a prescription are created on ETP with a status of "To be Dispensed".
1.	Prescriptions are requested by a Dispensing Site either individually for a Patient or en masse for a specified Dispensing Site. When a prescription's details are sent to a Dispensing Site all items' statuses change to "With Dispenser" (except any already "Cancelled" and any repeat dispensing prescription items which have "Expired").
2.	Patient chooses not to receive a medication item or dispenser chooses not to dispense on clinical grounds. Dispensing Site notifies that an item has not been dispensed. Item status set to "Not Dispensed".
3.	Dispenser completes dispensing an item for the Patient. Dispensing Site notifies that the item has been completed. Item status set to "Dispensed".
4.	Dispenser partially dispenses a prescription and an individual item is left owing to be dispensed at some point in the future. Dispensing Site notifies that the item has been left owing. Item status set to "With Dispenser - Owing".
5.	Dispenser partially dispenses a prescription and an individual item is left part dispensed to be completed at some point in the future. Dispensing Site notifies that the item has been partially dispensed. Item status set to "With Dispenser - Partial".
6.	Dispenser partially dispenses a prescription and an individual item, previously owing, is left part dispensed to be completed at some point in the future. Dispensing Site notifies that the item has been partially dispensed. Item status set to "With Dispenser - Partial".
7.	Dispenser further partially dispenses a prescription and individual item. Dispensing Site notifies that the item is still partially dispensed. Prescription status remains "With Dispenser – Active". Item status remains "With Dispenser - Partial".

8.	Dispenser completes dispensing an item that was previously partially dispensed. Dispensing Site notifies that the item has been completed. Item status set to "Dispensed".
	ETP determines under expiry rules that a prescription still in a "With Dispenser - Active" status has expired. An item under these conditions in the "With Dispenser - Partial" state will have its status updated to "Dispensed".
9.	Dispenser completes dispensing an item that was previously owing. Dispensing Site notifies that the item has been completed. Item status set to "Dispensed".
10.	Patient chooses not to receive a medication item previously identified as owing. Dispensing Site notifies that an item has not been dispensed. Item status set to "Not Dispensed".
	ETP determines under expiry rules that a prescription still in a "With Dispenser - Active" status has expired. An item under these conditions in the "With Dispenser - Owing" state will have its status updated to "Not Dispensed".
11.	Dispenser unable to dispense all of the Items on a prescription, dispenses nothing, and releases entire prescription for dispensing elsewhere.
	11a Dispensing Site notifies that the prescription is returned. All items' statuses change to "To be Dispensed" (except any already "Cancelled" and any repeat dispensing prescription items which have "Expired").
	11b Dispensing Site notifies that the prescription is returned. A Prescribing Site has in the interim requested cancellation of the prescription or a specific item, thus item status set to "Cancelled" to prevent dispensing elsewhere.
	11c Dispensing Site notifies that the prescription is returned. In the interim the prescription has past its expiry date, thus item (and prescription) status set to "Expired" to prevent dispensing elsewhere.
12.	Prescribing Site requests cancellation of an existing prescription or a specific item. Item status set to "Cancelled".
13.	On creation of the next issue of a Repeat Dispensing Prescription, where an individual item has in the interim been cancelled, the item will have its status set to "Cancelled".
14.	ETP determines under expiry rules that a prescription still in a "To be Dispensed" status has expired. Item status set to "Expired".
15.	ETP determines under expiry rules that a prescription still in a "With Dispenser" status has expired. Item status set to "Expired".
16.	A protocol supply or personal administration is a combined prescribing/dispensing event. Notification of such an event will cause a prescription to be created on ETP with all items' statuses set to "Dispensed".
17.	On creation of the next issue of a Repeat Dispensing Prescription, where an individual item is not to be included (i.e. has a maximum number of issues less than this issue number), the item will have its status set to "Expired".
18.	A request to record a medication update will not result in a prescription being created on ETP. The Patient medical record only is updated and this requirement is satisfied by PSIS Provision of Care when available.

6.11.8.3 Valid State Combinations

The following table provides valid combinations of prescription and item state. It illustrates which item states are valid for a given prescription state and in what circumstances.

Valid State Combinations

Scenario	Prescription Status	Valid Item States	Notes
Initial state of prescription when stored on ETP waiting to be pulled down by a dispensing site	To be dispensed	To be dispensed	Initial state of an item
		Cancelled	Item only has been cancelled
		Expired	Item on a Repeat dispensing prescription not included on new issue
Prescription has been cancelled (or multiple item cancellations have resulted in total cancellation)	Cancelled	Cancelled	Item or whole prescription has been cancelled
		Expired	Item on a Repeat Dispensing Prescription not included on this issue
Prescription has been pulled down by a dispensing site but no dispensing activity has yet taken place – the prescription may still be returned	With dispenser	With dispenser	Initial state of an item when pulled down by a dispenser
		Cancelled	Item only has been cancelled
		Expired	Item on a Repeat Dispensing Prescription not included on this issue
Prescription dispensing has commenced Something must have been dispensed i.e. at least one item must be "Dispensed" or "With Dispenser – Partial"	With dispenser - active	Dispensed	Dispensing for the item is complete
When prescription changes from "With Dispenser" to "With Dispenser – Active", all item states must change (except "Cancelled" and "Expired"). Note. Marking all items as "With dispenser – owing" is not a valid state transition as no physical supply has taken place.		With dispenser - partial	Item has been partially dispensed with expectation of further dispensing to follow

Scenario	Prescription Status	Valid Item States	Notes
		With dispenser - owing	None of the item has been dispensed with expectation of further dispensing to follow
		Not dispensed	Item has not and will not be dispensed
		Cancelled	Item only has been cancelled
		Expired	Item on a Repeat Dispensing Prescription not included on this issue
Whole prescription has not and will not be dispensed	Not Dispensed	Not Dispensed	Item has not and will not be dispensed
		Cancelled	Item only has been cancelled
		Expired	Item on a Repeat Dispensing Prescription not included on this issue
Prescription dispensing is complete (at least one item must have status "Dispensed")	Dispensed	Dispensed	Dispensing for the item is complete
		Not Dispensed	Item has not and will not be dispensed
		Cancelled	Item only has been cancelled

Scenario	Prescription Status	Valid Item States	Notes
		Expired	Item on a Repeat Dispensing Prescription not included on this issue
Prescription has expired A prescription expires after an elapsed period following its expiry date, the period determined by its current status When an incomplete prescription ("With Dispenser" or "With Dispenser - Active") expires outstanding item statuses are updated to "Dispensed" or "Not Dispensed"	Expired	Expired	Item was "To be Dispensed" or "With Dispenser" when prescription expired OR Item was already expired (due to not being included on a Repeat dispensing prescription issue) when prescription expired
		Cancelled	Item was already cancelled when prescription expired
		Dispensed	Item was already "Dispensed" or "With Dispenser – Partial" when prescription expired.
		Not Dispensed	Item was "With Dispenser – Owing" when prescription expired.

Ref	Requirement		
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Ref	Requirement		
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6.11.1	The System <u>must</u> calculate the "dispensing window" for each prescribed medication item.		
6.11.2	If the current date is outside the "dispensing window" then the System <u>must</u> provide a suitable message to the user so that clinical judgement can be used to determine whether the medication item should be provided to the patient.		
6.11.3	The System must implement the "Dispense Notification" interaction.		
6.11.4	The "Author" entity of the "Dispense Notification" interaction <u>must</u> be populated with the credentials of the currently logged on user.		
6.11.5	The "effectiveTime" attribute within the "Dispense Notification" interaction <u>must</u> reflect the dispensing supply date (when medication was supplied to the patient or patient representative) as closely as business processes allow.		
6.11.6	The System <u>must not</u> apply a Content Commitment Electronic Signature to a "Dispense Notification" interaction.		
6.11.7	The System <u>must</u> be configured to receive and process a positive application acknowledgement for the "Dispense Notification" interaction.		
6.11.8	The System <u>must</u> set the status of a fully dispensed medication item within the prescription to "Item dispensed" (0001).		
6.11.9	The System <u>must</u> set the status of a prescription that has either partially dispensed or owing medication items to "With Dispenser – Active" (0003).		
6.11.10	The System <u>must</u> set the status of a partially dispensed medication item within the prescription to "Item dispensed – partial" (0003).		
6.11.11	The System <u>must</u> set the status of an owing medication item within the prescription to "Item dispensed – owing" (0004).		
6.11.12	The System <u>must</u> set the status of a prescription that has all items either "Item fully dispensed" (0001) or "Item not dispensed" (0002), but at least one item fully dispensed, to the prescription status of "Dispensed" (0006).		
6.11.13	The System <u>must</u> set the status of a prescription that has all items either "Item cancelled" (0005) or "Item not dispensed" (0002) to the prescription status of "Not Dispensed" (0007).		

Ref	Requirement
6.11.14	The Dispense Notification <u>must</u> always contain the same number of "SuppliedLineItem" entities as the number of prescribed items.
6.11.15	The Dispense Notification <u>must</u> always contain a "SuppliedLineItemQuantity" entity for each different dm+d item dispensed, when the dispensed quantity is greater than zero.
6.11.16	The System <u>must</u> set the status of a medication item that cannot, and will not, be dispensed to "Item not dispensed" (0002).
6.11.17	The System <u>must</u> set a "Not Dispensed Reason" for items not dispensed.
6.11.18	When an item is marked as not dispensed through the actions of an end user then the end user <u>must</u> be asked to select a valid reason code.
6.11.19	When an item is marked as not dispensed through the actions of the system then the system <u>must</u> use a relevant reason code.
6.11.20	The System <u>must</u> implement the 'Dispense Proposal Return' message so that a prescription can be returned to the Spine for dispensing elsewhere.
6.11.21	A returned prescription <u>should</u> be removed from the local System or marked as such so that it is clear that the prescription is not intended for dispensing.
6.11.22	If no response is received after 60 seconds from a 'Dispense Proposal Return' interaction, then assume failure. The System <u>should</u> automatically resubmit the 'Dispense Proposal Return' interaction. If it fails the second time then the user <u>must</u> be informed of a possible system failure and that the issue needs to be reported to the local service help desk.
6.11.23	The local system <u>should</u> implement in-field validation on data entry fields to reduce the risk of data entry mistakes.
6.11.24	The System <u>must</u> adhere to the prescription status workflow defined within this section.
6.11.25	The System <u>must</u> adhere to the item status workflow defined within this section.

Ref	Requirement
6.11.26	The System <u>must</u> adhere to the start and end dates defined for a "Delayed Prescribing" prescription and no permit dispensing activities to be completed outside the defined dispensing period.
6.11.27	The System <u>must</u> make it visible to the user when a prescription is received that is for a delayed prescription, together with the defined start and end dates for the dispensing period.

6.12 Patient/Patient Representative Declaration

When a prescription is collected by the patient, or patient's representative, they could be required to sign the declaration on the rear of the FP10/token to indicate whether they have paid for their medication or if they are fee exempt.

6.12.1 No Declaration for Age Exempt Patients

Legislation changed in April 2005 to remove the need for patients who are ageexempt to sign a declaration.

A patient's exemption status applies at the time of dispensing and it is the responsibility of the dispensing system to calculate the patient's exemption status.

The electronic prescription contains two exemption attributes;

- Permanent Exemption
- Temporary Exemption.

Both attributes have high and low data values. The permanent exemption range can be used by a dispensing system to calculate if the patient is age-exempt. If the current date falls within the high/low range, then the patient is **not** age-exempt. An example is provided below.

Patient's Date of Birth = 16/12/1974

Permanent Exemption Low = DoB + 16yrs - 1day = 15/12/1990

Permanent Exemption High = DoB + 60yrs - 1 day = 15/12/2034

If today's date was 30/11/2004, then this falls within the date high/low range therefore the patient is *not* age-exempt.

If today's date was 16/12/2034, then this falls outside the date high/low range therefore the patient *is* age-exempt.

The temporary exemption range will not initially be used as it is intended for non-age related exemptions that may, over time, be available from the Spine.

6.12.2 Use of a "Dispensing Token"

When a patient is using a nominated dispenser, the presentation of a prescribergenerated prescription token is optional. In these circumstances, a paper form to capture the patient's declaration will not be available and hence the dispenser will be required to print a "Dispensing Token" for this purpose. Requirements for over-printing the dispenser token are detailed in the document "EPS Dispensing Token Specification" (ref: NPFIT-ETP-EDB-0080).

The over-printing specification details the requirements for printing the left hand side of the stationery. New pre-printed stationery for the dispensing token has been produced and is known as FP10DT. This stationery is based on the FP10SS stationery and therefore contains a blank right hand side.

The following information contained within the electronic prescription must be printed on the right hand side of the dispensing token.

- Medication specific additional instructions (from HL7 entity "Additional Instructions")
- Patient specific additional instructions (from HL7 entity "Additional Instructions")

Refer to section 6.10.3 for details related to information contains within "Additional Instructions".

If the dispenser wishes to provide additional written instructions then this can also be conveyed on the right hand side.

Processes for the ordering and receipt of dispenser token stationery and the management of paperwork for the NHS BSA will be communicated to pharmacy by the relevant organisations.

Refer to NHS BSA documentation for what paperwork needs to be posted to the NHS BSA at the end of each month.

Ref	Requirement
6.12.1	The System <u>must</u> calculate the patient's age-related prescription charge exemption status based upon the information contained in the message and provide this information to the end-user.
	Age-exempt patients are not required to sign the declaration on the rear of the token.
6.12.2	The System <u>must</u> capture all the required fee exemption and declaration information for inclusion in the reimbursement data block for the message.
6.12.3	The System <u>must</u> be capable of printing a dispensing token, as defined within the EPS Dispensing Token Specification, for the capture of a patient declaration when required.
6.12.4	The System <u>must</u> print the following on the right hand side of the dispensing token;
	Review date
	Medication specific additional instructions (see section 6.10.3)
	• Patient specific additional instructions (see section 6.10.3)

6.12.5 The information printed on the dispensing token <u>must</u> be taken from the electronic prescription.

6.13 Electronic Prescription Endorsements

Prescriptions that are electronically signed by a prescriber must be reimbursed electronically through the EPS. Hand-signed prescriptions must be reimbursed from the FP10 using existing processes. The actual reimbursement claim remains the FP34C paper form.

The EPS implements electronic endorsing of prescriptions via the "Dispense Claim Information" HL7 interaction. The coded medication and endorsement information contained within the HL7 message is used by the NHS BSA as part of their prescription reimbursement processing. The rules used by the NHS BSA for reimbursement are the same as for FP10 prescriptions.

Once dispensing of an electronically signed prescription is complete an electronic endorsement can be submitted to the Spine using the "Dispense Claim Information" HL7 interaction. The user must be given the opportunity to confirm and edit the business relevant information within electronic endorsement, for example any coded Drug Tariff endorsements, and is able to submit the endorsement at any time after dispensing has been completed.

For details on how to endorse electronic prescriptions, refer to the document "Guidance for Endorsement" (Ref: NPFIT-ETP-EIM-0015).

The reimbursement information data block within the "Dispense Claim Information" message contains a number of attributes. The following attributes must be populated for reimbursement and counter-fraud purposes;

- Reimbursement organisation
- Endorsements
- Prescription charge payment
- Prescription charge exemption code
- Evidence of exemption seen.

The "Charge Payment" attribute is a Boolean value. This will be true if any charge was paid by the patient or patient's representative, otherwise false.

The System should alert the user when the default value of 'true' is to be applied for the 'Charge Payment' attribute when no user affirmation of the patient's payment/exemption status has been recorded. This will aid the user in ensuring the correct charge/exemption status has been recorded.

Once an electronic endorsement has been submitted, no further dispense notifications will be accepted by the Spine, subject to corrections – see section 6.17 Update Semantics.

A dispenser Advanced Electronic Signature is **not required** on the "Dispense Claim Information" HL7 interaction.

For Spine 2 compliance, dispensing system end-points can be optionally configured to receive a positive application acknowledgement for the "Dispense Claim Information" interaction. The system should be configured this way to simplify error handling.

6.13.1 Claim Amendment

An amended claim uses the "Reimbursement Claim Resubmit" interaction containing a "Dispense Claim Information" message where the 'priorMessageRef' entity is populated with the message UUID for a previous claim.



Figure 12 - Claim Amendment

The NHS BSA rules for processing amended claims are as follows;

- An amended claim must contain all the claim information relevant for the prescription. This is opposed to sending only the difference in data between the two messages.
- An amended claim must reference the previous claim (or previous claim amendment) for the same prescription.
- An amended claim must be received within the same reimbursement period as the original claim, where the reimbursement period is defined by the NHS BSA and, at the time of writing, was up to the 5th day of the following month.
- In the case of more than one claim amendment, each amended claim must reference the previous amended claim and not the original claim.

Ref	Requirement	
6.13.1	The System <u>must</u> ensure that an electronic endorsement can only be sent for a prescription with a valid advanced electronic signature.	
6.13.2	2 The System is <u>must not</u> apply an Advanced Electronic Signature electronic endorsement messages.	
	Note . In the case where a message definition includes a signatureText element but no signature is required, the element is coded as:	
	<signaturetext nullflavor="NA"></signaturetext>	

Ref	Requirement
6.13.3	The System <u>must</u> prevent the submission of an electronic endorsement until all medication items on the prescription have been completed.
	Note . A completed medication item has the status of either "Item fully dispensed (0001)", "Item not dispensed (0002)", "Expired (0006)" or "Item cancelled (0005)".
6.13.4	Once an electronic endorsement has been submitted, the System <u>must</u> prevent any further dispensing activities on that prescription (subject to corrections – see section 6.17 Update Semantics)
6.13.5	The System <u>must</u> be configured to receive and process a positive application acknowledgement for the 'Dispense Claim Information' interaction.
6.13.6	The System <u>must</u> allow the user to amend relevant reimbursement data submitted as part of a 'Dispense Claim Information' message so that an amended 'Dispense Claim Information' message is submitted to the NHS BSA.
6.13.7	An amended 'Dispense Claim Information' message <u>must</u> contain all the claim information relevant for the prescription.
6.13.8	An amended 'Dispense Claim Information' message <u>must</u> reference the previous claim (or previous claim amendment) for the same prescription.
6.13.9	An amended 'Dispense Claim Information' message <u>must</u> be received within the same reimbursement period as the original claim.
6.13.10	In the case of more than one claim amendment, each amended claim <u>must</u> reference the previous amended claim and not the original claim.
6.13.11	The System <u>must</u> alert the user when the default value of 'true' is to be applied for the 'Charge Payment' attribute when no user affirmation of the patient's payment or exemption status has been recorded.
6.13.12	The System <u>must</u> allow the user to suppress the alert within requirement 6.13.11, for example; "[] Do not show this message again", and restore the alert message again if/when required.

6.14 Emergency Supply

Dispensers are sometimes called upon to make an emergency supply of medication without the patient having a prescription from an authorised prescriber.

Existing guidelines and best practice for emergency supply apply. When an electronic prescription is provided following an emergency supply then this should be handled using EPS processes with a submission of an electronic dispense notification and electronic reimbursement claim.

Ref	Requirement
6.14.1	An electronic prescription received following an emergency supply <u>must</u> be processed using normal electronic dispensing processes.

6.15 Housekeeping Processes

Compliance for housekeeping covers three processes;

- Deferred prescription reimbursement claims
- Prescriptions with outstanding items (i.e. partially dispensed or owing prescriptions)
- Expired prescriptions.

6.15.1 Deferred Reimbursement Claim Submission

The submission of a reimbursement claim for a prescription where all of the items have been 'fully dispensed' or 'not dispensed' must be made no later than the 5th day of the month following that in which the supply was made. Where the prescription has not been completely dispensed (i.e. partial dispensing) the claim can be deferred until all dispensing activity is complete by a dispenser. The System is required to provide the user with a view of un-endorsed prescriptions so these can be completed when appropriate.

The System must indicate on the view of un-endorsed un-submitted Electronic Reimbursement Endorsement messages, which have been defaulted to "patient paid" as no user affirmation of the patient's payment/exemption status has been recorded. This will aid the user in ensuring no prescriptions are submitted as "patient paid" in error.

The System must notify the user of the number of un-endorsed un-submitted Electronic Reimbursement Endorsement messages for the claim month, leading up to the cut-off date for claim submissions to the NHS BSA.

See section 6.15.4 for rules for when un-endorsed prescriptions are sent to the NHS BSA marked as having no associated claim. Once this occurs, the dispenser cannot submit a claim for the prescription. The system must make the date when a prescription will be sent to the NHS BSA marked with no claim visible to the user as a clear reminder to submit claims for dispensed prescriptions.

6.15.2 Prescriptions with Outstanding Items

Prescriptions that have been partially dispensed or have owing items must be visible to the dispenser so that relevant stock can be ordered and these prescriptions can be completed. The System is required to provide the user with a view of prescriptions with outstanding items so these can be completed when appropriate.

See section 6.15.4 for rules for when prescriptions with outstanding items are marked as expired. The system must make this date visible to the user as a clear reminder to completed dispensing activities for prescriptions.

6.15.3 **Prescription Expiry**

The System is required to calculate the expiry date for prescribed items. The System must inform the dispenser that a prescribed item has expired and prevent the dispensing of expired items.

The dispensing system must calculate the expiry based on the date of prescribing contained within the electronic prescription message and the expiry rules defined by the Dept. of Health. In addition, the following applies when using the EPS;

- A prescribed item that is partially dispensed or owing will not expire, however see section 6.15.4 Spine Data Cleansing
- A prescribed item that is recorded as fully dispensed, recorded as not dispensed or cancelled will not expire, however see section 6.15.4 Spine Data Cleansing
- Where a prescription has expired, no items on that prescription can be dispensed
- Where a prescription contains items of different expiry rules, individual items that have expired cannot be dispensed, while items yet to expire can be dispensed. A Dispense Notification can be submitted after expiry provided the 'effectiveTime' of the Dispense Notification reflects the date/time the medication was dispensed, opposed to the date/time the dispensing event was recorded within the system.

Expiry calculations operate on whole month and day boundaries. The expiry time is 23:59:59 on the last day of the expiry period (e.g. 6 months). So to calculate the expiry date, the following process could be used:

- 1. Change the time to 23:59:59
- 2. Add the expiry period to month (e.g. +6 months), wrapping to the next year if required
- 3. If the day is greater than the maximum days in the new month, set the day to the maximum day for the new month.

For example:

Prescribed "05/01/2004 17:19:11" → Expires "05/07/2004 23:59:59" Prescribed "31/08/2004 12:18:30" → Expires "28/02/2005 23:59:59" Prescribed "30/08/2004 12:18:30" → Expires "28/02/2005 23:59:59" Prescribed "29/08/2004 12:18:30" → Expires "28/02/2005 23:59:59" Prescribed "28/08/2004 12:18:30" → Expires "28/02/2005 23:59:59" Prescribed "27/08/2004 12:18:30" → Expires "28/02/2005 23:59:59" After a prescription has expired within the local System it must be returned to the Spine using the "Dispense Proposal Return" message. The prescription should then be removed from the local System.

Expired items must be recorded with an item status of "Expired" within the Dispense Notification interaction following either a dispensing event or if all items on a prescription have expired. Only if all items on a prescription have expired should the prescription status be set to "Expired".

6.15.4 Spine Data Cleansing

The Spine will implement data cleansing routines for the purposes of managing the EPS data store within the Spine. The objective of data cleansing is to remove 'incomplete' prescriptions that are outstanding after an appropriate period of time. The time period parameters will be system configurable within the Spine to cater for future changes to the requirement.

Spine Data Cleansing Routine	Implications for Subsequent Dispensing Processes
A prescription held on the Spine that is fully dispensed but with no reimbursement claim submitted will be sent to the reimbursement agency without a claim block by the Spine after 180 days.	Dispensers have up to 180 days in which to submit their reimbursement claim after the date of dispensing as defined within the dispense notification that 'competed' all prescribed line items, where 'completed' means each line item has a status of either 'Dispensed', 'Not Dispensed', 'Expired' or 'Cancelled' An electronic reimbursement claim submission after this time from the dispenser will be rejected by the Spine.
A prescription held on the Spine that still has partially dispensed or owing items will be changed to "expired" on the Spine 180 days after the last dispensing event. The prescription will be sent to the reimbursement agency without a claim block. Partially dispensed items will be marked as "Dispensed". Owing items will be marked as "Not Dispensed".	An electronic reimbursement claim submission from the dispenser will be rejected by the Spine. If further dispensing events are required, the dispenser should refer the patient back to their GP for a new prescription.
A prescription held on the Spine with no items dispensed will be changed to "expired" after its expiry date.	An expired prescription cannot be dispensed. If dispensing events are required, the dispenser should refer the patient back to their GP for a new prescription.
<i>Expired</i> prescriptions held on the Spine will be removed after 90 days.	No processing is possible on these prescriptions.

The implications of Spine data cleansing are outlined in the table below.

Spine Data Cleansing Routine	Implications for Subsequent Dispensing Processes
A prescription with a status 'Dispensed' will be deleted from the EPS 9 days after the electronic reimbursement or "no claim notification ⁵ " as been sent to the reimbursement agency.	During the period, a dispensing record can still be amended to correct clinical errors provided the overall status of the prescription is not changed.

The System should inform the user at a suitable time before Spine data cleansing activities take place which could impact dispensing processes.

For example, informing the pharmacist that fully dispensed prescriptions which have not yet been claimed for will be sent to the reimbursement agency with no claim. This will ensure the pharmacist submits outstanding claims if he/she intends to.

Ref	Requirement
6.15.1	The System <u>must</u> provide the user with a view of un-endorsed prescriptions, including the date when the prescription is scheduled to be sent to the NHS BSA with no associated claim. This will allow the user to more easily identify and send a claim message where appropriate.
6.15.2	The System <u>must</u> provide the user with a view of prescriptions with outstanding items, including the date when the prescription is scheduled to be marked as expired by the EPS, so these can be completed when appropriate.
6.15.3	The System <u>must</u> calculate the expiry date for prescribed items based on the rules defined within this section.
6.15.4	The System <u>must</u> prevent the dispensing of an expired item. A Dispense Notification can be submitted after expiry provided the 'effectiveTime' of the Dispense Notification reflects the date/time the medication was dispensed, opposed to the date/time the dispensing was recorded within the system.

⁵ A 'no claim notification' is a Spine generated message to the NHS BSA comprising of prescribing and dispensing information but no claim information as this was not submitted by the dispensing contractor within the allotted timeframe.

Ref	Requirement
6.15.5	An expired prescription <u>should</u> be removed or archived from the local System.
	Expired items must be recorded as "Not Dispensed" using the reason code "0008 Item or prescription expired" within a Dispense Notification.
	If all items on a prescription have expired the overall prescription status must be "0007 Not Dispensed" using the reason code "0008 Item or prescription expired".
	The Spine will update prescription and item status values to "Expired" on receipt of a Dispense Notification recorded in this way.
6.15.6	The System <u>should</u> inform the user at a suitable time before Spine data cleaning activities take place which could impact dispensing processes.
6.15.7	The System <u>must</u> indicate on the view of un-endorsed un-submitted Electronic Reimbursement Endorsement messages, which have been defaulted to 'patient paid' as no user affirmation of the patient's payment or exemption status has been recorded.
6.15.8	The System <u>must</u> notify the user of the number of un-submitted Electronic Reimbursement Endorsement messages for the claim month, leading up to the cut-off date for claim submissions to the NHS BSA. For example; 10, 5 and 2 working days before the 5 th of the month.

6.16 Exception Handling

The national architecture of the Spine is robust and resilient. However exception handling processes must be implemented by end-systems to cater for unexpected system outages and contingency plans.

Where defined in the MIM, an interaction may trigger a negative "Application Acknowledgement" message indicating that processing the interaction has failed.

The error code will be "5000" and the error description will contain a description of the message that must be displayed to the end user.

Ref	Requirement
6.16.1	On receipt of a negative Application Acknowledgement, the System <u>must</u> display the error description to the user.
6.16.2	On receipt of a negative Application Acknowledgement, the System <u>must</u> audit the error in such a way that a system support engineer can view the error within a system activity audit trail to identify the

date/time and system action that triggered the error.

6.17 Update Semantics

Update semantics is the mechanism to correct dispensing or claim information submitted to the EPS.

Incorrect dispensing information may confuse clinical colleagues and dispensers have a responsibility to maintain an accurate patient medical record. Further, later in 2015, it is planned to make visible dispensing information to the prescribing organisation from where the prescription was written.

Incorrect claim information may result in incorrect financial reimbursement from the BSA.

6.17.1 Specific Update Rules for Repeat Dispensing

The repeat dispensing model is driven by the status management of the prescriptions issued under that repeat dispensing authorising prescription (for example, 1 of 12) electronically signed by the prescriber.

The fundamental rules adopted for repeat dispensing are that;

- At any one time there can be no more than one issue of that repeat authorisation available, for example, prescription issues 3 of 12 and 4 of 12 cannot co-exist.
- The next issue of a prescription is released by the Spine when the previous issue of the prescription has been fulfilled (completed by the dispenser). Hence, for example, issue 4 of 12 will be available for supply when 3 of 12 have been completed.

6.17.2 Guidance for "Withdraw ETP Message"

The "Withdraw ETP Message" has two purposes where the term "withdraw" is akin to a delete operation;

- 1) To withdraw the last dispensing event against an instance of a prescription
- 2) To withdraw all dispensing events against an instance of a prescription.

When a dispensing event is required to be corrected it could be implemented by a "Withdraw ETP Message" interaction followed by a "Dispense Notification" interaction but it is recommended that such a correction is implemented by a single amended "Dispense Notification" interaction, see section 6.17.3.

The entity "WithdrawType" determines which of the above operations is executed.

The mandatory entities are as follows;

Patient - containing the NHS number of the patient

Participant – SDS attributes for the message author

WithdrawID - the Prescription ID

WithdrawReason – coded reason codes

WithdrawType – specifies withdraw of either the last ("LD") or all ("AD") dispensing events against an instance of a prescription

The optional elements are required in certain prescription/withdraw scenarios.

When withdrawing the LAST ("LD") dispensing event, the following entities are required;

DispenseNotificationRef – the UUID of the last dispense notification and the one that is to be withdrawn

RepeatInstanceInfo – Required for repeat prescribing and repeat dispensing prescriptions only. The repeat number of the prescription instance.

When withdrawing ALL ("AD") dispensing events, the following entity is required;

RepeatInstanceInfo – Required for repeat prescribing and repeat dispensing prescriptions only. The repeat number of the prescription.

The request to withdraw the last or all dispense notifications will fail in the following scenarios;

- The prescription is not found within the EPS
- The prescription has no dispensing recorded against it
- The ID of the dispense notification is not the last dispense notification against the prescription (when withdrawing the last dispense)
- The repeat instance value, if a repeat prescription or repeat dispensing instance, does not match the repeat instance of the last dispense notification against the prescription
- A claim for the prescription has been accepted by the EPS.

Note. There are no known scenarios where multiple instances of the 'DispenseNotificationRef entity are required.

Note. The Spine will ignore the optional 'DispenseNotificationRef' entity if this is populated when withdrawing all supply events.

Note. To withdraw all dispensing events related to a series of repeat dispensing prescription instances, the system will be required to send a withdraw all message for each separate instance of the repeat dispensing prescription.

6.17.3 Amend Last Supply Event

The last Dispense Notification can be amended using the same interaction as a normal Dispense Notification. The 'replacementOf' act relationship contains the ID of the last dispense notification which will be replaced with the new dispense notification.

An amended Dispense Notification is the only mechanism to correct dispensing errors after a claim has been accepted by the EPS. Therefore it is mandatory that this functionality is implemented by the system.

6.17.4 Create New Supply Event History (Rebuild Dispense History)

To update the whole supply event history for a prescription, it is necessary to cancel all previous supply events and build a new supply event history for that prescription. This can be achieved by a series of interactions, starting with a "Withdraw ETP Message", followed by one or more "Dispense Notifications". Alternatively it can be achieved by a single "Rebuild Dispense History" interaction containing the same messages as the previous method, but combined into one single, more complex message.

The "Rebuild Dispense History" message contains the ID of the prescription, the reason for the request and one or more complete dispense notifications that will form the new dispense history. On receipt, the Spine will withdraw all existing dispense notification against the prescription and replace them with the dispense notifications contained within the message.

The optional entity "RepeatInstanceInfo" is required when rebuilding repeat prescribing or repeat dispensing histories. When rebuilding the dispense history for a repeat prescribing prescription, set the "RepeatInstanceInfo" value to "1". When rebuilding the dispense history for a repeat dispensing prescription, set the "RepeatInstanceInfo" value to the appropriate repeat number for the prescription.

When rebuilding a dispense history, the number of dispense notification messages contained may be more, less or the same as the original dispense notification they are replacing.

Within the dispense notification messages contained within a Rebuild Dispense History message, the entity "priorMessageRef" can be omitted as the reference to which prescription the dispense notifications apply is contained within the main payload of the Rebuild Dispense History message.

The order in which dispense notifications occur within a Rebuild Dispense History message and the prescription/item status values must adhere to the valid state combinations detailed within section 6.11.8.

6.17.5 Claim Corrections

Where a claim has been submitted with errors, these can be corrected by amending the claim. See section 6.13.1.

Where claim corrections change the clinical dispensed information, for example, the dm+d concept dispensed, quantity or supply instructions, and then an amended Dispense Notification should also be submitted to align with the amended claim. This can be submitted either before or after the amended claim as these are processed independently.

6.17.6 Specific Repeat Dispensing Scenarios

The mechanisms for amending or withdrawing dispense notifications related to repeat dispensing prescriptions can be complex. Once the Spine receives the final dispense notification for an issue, the next becomes available to download. This presents the question related to update semantics of which is the "last dispense"?

The Spine treats the "last dispense" as the last issue of a repeat dispensing prescription that is recorded as 'complete' on the Spine (i.e. has all items of status either "Dispensed" or "Not Dispensed").

Therefore even if the next issue has been downloaded, or even partially dispensed, the previous issue can be amended or withdrawn on the Spine.

If the previous issue is withdrawn, it must be replaced if the current issue is to be dispensed in order to maintain the integrity of the sequence of issues.

A series of repeat dispensing issues can be withdrawn in sequence if required as withdrawing the last dispense causes the previous one to become the 'new' last dispense, so it is possible to roll back the various dispenses on a one-by-one basis.

Ref	Requirement
6.17.1	The System <u>should</u> implement the "Withdraw ETP Message" HL7 message to allow the last dispense notification to be withdrawn and cancelled.
6.17.2	The System <u>should</u> implement the "Withdraw ETP Message" HL7 message to allow all dispense notifications against a prescription to be withdrawn and cancelled.
6.17.3	The System <u>must</u> implement either the 'withdraw last' or 'withdraw all' implementations of the "Withdraw ETP Message" message.
6.17.4	The System <u>must</u> allow a Dispense Notification HL7 message to be created to amend the last dispense notification utilising the 'replacementOf' act relationship.
6.17.5	The System <u>could</u> implement the "Rebuild Dispense History" HL7 message to replace and correct a complete dispensing history against a prescription.

Appendix A: Messaging Vocabularies Maintained Outside the DMS

A1: PrescriptionType

Description: Describes the prescribing location and prescriber type of the prescription

Assigned OID: 2.16.840.1.113883.2.1.3.2.4.17.25

Version: 07

Date: 2015-03-01

Code	Description	Note
0001	General Practitioner Prescribing	Retired from Publication as from 26-Sep- 2013
0002	Intentionally left blank	Retired from Publication as from 26-Sep- 2013
0003	Nurse Practitioner Prescribing	Retired from Publication as from 26-Sep- 2013
0004	Hospital Prescribing	Retired from Publication as from 26-Sep- 2013
0006	Dental Prescribing	Retired from Publication as from 26-Sep- 2013
0007	Supplementary Prescriber Prescribing	Retired from Publication as from 26-Sep- 2013
0009	General Practitioner Prescribing: Private	Retired from Publication as from 26-Sep- 2013
0012	Extended Formulary Prescriber	Retired from Publication as from 26-Sep- 2013
0101	General Practitioner Prescribing - GP	
0102	General Practitioner Prescribing - Trainee Doctor/GP Registrar	
0103	General Practitioner Prescribing - Deputising Services	
0104	General Practitioner Prescribing - Practice employed Nurse Independent/Supplementary prescriber	
0105	General Practitioner Prescribing - Practice employed Community Practitioner Nurse prescriber	
0106	General Practitioner Prescribing - PCT employed Nurse Independent/Supplementary prescriber	Retired from Publication as from 20-Feb- 2015
0107	General Practitioner Prescribing - PCT employed Community Practitioner Nurse prescriber	Retired from Publication as from 20-Feb- 2015
0108	General Practitioner Prescribing - Practice employed Pharmacist prescriber	
0109	General Practitioner Prescribing - PCT employed Pharmacist prescriber	Retired from Publication as from 20-Feb- 2015
0110	General Practitioner Prescribing - Locum	
0113	General Practitioner Prescribing - Practice employed Optometrist	
0114	General Practitioner Prescribing - Practice employed	

Code	Description	Note
	Podiatrist/Chiropodist	
0116	General Practitioner Prescribing - Practice employed Radiographer	
0117	General Practitioner Prescribing - Practice employed Physiotherapist	
0119	General Practitioner Prescribing - PCT employed Podiatrist/Chiropodist	Retired from Publication as from 20-Feb- 2015
0120	General Practitioner Prescribing - PCT employed Optometrist	Retired from Publication as from 20-Feb- 2015
0121	General Practitioner Prescribing - PCT employed Radiographer	Retired from Publication as from 20-Feb- 2015
0122	General Practitioner Prescribing - PCT employed Physiotherapist	Retired from Publication as from 20-Feb- 2015
0123	General Practitioner Prescribing - Hospital prescriber	
0304	Nurse Practitioner - Practice employed Nurse Independent/Supplementary prescriber	
0305	Nurse Practitioner - Practice employed Community Practitioner Nurse prescriber	
0306	Nurse Practitioner - PCT employed Nurse Independent/Supplementary prescriber	Retired from Publication as from 20-Feb- 2015
0307	Nurse Practitioner - PCT employed Community Practitioner Nurse prescriber	Retired from Publication as from 20-Feb- 2015
0406	Hospital Prescribing - Hospital Prescriber	
0607	Dental Prescribing - Dentist	
0708	Supplementary Prescribing - Practice employed Pharmacist	
0709	Supplementary Prescribing - PCT employed Pharmacist	Retired from Publication as from 20-Feb- 2015
0713	Supplementary Prescribing - Practice employed Optometrist	
0714	Supplementary Prescribing - Practice employed Podiatrist/Chiropodist	
0716	Supplementary Prescribing - Practice employed Radiographer	
0717	Supplementary Prescribing - Practice employed Physiotherapist	
0718	Supplementary Prescribing - PCT employed Optometrist	Retired from Publication as from 20-Feb- 2015
0719	Supplementary Prescribing - PCT employed Podiatrist/Chiropodist	Retired from Publication as from 20-Feb- 2015
0721	Supplementary Prescribing - PCT employed Radiographer	Retired from Publication as from 20-Feb- 2015
0722	Supplementary Prescribing - PCT employed Physiotherapist	Retired from Publication as from 20-Feb- 2015
0901	Private prescribing - GP	
0904	Private prescribing - Nurse prescribing	
0908	Private prescribing - Pharmacist prescribing	
0913	Private prescribing - Optometrist	
0914	Private prescribing - Podiatrist/Chiropodist	

Code	Description	Note
0915	Private prescribing - Physiotherapist	
0916	Private prescribing - Radiographer	