nehta

Concept of Operations

Electronic Transfer of Prescription 1.1

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National E-Health Transition Authority

National E-Health Transition Authority Ltd

Level 25

56 Pitt Street

Sydney, NSW, 2000

Australia.

www.nehta.gov.au

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Name	Title	Signature
Stephen Johnston	Head of Product and Solutions Development	
Dr. Leonie Katekar	Director, Clinical Unit and Clinical Lead	
Toby Mathieson	Program Manager e-Medication Management	

Table of Contents

Preface

Document Purpose

This document describes the Electronic Transfer of Prescriptions (ETP) service concept developed by NEHTA and its relationship with proposed, interlocking services which make up NEHTA's broader approach to Electronic Medications Management (eMM). It argues that the widespread adoption of the clinically validated ETP service specification will provide ongoing benefits for participants within the Australian health sector by justifying the ETP service, describing its workings, outlining potential implementations, and noting its key privacy and policy considerations.

Intended Audience

This document is intended to be read and understood by:

- Software vendors of products involved in medications management
- Organisations that implement and operate ETP Services
- Clinicians
- Health Service Executives and Managers
- Chief information Officers
- Medicare Australia
- The Department of Health and Ageing (DoHA).

Document Map

The following diagram represents the relationship between this document and others within the Electronic Transfer of Prescription Release 1.1 package.
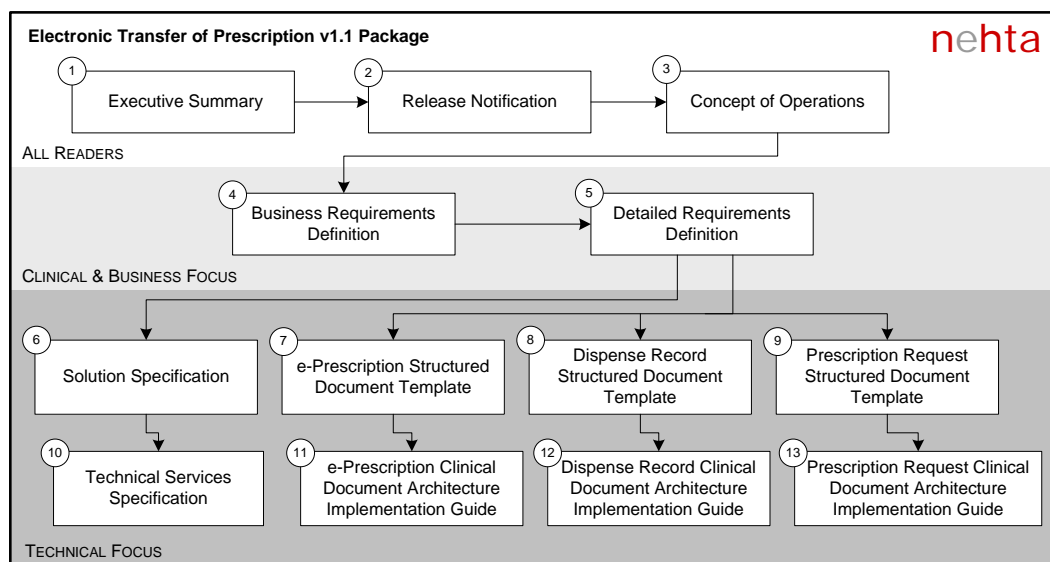
Figure 1   ETP - Document Map

Definitions, Acronyms and Abbreviations

For lists of definitions, acronyms and abbreviations, see the Definitions section at the end of the document on page 25.

References and Related Documents

For lists of referenced documents, see the References section at the end of the document on page 29.

1   eMM Overview

1.1   Background

NEHTA's Electronic Medications Management (eMM) program is responsible for developing e-health specifications that are designed to provide improved medication-related outcomes across the Australian health sector, and for supporting organisations in the implementation of those specifications. Electronic Transfer of Prescriptions (ETP) delivers the first of several capabilities within the eMM program.

This section outlines key drivers for eMM and the rationale for selecting ETP as the initial eMM service to be specified by NEHTA (section 1.5), based upon the strategic need to initiate and accelerate e-health engagement with the wider health sector.

1.2   Potential

Australia has a rapidly changing healthcare environment with increased consumer expectations, technological advances, economic pressures and socio-demographic changes. Healthcare today demands:

- A shift from institution-centred to patient-centred care

- Greater emphasis on continuity of care, supporting quality and safety, health promotion and maintenance

- More integrated healthcare, in which healthcare providers and consumers are unimpeded by organisational and administrative barriers.

Medications are crucial to healthcare delivery and significant health funding is allocated for their provision and administration. However, evidence shows that there is room for improving the management of medications in Australia:

- Almost 70,000 hospital admissions per year are associated with adverse drug events [IMS2002]

- 30% of unplanned hospital admissions in those over 75 years of age are associated with prescribing errors [ADE2001]

- Issues relating to adherence are commonplace, as identified by a study where 19% of individuals prescribed common antihypertensive medications failed to collect a second prescription [MJA2008]

- Poor adherence can have significant consequences, as in a recent study suggesting that individuals who reported poor adherence to prescribed medications for cardiovascular disease showed a 20–23% higher cardiovascular event rate [MJA2009].

Improving medication management in Australia is the objective of several national medicines policies, including Quality Use of Medicines (QUM) [QUM2002] and the APAC Guidelines [APAC2005]. eMM supports these policies and objectives primarily though improving the quality and availability of medications-related healthcare information.

1.3   Requirements

NEHTA has identified six capabilities required for comprehensive eMM, listed below. Only the first capability is delivered by ETP. The remaining capabilities are the subject of proposed future initiatives and may not necessarily be delivered in sequential order.

Exchange of electronic prescribing and dispensing messages
The generation and exchange of standardised, secure electronic documents that represent prescriptions and their associated dispensing records.

Adherence monitoring
Supports the timely notification of authorised healthcare providers and individuals when deviations from the expected sequence of dispensing events are detected. Adherence monitoring requires records of an individual's prescribed and dispensed (and/or supplied) medications, and will make use of the electronic prescribing and dispensing records described above. The full medico-legal effects of this capability need to be understood by participants and agreement secured prior to implementation.

Electronic Medication Profile
Supports the storage of medication reviews that are performed by healthcare providers. The documents produced by these medication reviews are referred to as Electronic Medication Profiles (eMP) and reflect existing paper-based current medication lists. These could be stored in Personally Controlled Electronic Health Record (PCEHR) repositories and/or sent directly between healthcare providers, or form part of electronic discharge summaries and referrals.

Medication History Lists
Supports the storage of a chronological record of an individual's prescribed and dispensed medications. Such records comprise a Medication History List (MHL) for each individual. These are either stored in dedicated MHL repositories or are stored with other types of individual electronic healthcare records in general purpose PCEHR repositories. In either case the repositories make MHLs available to the individual, their authorised representatives, and to the healthcare providers who require this information to service the individual and who are authorised to do so by the individual.

Clinical Decision Support

Many of the proposed benefits of eMM have been based on expectations that clinical decision support will improve safety and quality, with considerable savings estimated. It is intended that eMM will be supported by decision support to guide health professionals and consumers to make the best decisions about medicines use.

This capability will identify and prioritise new opportunities for decision support arising from the eMM processes and ensure specifications developed as part of the EMM program support future clinical decision support development.

Future Permissible Secondary Uses

This capability supports the access and use of de-identified data related to eMM processes for monitoring the safety, effectiveness and cost-effectiveness of medicines use. It includes:

1. Determination of permissible secondary uses and governance of the data;

2. Processes for collection, storage and analysis of more complete and more detailed consumer medications data than is currently possible

3. Use of this data to identify quality improvement opportunities.

These six capabilities reflect various stages in the evolution of eMM and are not to be interpreted as a roadmap for national implementation across all healthcare communities. Different communities will likely vary in their support of these capabilities depending on the rate at which they can implement changes to existing policies and practices and how rapidly the required e-health foundation services become available to them.

1.4   Benefits

eMM has the potential to achieve:

- Better clinical decision making, leading to safer and higher quality care, through timely access to selected health information about an individual

- Improved efficiency in the Australian healthcare sector through improvements to health information flows, a reduction in duplicate prescribing, and the provision of timely and accurate medication reviews

- Reduced reliance on the individual's recollection of their medication history

- Better support for a mobile population as they cross jurisdictional boundaries

- Improved consistency in (and therefore better consumer understanding and control of) the policies, processes and mechanisms that are put in place to ensure the privacy of electronic healthcare records

- More informed individuals who take an active role in the management of their own medications

- Improved support for future permissible secondary uses of data to deliver further public benefits, such as more targeted health initiatives, public health planning, research, education and disease detection.

Benefits expected to flow from the above improvements include:

- For Consumers

  – Improvements in the self-management of chronic illness

  – Improved health outcomes through better medication adherence and reduced adverse events due to medication use.

- For Clinicians

  – Increased knowledge of, and access to, medication histories for improved decision making

  – Improved dispensing and administration of the right drug to the right patient

  – Reduced cases of adverse drug events

  – Reduced time spent on the administration of repeat, lost and "owed" scripts.

- For Jurisdictions and the Healthcare Industry

  – Support for improvements in the efficiency of the health system by:

    - Reduced number of patients suffering from adverse drug reactions

    - Reduced demand for in-patient services and beds, caused by adverse drug events.

The benefits related specifically to ETP are listed at section 2.2.

1.5   Rationale for ETP

The National E-Health Strategy, endorsed by the Australian Health Ministers' Advisory Council (AHMAC), recommends the establishment of a "Prescriptions

Service" as the highest priority initiative within eMM [AHMC2008]. The strategy prioritises an electronic prescriptions service because it provides an early opportunity for connecting a significant group of healthcare providers at the national scale.

The 2010-11 Federal Budget identifies ETP as a key indicator of progress in e-Health calling for the completion of nationally agreed ETP specifications by June 30, 2011 [COMMAUS2010].

The ETP market is being established with commercial operations currently supporting the electronic transfer of prescription information. However these services are dependant upon paper prescriptions to provide the prescriber's signature. The emergence of these services now requires a nationally interoperable approach to ensure consumers are able to obtain their medications in a timely manner from the pharmacy of their choice. This will be achieved through the development and use of common prescription information, encryption and interface specifications.

The Fifth Community Pharmacy Agreement [DOHA2010] provides a payment to dispensers that dispense from electronic prescriptions generated and transmitted by software that complies with nationally agreed specifications and standards.

Connecting prescribing and dispensing systems (via intermediary repositories) using NEHTA ETP specifications will drive adoption of national standards for clinical information, terminology and secure communications in both prescribing and dispensing organisations. Consequently, this standards-based connectivity should deliver immediate benefits to healthcare providers and consumers, while also laying foundations for achieving the longer-term goals of the National E-Health Strategy.

2 ETP Operating Model

2.1 Scope

Figure 2 shows the scope of ETP in terms of the Medication Management Cycle defined by the Australian Pharmaceutical Advisory Council [APAC2005]. ETP primarily improves the flow of information between a Prescriber and one or more Dispensers that occurs for each "prescribing-dispensing process" (PDP).
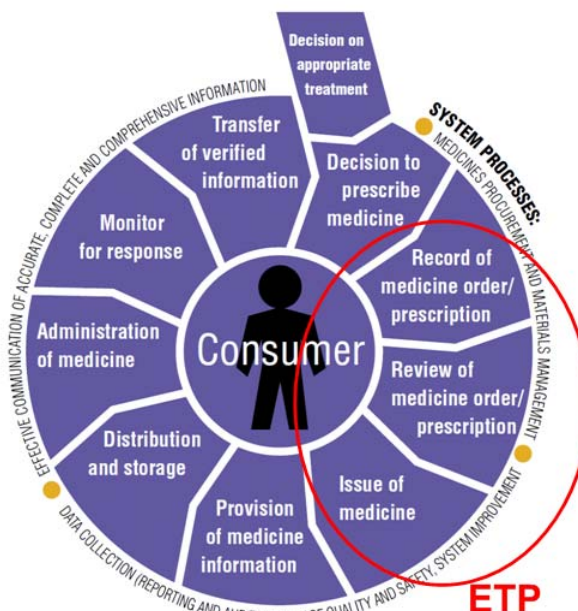
Figure 2   Scope of ETP in the Medication Management cycle[1]

Specifically, the full vision and scope of ETP includes:

- The transfer of a digitally-signed legal electronic prescription from a prescriber to a dispenser where the transfer has the potential to cross an organisational boundary (such as primary care, outpatient, and discharge scenarios) (Release 1.1)

- The ability for individuals to have their prescription dispensed at the community pharmacy of their choice where applicable (Release 1.1)

- The ability for healthcare organisations such as residential care facilities and private hospitals to direct prescriptions to their contracted pharmacy in instances where they have consent to obtain medication on the individual's behalf (Release 1.1)

- Provision for paperless processing of claims for Pharmaceutical Benefits Scheme (PBS) payments in relation to digitally-signed legal electronic prescriptions (not included in Release 1.1, part of future work - see note below)

The scope of ETP excludes:

- The transfer of prescriptions or medication orders solely within an organisational boundary (such as public hospital inpatient scenarios), although aspects of the specifications have potential for reuse in this context

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[1] This figure is adapted from [APAC2005] and is copyright Commonwealth of Australia. It is reproduced by permission.

- The provision of prescribed and dispensed records to an individual's Personally Controlled Electronic Health Record (PCEHR), although provision is made for this to be added in the future

- Changes to existing mechanisms for gaining prescriber approval for PBS Authority prescriptions

- Provision of PBS S100 medications where a prescription is not used

Note: Whilst provision is made for the paperless processing of claims for PBS payments, NEHTA continues to work with the Department of Health and Ageing and Medicare Australia to develop the detailed requirements and plans for this capability including consumer confirmation of supply on PBS medications.

2.2   Benefits of ETP

The benefits that are expected to result from improving prescribing-dispensing information flows are listed below. ETP functionality will be implemented incrementally and so not all benefits will be available immediately and will contribute to future broader eMM benefits. This ETP Release 1.1 supports authoritative and legal electronic prescriptions and the goal is for the majority of Australian prescriptions to be electronic.

- Direct benefits for Consumers

    – Improved health outcomes through lower dispensing error rates

    – Electronic prescriptions will allow more flexibility and convenience for the consumer (e.g. the existing need for consumers to re-visit their prescriber to have lost prescriptions re-issued can be avoided in many instances).

- Direct benefits for Prescribers

    – Prescribers can avoid hand-signing prescriptions through the use of electronic signatures

    – Prescribers can more easily generate prescriptions when they are remote from their local practice systems and records.

- Direct benefits for Dispensers

    – Reduced dispensing time due to the elimination of the need to re-key data that is contained on a prescription

    – Lower rates of transcription error leading to fewer dispensing and Pharmaceutical Benefits Scheme (PBS) claiming errors

    – Reduced time spent on the administration of lost and "owed" scripts.

- Direct benefits for Pharmaceutical Benefits Scheme Administrators

    – The electronic creation, transmission and storage of prescriptions provides the potential to significantly improve compliance checking and other administrative processes

    – Directly linking prescriptions and dispensing records leads to more complete and higher quality data

    – Making all prescription records available (regardless of co-payment or safety net limits), leading to more complete and better quality data.

- Indirect benefits through improved interoperability of clinical information systems (CIS)

    – Establishing standards for prescribing and dispensing documents and messages drives a higher level of interoperability. This, in

turn, supports more advanced eMM capabilities and leads indirectly to more appropriate and safer usage of medications (ETP plus additional eMM capabilities).

2.3   Electronic Prescriptions

ETP Release 1.1 is built around the concept of an electronic prescription. Electronic prescriptions as specified in ETP are electronic clinical documents that contain all information relating to a single order to supply a single medication to an individual. Electronic prescriptions are digitally signed by the prescriber and are sent to a prescription exchange from where they can be retrieved by an authorised pharmacist. Each electronic prescription is identified by its own unique and secret document access key (DAK) which is created at the time of prescribing and provided to the individual or their agent. The individual or their agent grants access to the electronic prescription by providing this secret key to the pharmacist.

2.4   Phased implementation

The ETP Release 1.1 defines the services and requirements to support a fully electronic process for the transfer of prescription and dispensed medication information (including repeat authorisations). It is acknowledged that incremental implementation will be required, both in terms of functionality and adoption within various healthcare communities.

ETP Release 1.1 is designed to support a paperless process where a prescription crosses organisational boundaries in primary care, hospital and residential care settings across Australia. However, the flexible design is likely to be suited to implementation in other settings, including where a prescription is issued and dispensed within the same healthcare organisation.

In order to support national requirements across settings with varying degrees and stages of information technology adoption, NEHTA has identified three possible ETP implementation levels. Different healthcare communities may adopt ETP at different implementation levels and at different times. For example, primary care and community pharmacy might commence adoption at ETP Level 1 and then progressively move through Levels 2 and 3, whereas residential care communities may be able to adopt Level 2 much earlier.

- **ETP Level 1 - Electronic copies of paper prescriptions** - This level describes the use of software incorporating the ETP specifications to transfer an electronic copy of a paper prescription, in a nationally consistent manner. This allows software vendors and healthcare providers to gain experience using the ETP process while still retaining the paper prescription as the authoritative document in order to mitigate clinical risk.

  To support Level 1 adoption, it is necessary to print a NEHTA-specified DAK barcode for each item on the paper prescription. Prescribing system vendors and their customers will need to agree with Medicare Australia on the appropriate location of these barcodes. NEHTA plans additional consultation to determine the level of guidance that may be appropriate in this respect.

- **ETP Level 2 - Electronic prescriptions** - This level adds an approved form of electronic prescriber's signature to make the electronic prescription authoritative and legal. In settings where the individual consents to a healthcare facility obtaining supply on their behalf (e.g. hospital inpatient and residential care settings), the facility sends an electronic notification of the prescription to the contracted pharmacy. In settings where the individual retains the choice of pharmacy (e.g. discharge, outpatient and primary care settings), the paper prescription is replaced with a printed prescription notification that contains information for the individual and a document access key

which the individual or their agent gives to the pharmacist to grant access to the electronic prescription. This prescription notification is not considered a legal prescription.

To support Level 2 adoption, NEHTA is working with Commonwealth, state and territory governments in relation to approval of the form of electronic signature. NEHTA will also work closely with peak professional bodies to assist them to develop appropriate practice guidelines in relation to the safe use of electronic prescriptions, particularly in situations of system non-availability. Adoption of Level 2 in community settings requires a high adoption rate by community pharmacies coupled with transitional arrangements to ensure that when an individual presents a prescription notification at any pharmacy, they are able to obtain their medication.

Level 2 adoption also introduces the opportunity for Medicare Australia to support paperless PBS claiming by community pharmacies. NEHTA continues to work with DOHA and Medicare Australia to develop the detailed requirements and plans for paperless PBS claiming from electronic prescriptions with digital signatures.

- **ETP Level 3 - Electronic prescription notifications for individuals** - This level adds the ability for prescribers to give individuals the choice to receive their prescription notification on paper or electronically.

To support Level 3 adoption, NEHTA will conduct additional consultation to determine the appetite for electronic prescription notifications for individuals and the appropriate level of national standardisation to ensure that both individuals and community pharmacies have the ability to handle electronic notifications.

2.4.1   Relationship to paper prescriptions and prescribing software

A significant percentage of paper prescriptions contain orders for more than one medication. Where this is the case, prescribing systems can continue to create paper prescriptions with multiple items, but generate separate electronic prescription documents for each individual item. Where this occurs, each individual document/item will have its own unique document access key.

When digital prescriber signatures are enabled, and the electronic document becomes the authoritative prescription, prescribing software can retain any existing user experience for prescribing multiple items in a single operation, and generate separate electronic prescriptions for each item.

2.5   ETP Conceptual Architecture
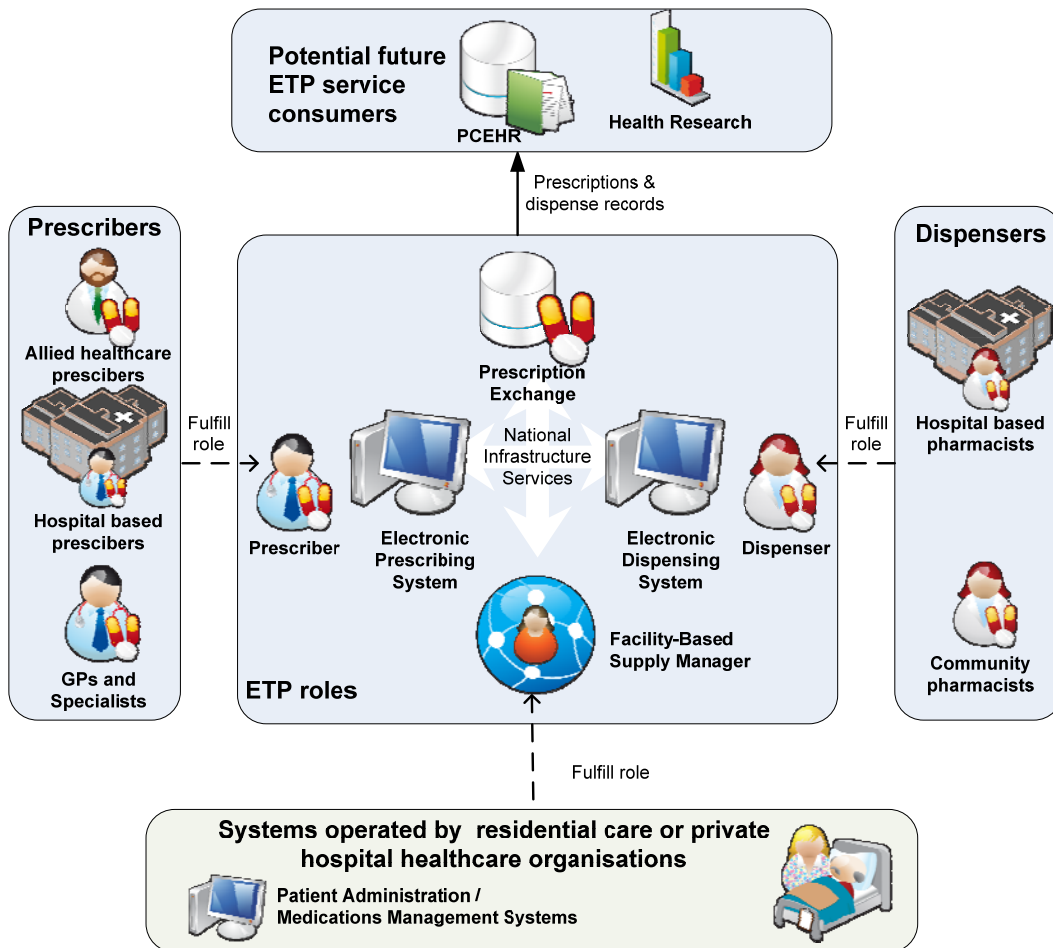
The ETP conceptual architecture is defined in terms of:

- The roles that are played by the various participants in ETP (section 2.5.1),

- The services offered by those roles (section 2.5.2), and

- A high level view of the processes supported by those services (section 2.5.3).

2.5.1   ETP Roles and Participants

The roles played by the various participants in ETP are shown in Figure 3.

Figure 3   ETP roles and participants

The main roles played by the various participants in ETP are:

- **Prescription Exchange (PE)**
  One or more Prescription Exchanges will be established and, by implementing the Prescription Exchange (PE) specifications, will be jointly interoperable. A PE has the following capabilities:

  – It provides an indirect communication path between the Prescriber and the Dispenser(s) in which the Dispenser(s) can be selected by the individual (or their agent) at any time after the prescription is created

  – It provides a single point of control for each prescription that allows the Prescriber to cancel a prescription

  – It manages the security of the records that it stores by requiring a "document access key" (DAK) to be provided for any access:

    - A document access key is used to identify and secure a single prescription which contains a single prescribed item

    - Each document access key provides access to the Prescription exchange (PE) records associated with one prescription, comprising one prescription and its associated dispense records (including repeat authorisations)

    - A document access key is simply a secret string of random text characters, plus the identity of the PE that contains the document

    - NEHTA will specify a standard barcode format for the document access key, and the barcode (plus text string) will be printed on a paper notification given to the individual, or in the future, through other electronic means.

- **Electronic Prescribing Systems (EPS)**
  An EPS is a system with the capability to interact with a PE to submit, cancel and retrieve prescriptions. This role may be filled by a Clinical Information System (CIS) with prescribing capabilities operated by a prescriber.

- **Electronic Dispensing Systems (EDS)**
  An EDS is a system with the capability to interact with a PE to retrieve prescriptions and their associated Dispense Records (including repeat authorisations) prior to dispensing, to submit dispense records after dispensing and, if necessary, to terminate or reverse a previously initiated dispensing process. This role may be filled by a Clinical Information System (CIS) with dispensing capabilities operated by a dispenser.

- **Facility-Based Supply Manager**
  A Facility-Based Supply Manager is a software agent operated by an organisation acting on behalf of an individual. It receives notifications that indicate when a new electronic prescription for the individual is available from a Prescription Exchange. This role may be filled by systems operated by a healthcare provider organisation (e.g. aged care facilities, Dispenser organisations, private hospitals, etc.) with the consent of the individual and is required to allow such organisations to obtain supply of medications on the individual's behalf.

- **Last Supply Notification Agent (not shown):**
  A Last Supply Notification Agent is a software agent that can receive notifications from EDS' that the last supply of a prescription has been dispensed. This role may be filled by systems operated on behalf of an individual with the consent of the individual. This could be a CIS operated by the individual's usual doctor, or it could be the individual's PCEHR.

2.5.2   ETP and related services

2.5.2.1   ETP Services

Figure 4 shows the ETP services and their use by ETP participants.
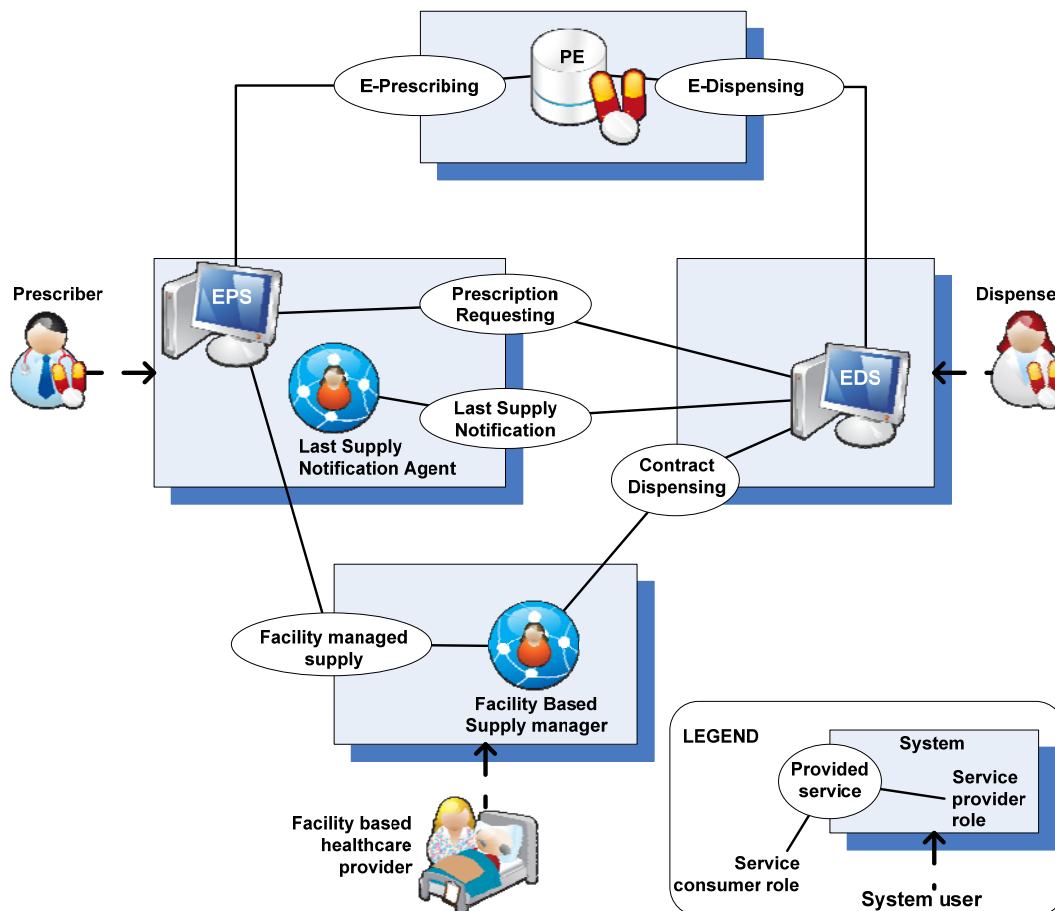
Figure 4   ETP Services

The ETP services are:

- **E-Prescribing Service:** Allows a Prescriber to participate in the ETP solution and thereby make their prescriptions available within a Prescription Exchange for dispensing. This service provides 3 service functions:

    – Prescribe: submit an electronic prescription document

    – Cancel Prescription: block Dispensers from accessing a previously submitted electronic prescription document

    – Retrieve Prescription: Get a copy of a previously submitted electronic prescription document.

- **E-Dispensing Service:** Allows a Dispenser to participate in the ETP solution and thereby download electronic prescriptions (and prior dispense records for a prescription) from a Prescription Exchange and subsequently upload resulting electronic dispense records linked to the prescriptions. This service provides four service functions:

    – Initiate Dispense Process: Initiate a dispensing process and retrieve the documents required for dispensing.

    – Terminate Dispense Process: Record the conclusion of a dispensing process that was abandoned and did not result in the dispensing of a medication.

- Finalise Dispense Process: Record the conclusion of a dispensing process that resulted in the dispensing of a medication, and provide an electronic dispense record.

- Reverse Dispense Process: Reverse the effect of a previously completed dispensing process, withdrawing a previously submitted electronic dispense record.

- Cancel Prescription: block Dispensers from accessing a previously submitted electronic prescription document. This service allows a Dispenser to cancel a prescription on behalf of a Prescriber and in consultation with a Prescriber. The scope and use of this service is to be defined with prescriber and dispenser professional bodies.

- **Prescription Requesting Service:** Allows a Dispenser to request that an identified Prescriber create an electronic prescription (i.e. an "owing prescription") that confirms an instruction previously given by that Prescriber to that Dispenser (in a form other than a prescription). Also provides for the Prescriber to respond to these requests by providing the Dispenser with an electronic prescription notification. This service provides two service functions:

  - Deliver Prescription Request: Deliver to an identified Prescriber a request to create an electronic prescription corresponding to a previous issued Prescriber instruction.

  - Deliver Prescription Notification: Deliver to an identified Dispenser Organisation an electronic prescription notification in response to a prior request received via the Prescription Requesting Service.

- **Facility Managed Supply Service**: Allows a Prescriber to notify a healthcare facility (via their Facility-Based Supply Manager when a new prescription has been sent to a Prescription Exchange for a Prescription Subject who is resident in that facility This service provides one function:

  - Deliver Prescription Notification: Deliver to an identified Facility-Based Supply Manager an electronic notification that indicates the successful invocation of the Prescribe service function of the E-Prescribing service.

- **Last Supply Notification Service**: Allows a Dispenser to notify a Prescriber or individual (via their Last Supply Notification Agent) of the last supply of a medication. This service provides one function:

  - Deliver Last Supply Notification: Deliver to an identified Last Supply Notification Agent an electronic notification that indicates the successful invocation of the Finalise Dispense Process service function of the E-Dispensing service for the last dispense of a prescription.

- **Contract Dispensing Service**: Allows a healthcare facility (via their Prescription Forwarding Agent) to send an electronic prescription notification to a Contracted Pharmacy. This will enable a Dispenser representing the Contracted Pharmacy to subsequently dispense and supply medications. This service provides one function:

  - Deliver Prescription Notification: Deliver to an identified Contracted Pharmacy a notification that indicates the successful invocation of the Prescribe service function of the E-Prescribing service.

2.5.2.2   National Infrastructure Services

The participants in ETP services will make use of National Infrastructure Services (NIS):

- Endpoint Location Service (ELS)

An ETP service participant will use the ELS to find the communication endpoint addresses of another organisation with which they wish to communicate.

- Healthcare Identifier (HI) Services

    ETP service participants will use the HI services to find the necessary healthcare identifiers given the names and other identifying attributes of individuals, healthcare individuals and healthcare organisations.

- National Authentication Service for Health (NASH) Directory Service

    The NASH Directory Service is used to get public key certificates and certificate revocation lists in order to support secure communications and to validate digital signatures.

- National Clinical Terminology & Information Service (NCTIS)

    ETP service participants will adopt the Australian Medicines Terminology (AMT) and Systematised Nomenclature of Medicine - Clinical Terms (SNOMED-CT) as the clinical terminology for use in ETP services. This will provide the mechanism for consistent and interoperable data exchange.

2.5.2.3   Future national services

- **Support for future uses of prescription information such as PCEHR and permissible secondary uses.**

    One of the key benefits of the ETP services is that their widespread adoption will lead to significant improvements in the availability, completeness and accuracy of comprehensive medication records. Due to privacy requirements, the mechanism to achieve this is necessarily indirect and is based on the individual providing consent, while also relying on the adoption of national e-Health standards.

    Once the majority of nationally deployed EDSs and EPSs are capable of creating and consuming standardised electronic clinical documents for the purposes of prescribing and dispensing, these documents could be available to support both PCEHRs and approves secondary uses, with the individual's consent.

    The ETP specifications do not assign responsibility for implementing longitudinal individual medication records within Prescription Exchanges; rather the ETP solution components are intended to be integrated with external systems that are better suited to such roles. The ETP solution supports this integration by allowing prescribers and dispensers to supply the electronic prescription/dispense record directly to an approved external system (e.g. a PCEHR). That is, they send a copy to the PE and another copy to the external system.

2.5.3   ETP Processes

This section shows examples of the primary use of each of the ETP service functions described in section 2.5.2.

2.5.3.1   Electronic Prescribing & Dispensing

The Prescriber initiates the process by indicating that a new prescription is to be transferred via the Prescription Exchange. Paper prescriptions will continue to be supported and used, for example, when the prescriber does not have access to Prescription Exchange Services.

For an electronic prescription, the Prescriber gives a Prescription Notification that includes the document access key (DAK) to the individual. This notification can be paper with a printed barcode, or in the future can be electronic depending upon the individual's preference. It will generally contain the same information as the electronic prescription for the benefit of the individual.

The individual can pass on the Prescription Notification to another person whom they wish to act as their agent in obtaining the medication.
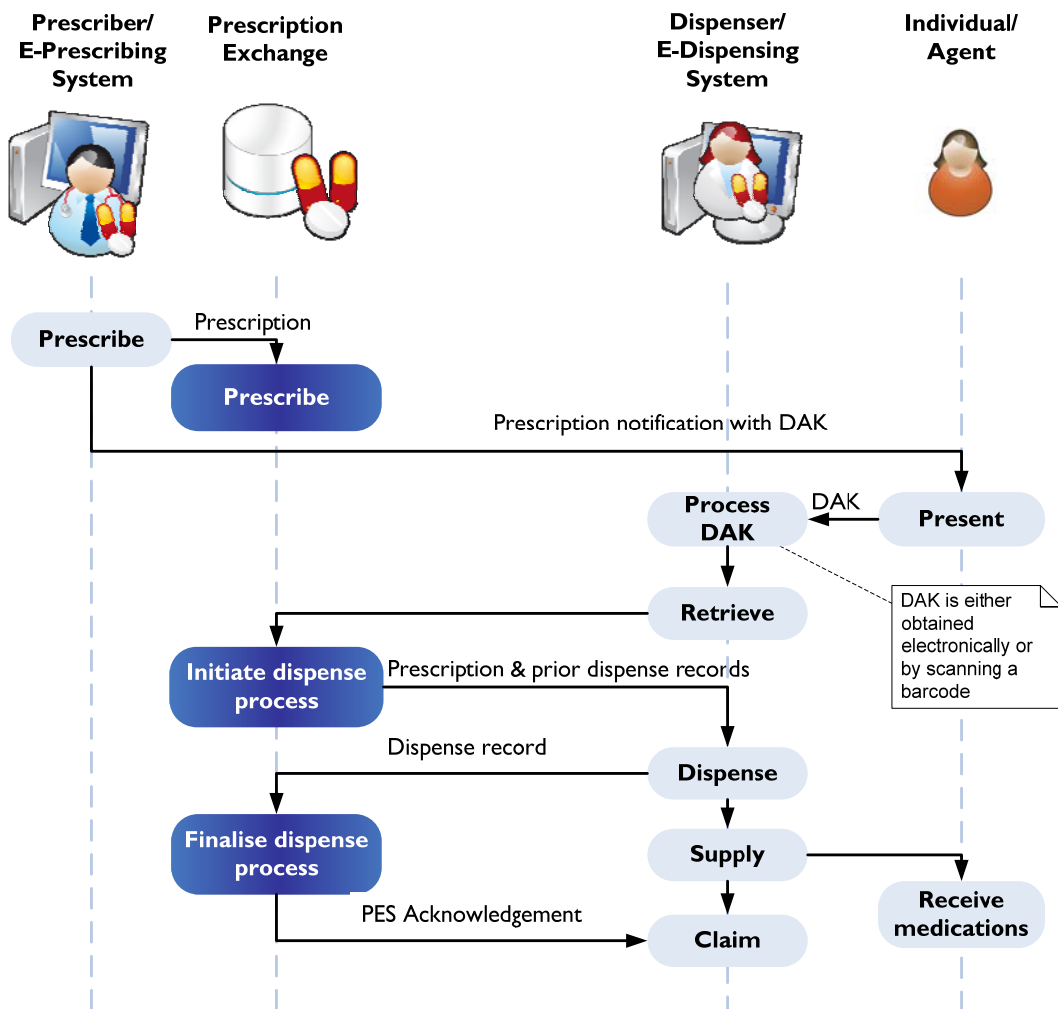
This process is shown in Figure 5

Figure 5   Electronic Prescribing & Dispensing

2.5.3.2 Facility-managed supply

Where an individual has given consent to an organisation such as a private hospital or residential care facility to obtain medication on their behalf, electronic agents may be used to deliver the prescription notification on the individual's behalf.

Figure 6 shows a scenario that may be appropriate where the individual resides in a residential care facility (RCF). The Prescriber initiates the process in the same manner as described above, but sends an electronic Prescription Notification to the Facility-Based Supply Manager. This Prescription Notification contains the individual's Healthcare Identifier and the DAK. The RCF then routes the notification to their contracted pharmacy.
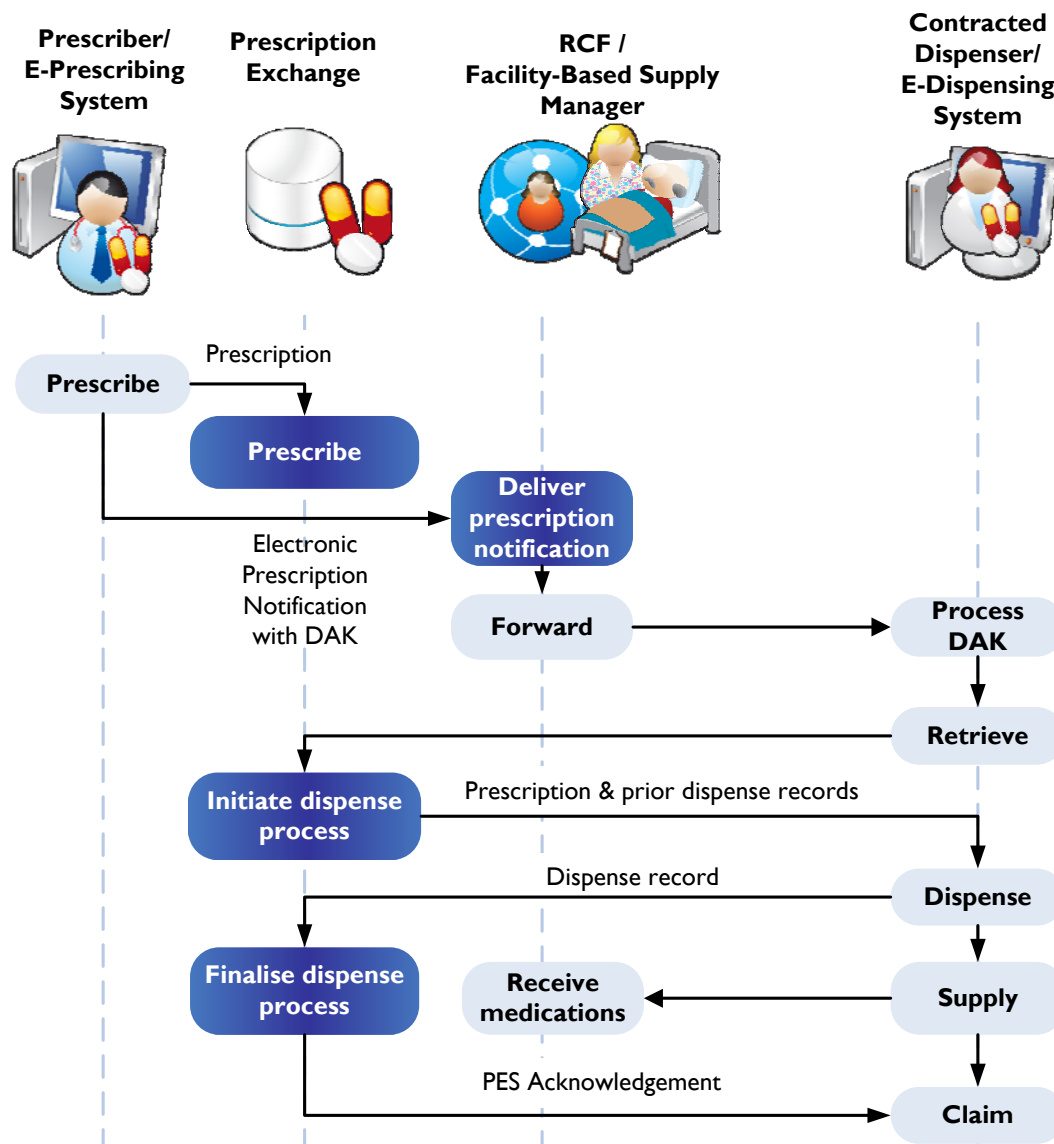
**Figure 6   Facility-managed supply**

Operation of a Facility-Based Supply Manager service is necessarily constrained by current and future confidentiality and privacy protection practices. That is to say, the individual's consent will generally be required in order to provide the service on the individual's behalf, and providers of the service are responsible for obtaining and recording this consent.

2.5.3.3   Dispensing on Prescriber's Instructions

There are instances where Dispensers dispense according to a Prescriber's instruction prior to recept of a legal prescription. These are referred to as "script owing" scenarios. ETP supports direct electronic communications between Prescribers and Dispensers that allow dispensing to occur before an electronic prescription has been made available. This is based on a Prescription Request being sent from the Dispenser to the Prescriber and a Prescription Notification being sent back to the Dispenser. This scenario is shown in Figure 7.
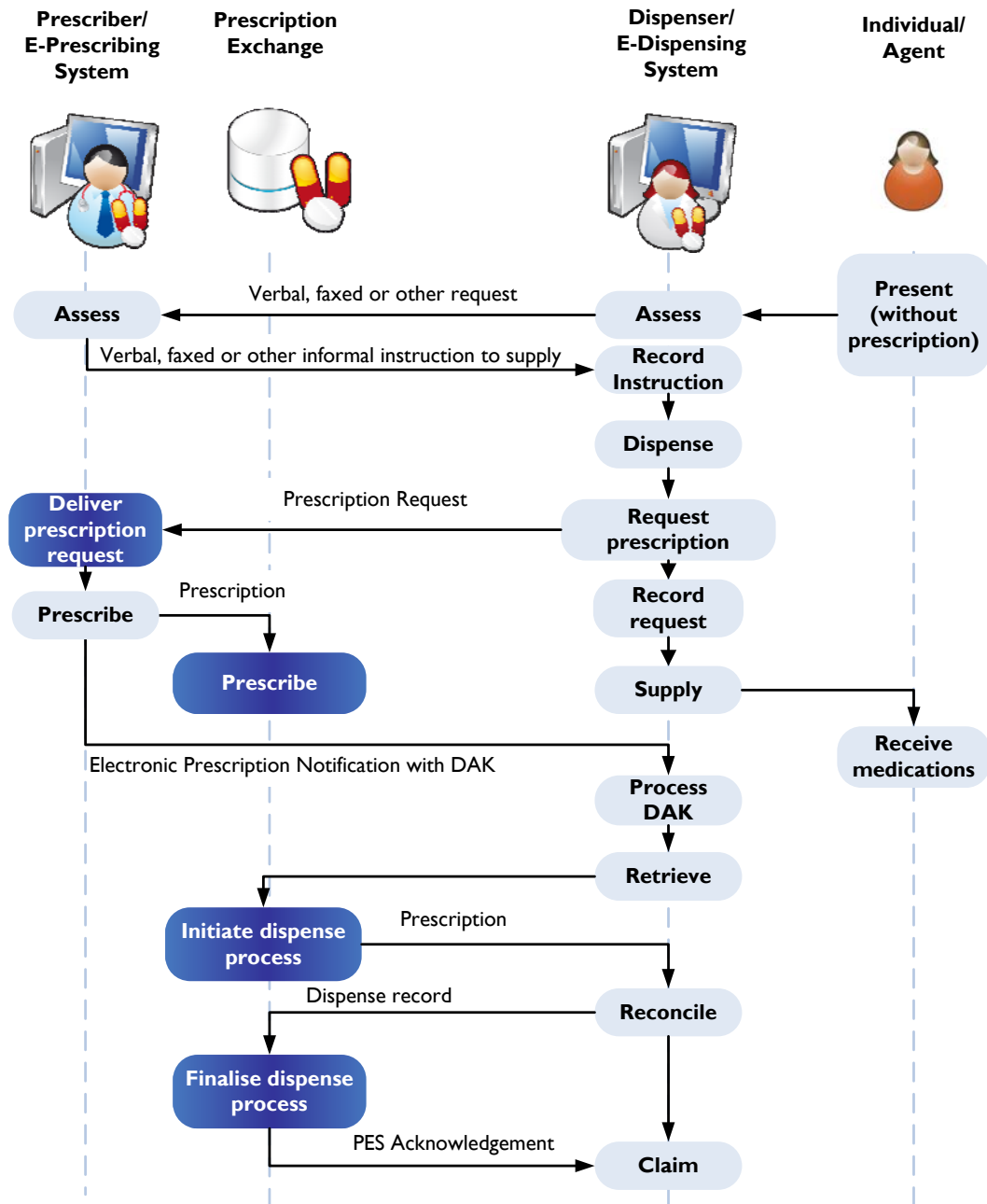
Figure 7   Dispensing on prescriber instructions

Note that although the dispense is recorded locally by the E-Dispensing System, at the time of dispense, the Prescrition Exchange dispensing services are not invoked until the prescription is received and reconciled.

2.5.3.4 Cancelling an electronic Prescription

The ETP service will support the ability to cancel any remaining supplies/repeats for a prescription. Cancellation can occur any time prior to the prescription expiry. An amendment is implemented as a cancellation followed by a submission of a new prescription. A prescription can be cancelled by any provider within the same organisation as the original prescriber, using the document access key.

The prescriber always contacts the individual to advise them not take any more of the medication and that no additional repeats are available. Any attempts to perform further dispensing will be rejected by the Prescription Exchange.
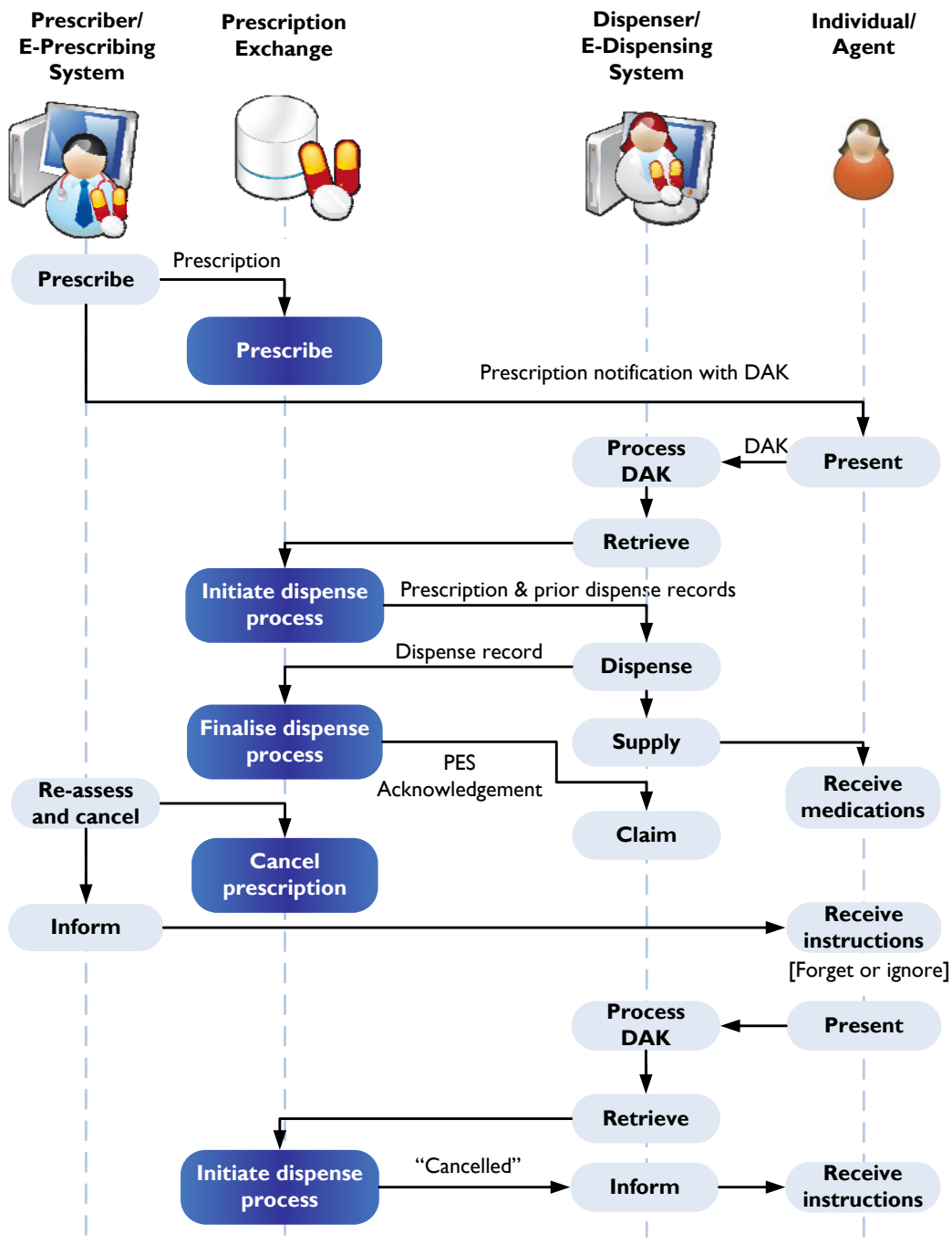
Figure 8   Cancelling an electronic Prescription

2.5.3.5   Reversing a dispense process

If the dispensing process was completed and the medication not supplied, the Dispenser will reverse the dispense action. This uses the "Reverse Dispense Process" system function as shown in Figure 9.

Figure 9   Reverse Dispense Process

2.5.3.6   Abandoning a dispense process

If the dispenser commences a dispense process, but is unable to complete it, they can abandon the dispense process. This uses the "Terminate Dispense Process" service function shown in Figure 10.
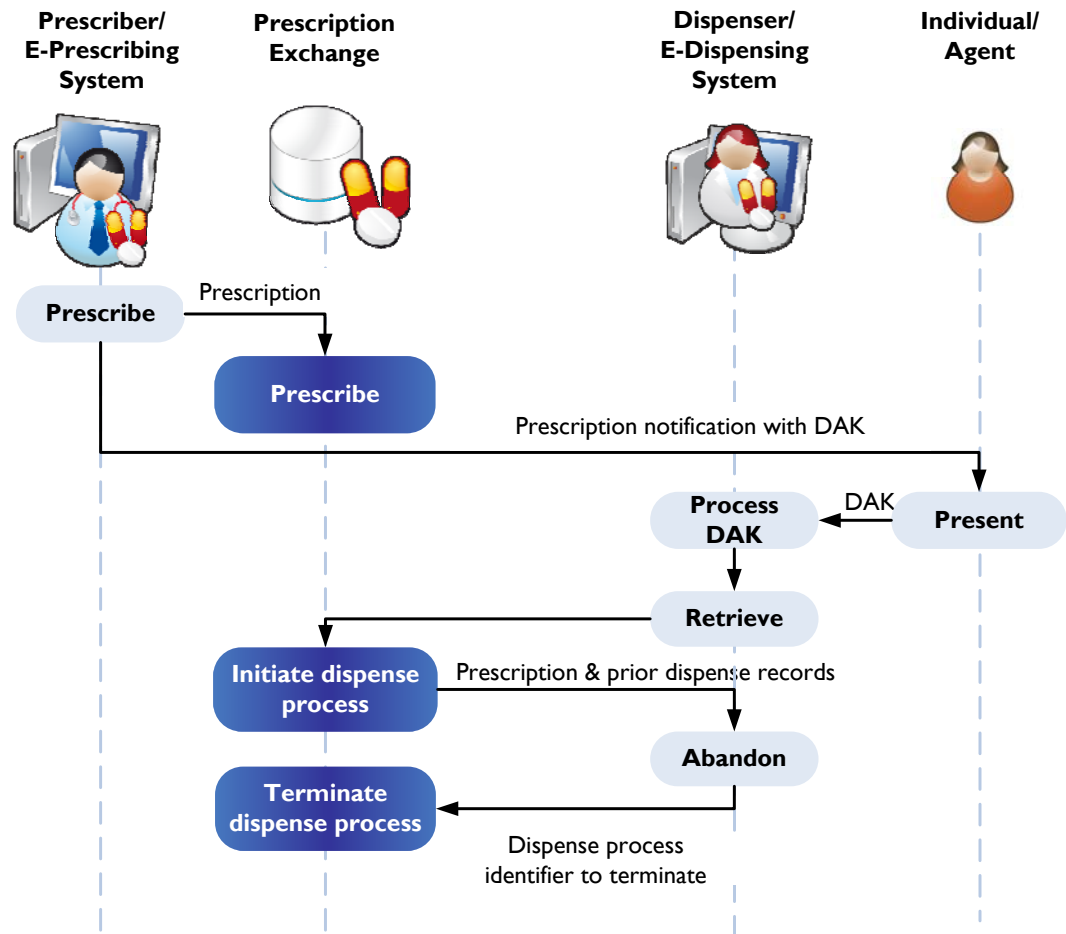
Figure 10   Terminate Dispense Process

2.5.4 Service resilience

The ETP services support prescribing, dispensing and supply of medication even when infrastructure failures prevent Prescribers or Dispensers from being able to contact a Prescription Exchange.

Figure 11 shows the operation of the technical services to allow a prescriber to prescribe when access to a Prescription Exchange is temporarily unavailable.
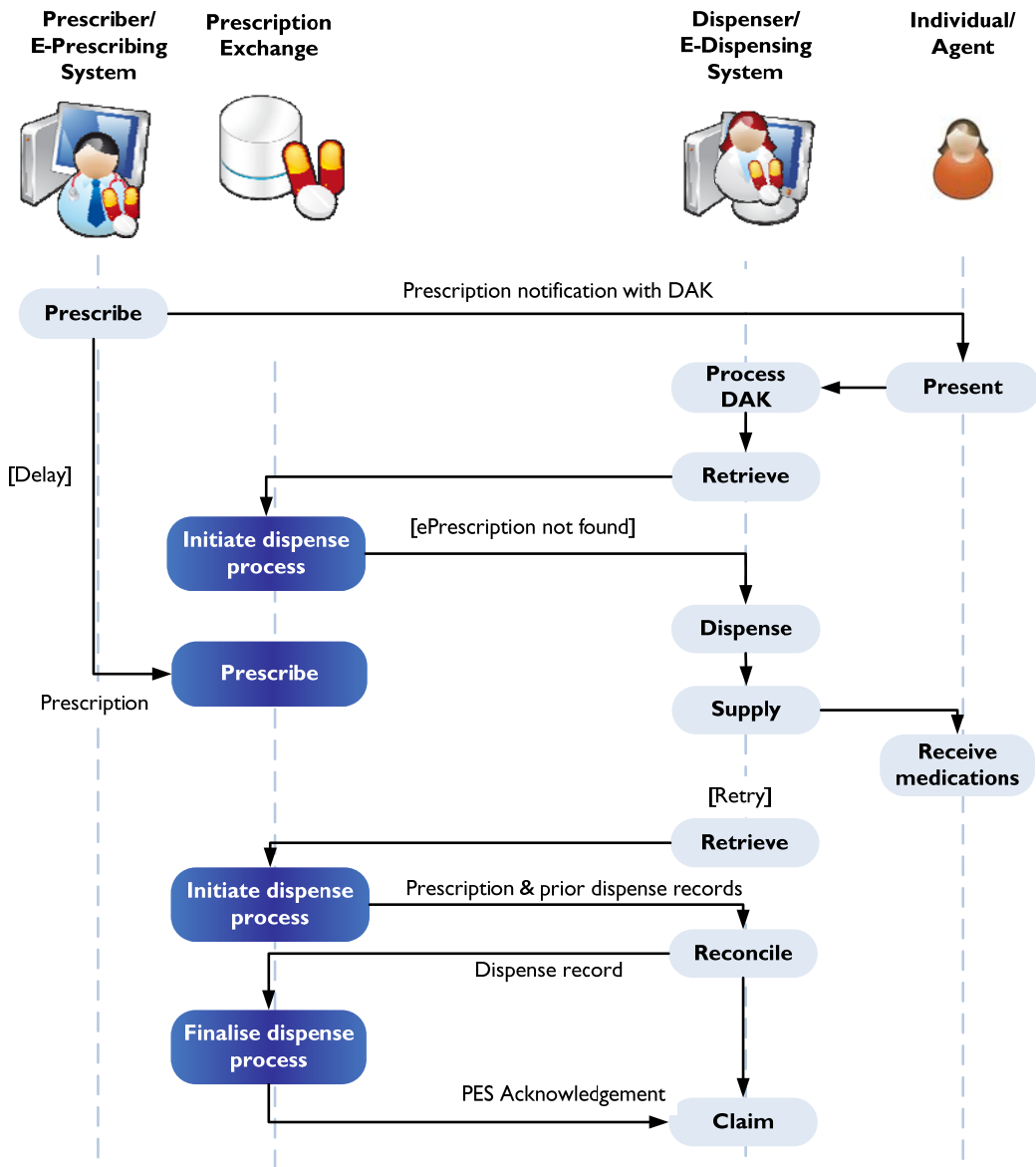
Figure 11   Prescribe without access to Prescription Exchange

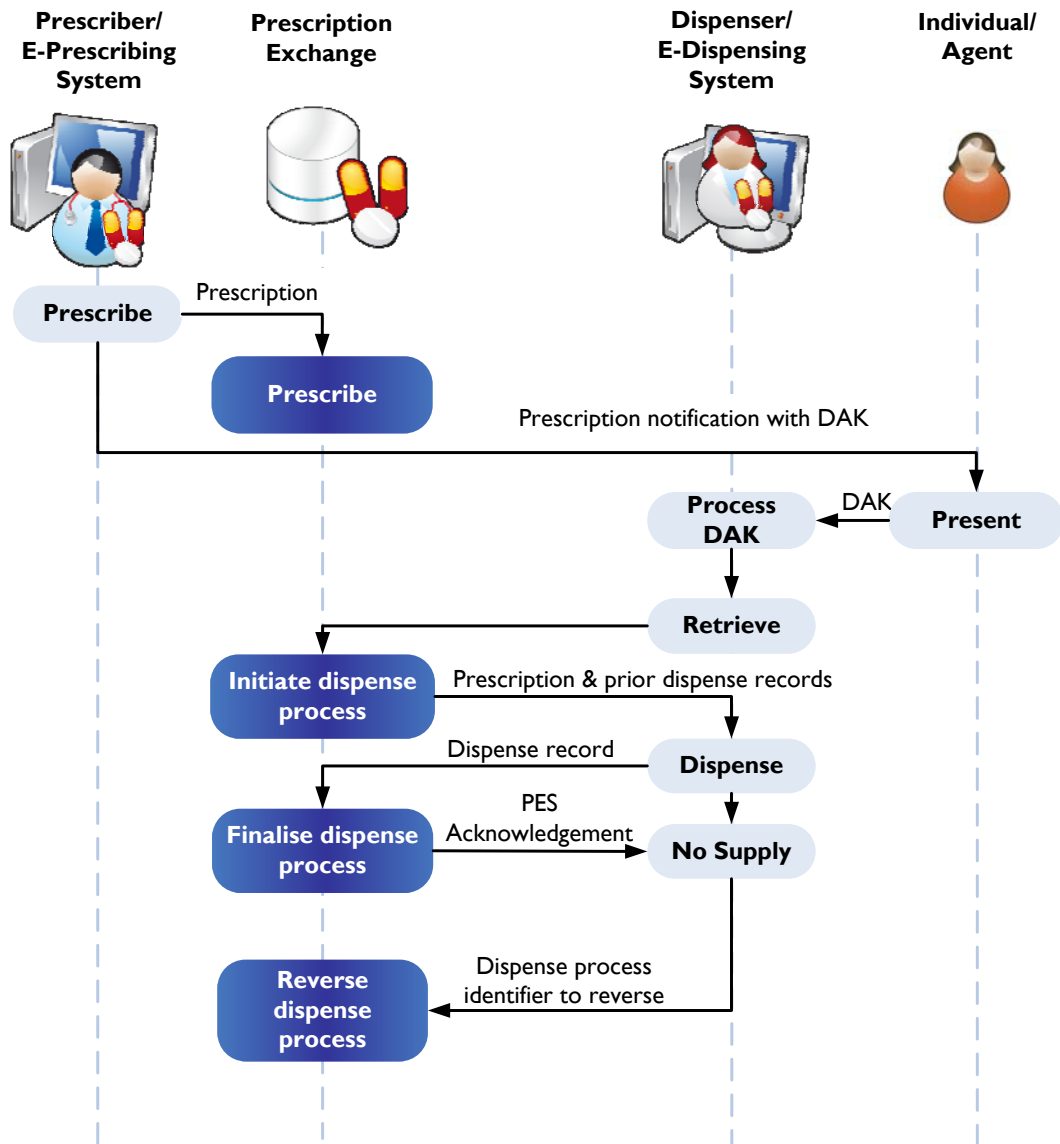Figure 12 shows the operation of the technical services to allow a dispenser to dispense and supply when access to a Prescription Exchange is temporarily unavailable.

Note that this scenario requires:

- That the printed Prescription Notification given to the Individual contains sufficient information to allow a dispenser to dispense and supply the medication

- That the dispenser has an offline capability to verify the validity of the Prescription Notification

- That appropriate policy and/or practices are in place to support the dispensing from the Prescription Notification

NEHTA continues to work with governments and industry to determine the appropriate policy and/or practices necessary to support this type of service resilience including mechanisms for offline verification of the validity of the prescription.

Figure 12   Dispense without access to Prescription Exchange

3   Enabling the Operating Model

3.1   Governance and Policy

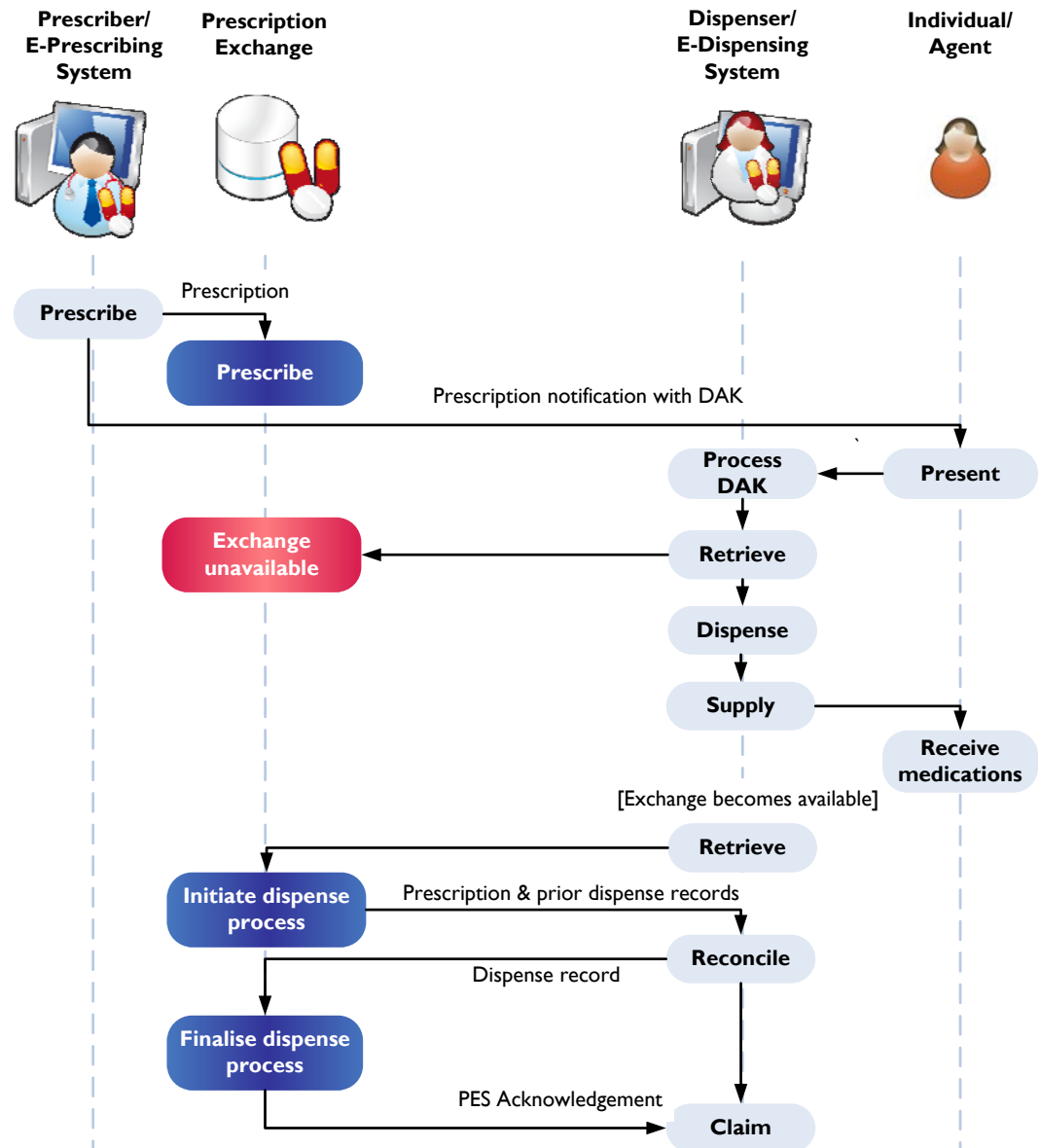NEHTA will continue working with governments and industry to develop governance arrangements for eMM services, including ETP, to ensure that interoperability, privacy and patient safety are reliably and effectively maintained and that associated risks are managed.

ETP Release 1.1 makes the significant transition to a process that does not require a paper prescription and introduces the use of electronic signatures for prescribers. The legal framework to support this electronic process is broadly in place with Commonwealth legislation supporting electronic prescribing and dispensing of PBS medications through changes to the National Health (Pharmaceutical Benefits) Amendment Regulations 2006 (the regulatory amendments became effective on 1 March 2007.) Most State and Territory legislation aligns with Commonwealth amendments.

The implementation of electronic signatures for prescribers will require each jurisdiction to approve electronic prescribing and dispensing in their respective state or territory.

Of most importance is the need for policy change at the Commonwealth level to achieve the full vision and scope of ETP. This will have particular significance to the process under which dispensed medications are authorised to be paid for under the PBS utilising electronic signatures and independent of paper. The changes required will have follow-on effects to the operations of Medicare Australia, in the areas of PBS claiming and compliance checking. NEHTA is currently working with the Department of Health and Ageing and Medicare Australia to specify and enable these changes.

3.2   Privacy

Australia's information privacy legislation gives individuals some control over the collection and handling of their personal information. It attempts to strike a balance between competing interests; that is, between the individual's right to privacy and the benefits of the free flow of information. Finding an appropriate balance between these interests is fundamental to the development of e-Health in Australia.

NEHTA has developed an overarching privacy management framework which ensures that NEHTA initiatives comply with information privacy protection laws while enabling appropriate clinical safety and convenience outcomes. NEHTA packages are built for use across Australia. However, information privacy protection in Australia is legislated under various Commonwealth and State/Territory statutes which overlap but are not identical. As a result, NEHTA's approach with regard to the ETP Package has been by reference to principles that commonly apply under Commonwealth and State/Territory statutes. In order to do this, NEHTA has identified a set of principles that are common to the Commonwealth and State/Territory statutes. These common principles are based on the National Privacy Principles (NPPs) set out under the Privacy Act 1988 (Cth) and incorporate requirements derived from the laws and administrative instructions of other jurisdictions. These common principles are set out in the Appendix A.

NEHTA recommends that healthcare providers (and other users of the ETP package) continue to exercise diligence and obtain independent legal advice to ensure that their operations meet the requirements specific to their jurisdiction.

3.3   Security Controls

The eMM services will implement a range of security controls to ensure that only appropriately authorised users are permitted to access the services. All access to the service by an external healthcare organisation will require the user to be authenticated with NASH credentials and will be undertaken on appropriately secure/encrypted links.

All access to the ETP repositories will be recorded within an audit log. This log will also enable an audit capability to monitor use of the ETP services.

4   Implementation

4.1   Adoption Model

The eMM services will be implemented incrementally; different jurisdictions and healthcare communities will be able to proceed at different rates depending on their particular drivers and constraints. The overall approach to implementation will see a mixture of:

- Initial deployments in which early adopters will collaborate with NEHTA to validate the eMM solutions and designs

- Broad implementation programs that may be supported by national funding and professional standards

- Vendor initiatives to achieve compliance with NEHTA specifications and designs

- An evaluation framework to measure the success of the project and identify lessons learned that can provide insight for future activities.

4.2   Change Management

In order to support the adoption of the eMM services, a mix of implementation support approaches will be provided by NEHTA. As lessons are learned from implementation in the field, it is expected that the mix will evolve to meet the changing environment. As suggested by the National E-Health Strategy, the initial approaches to supporting adoption of e-Health (in general) and eMM (in particular), may include:

- Creation of stakeholder reference forums and working groups to ensure that a wide range of stakeholders are engaged and represented in the ongoing evolution of the eMM services

- Support for software vendors to successfully and effectively integrate ETP into their product offerings

- National awareness campaign to educate individuals, providers and vendors about the eMM services

- Financial incentives programs to incentivise providers to adopt systems certified to support the eMM services

- Links to national healthcare provider accreditation programs to encourage providers to adopt certified systems

- Support for healthcare organisations regarding changing business processes and practices

- Vocational training for providers and their administrative support staff who need to use the eMM services.

Definitions

This section explains the specialised terminology used in this document.

Shortened Terms

This table lists abbreviations and acronyms in alphabetical order.

Term	Description
AMT	Australian Medicines Terminology
CIS	Clinical Information System
DAK	Document Access Key
DoHA	Department of Health and Ageing
DR	Dispense Record
EDS	Electronic Dispensing System
EHR	Electronic Health Record
ELS	Endpoint Location Service
eMM	Electronic Medications Management
EPS	Electronic Prescribing System
ETP	Electronic Transfer of Prescription
MHL	Medications History List
NASH	National Authentication Service for Health
NCTIS	National Clinical Terminology & Information Service
NEHTA	National E-Health Transition Authority
NPC	National Product Catalogue
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record
PDP	Prescribing-Dispensing Process
PE	Prescription Exchange
PES	Prescription Exchange Service
PES-DR or DR	Prescription Exchange Service - Dispense Record
PHR	Personal Health Record
RCF	Residential Care Facility
QUM	Quality Use of Medicines
SNOMED CT	Systemised Nomenclature of Medicine, Clinical Terms

Glossary

This table lists specialised terminology in alphabetical order.

Term	Description
Clinical Information System	Information Computer Technology used to store, manage and communicate healthcare information for healthcare providers and individuals, including the transfer of that information between information systems.
Document Access Key	An alpha-numeric string that is used to identify and protect the set of clinical documents (Prescription and Dispense Records) for one prescription.
Australian Medicines Terminology	NEHTA specifications that standardise the identification, naming, and describing of medicine information. The Australian Medicines Terminology (AMT) delivers standardised identification of brand (trade) products and equivalent generic medicines along with associated components that are supported through standard naming conventions that accurately describe medications.
Dispense Record	Electronic record generated by a pharmacy information system that records medications dispensed or deferred.
Document Access Key	An alpha-numeric string that is used to identify and protect the set of clinical documents (Prescription and Dispense Records) for one prescription.
e-Health	Use of information and communication technology to enable better healthcare outcomes.
Electronic Dispense Document	Electronic record generated by a pharmacy information system that records medications dispensed or deferred.
Electronic Dispensing System	A component of a clinical information system used to dispense medications.
Electronic Medications Management	Use of electronic systems to facilitate and enhance the communication of a prescription or medication order, aiding the choice, administration and supply of a medication through knowledge and decision support, and providing a robust audit trail for the entire medications use process.
Electronic Prescribing System	A component of a clinical information system used to prescribe medications.
e-Prescribing	Electronic prescribing is the process by which a prescription is electronically generated by a prescriber, authenticated with an electronic signature, securely transmitted to a Prescription Exchange Service for dispensing and supply, downloaded by a supplier, seamlessly integrated into the dispensing software and, in the case of Australian government subsidised prescriptions, is available to be electronically sent to Medicare Australia for claiming purposes. This definition does not preclude the use of paper-based processes to support electronic prescribing activity. Repeat and deferred supply authorisations which are uploaded to a Prescription Exchange Service by a supplier are not electronic authorisations, unless the original prescription was generated by a prescriber as an electronic prescription.
Electronic Prescription (or e-Prescription)	A prescription generated in an electronic manner and in a form approved by the relevant State, Territory or Commonwealth Departments of Health to convey a prescriber's authority to supply a medication.
Electronic Transfer of Prescription	A component of the EMM program of work that is concerned with the transfer of prescriptions, and its related information, in an electronic manner between participants.
Health Level Seven	A non-profit organisation involved in the construction and setting of Healthcare standards. "HL7" is also used to refer to some of the specific standards created by the organization (e.g., HL7 v2.x, v3.0, HL7 RIM).

Term	Description
Healthcare Provider Identifier - Individual	A 16 digit unique number used to identify individual providers who deliver healthcare in the Australian healthcare setting.
Healthcare Provider Identifier - Organisation	A 16 digit unique number used to identify organisations which deliver care in the Australian healthcare setting.
Individual	Persons who are, or could be, the subjects of care in the context of a healthcare event.
Individual Electronic Health Record	A secure, private electronic record of an individual's key health history and care information.
Individual Healthcare Identifier	A 16 digit unique number used to identify individuals who receive care in the Australian Healthcare system.
National Authentication Service for Health	A system for verifying the authenticity of patients and professionals for the purpose of ensuring the privacy of a person's electronic health data, while enabling secure access to the data by the person's authorised health providers.
National Clinical Terminology and Information Service	The National Clinical Terminology and Information Service (NCTIS), established by NEHTA, is developing the terminology and information products to support the requirements of e-health for the Australian healthcare community.
National E-Health Transition Authority	NEHTA Limited is a not-for-profit company established by the Australian, State and Territory governments to develop better ways of electronically collecting and securely exchanging health information.
Personal Health Record	A type of PCEHR that is initiated and maintained by the individual.
Personally Controlled Electronic Health Record	A secure, private electronic record of an individual's key health history and care information.
Pharmaceutical Benefits Scheme	A scheme set up under the National Health Act. Within Medicare Australia it is a system administered according to the Business Partnership Agreement with the Department of Health and Ageing (DoHA). Through the Pharmaceutical Benefits Scheme the Australian Government makes a range of necessary prescription medicines available at affordable prices to all Australian residents and those overseas visitors eligible under reciprocal Healthcare Agreements by paying part of the cost of the medicine to pharmacies.
Prescription	A request from a prescriber to dispense a therapeutic product. Describes the medication that the prescriber (a doctor in most cases) wants to be taken by the patient. It is input to the dispense process. Prescriptions are also used as input for the patient or the nurse on how to use the medication.
Prescription Exchange	An intermediary that stores Prescription and Dispense Records to allow them to be accessed by any authorised dispenser.
Prescription Exchange Service	An e-Health Service that provides Prescription Exchange functions.
Prescription Exchange Service - Dispense Record	A dispense record submitted to a Prescription Exchange Service (see Dispense Record).
Public Key Infrastructure	A set of hardware, software, people, policies, and procedures needed to create, manage, store, distribute, and revoke digital certificates.
Quality Use of Medicines	A central objective of the National Medicines Policy, applying to decisions about medicine use by individuals and decisions that affect the health of the population. Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy. It means selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using medicines safely and effectively. The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population. Australia's National Medicines Policy is a cooperative

Term	Description
	endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines. The term "medicine" includes prescription and non-prescription medicines, including complementary healthcare products.
Reciprocal Healthcare Agreements	The Australian Government has signed Reciprocal Health Care Agreements (RHCA) with the governments of the United Kingdom, Sweden, the Netherlands, Belgium, Finland, Norway, Malta and Italy which entitles visitors to limited subsidised health services for medically necessary treatment while visiting Australia.
Regulation 24	Government legislation that allows the Subject of Care to receive the supply of multiple repeat medication items concurrently. This regulation allows pharmacists to supply a pharmaceutical benefit and all of its repeats at the one time. The prescription must be endorsed by the doctor with the words 'Regulation 24' or 'Reg 24' if it is a medicine supplied under the PBS or 'hardship conditions apply' if it is being supplied under the RPBS.
Repatriation Pharmaceutical Benefits Scheme	The Repatriation Pharmaceutical Benefits Scheme (RPBS) provides a wide range of Pharmaceuticals and dressings at a concession rate for the treatment of eligible veterans, war widows/widowers, and their dependants.
Individual Health Identifier	A unique 16 digit number used to identify individuals who receive care in the Australian Healthcare system.
Unit Record	An 8 digit alphanumeric number that is predominantly used in hospitals as an internal organisational number that serves to identify certain Subject of Care classes (e.g. new born babies).

References

At the time of publication, the document versions indicated are valid. However, as all documents listed below are subject to revision, readers are encouraged to use the most recent versions of these documents.

Package Documents

The documents listed below are part of the suite delivered in the Discharge Summary Package.

Electronic Transfer of Prescription Package Documents			
[REF]	Document Name	Publisher	Link
[ETP-ES2010]	Electronic Transfer of Prescription Release 1.1 – Executive Summary	NEHTA 2010	http://www.nehta.gov.au/e-communications-in-practice/emedication-management
[ETP-RN2010]	Electronic Transfer of Prescription Release 1.1 – Release Note		
[ETP-CO2010]	Electronic Transfer of Prescription Release 1.1 – Concept of Operations		
[ETP-BR2010]	Electronic Transfer of Prescription Release 1.1 – Business Requirements Definition		
[ETP-DR2010]	Electronic Transfer of Prescription Release 1.1 – Detailed Requirements Definition		
[ETP-SS2010]	Electronic Transfer of Prescription Release 1.1 – Solution Specification		
[ETP-EP_SDT2010]	Electronic Transfer of Prescription Release 1.1 – e-Prescription Structured Document Template (SDT)		
[ETP-ED_SDT2010]	Electronic Transfer of Prescription Release 1.1 – Dispense Record Structured Document Template (SDT)		
[ETP-PR_SDT2010]	Electronic Transfer of Prescription Release 1.1 – Prescription Request Structured Document Template (SDT)		
[ETP-TSS2010]	Electronic Transfer of Prescription Release 1.1 – Technical Services Specification		
[ETP-EP_CDAIG2010]	Electronic Transfer of Prescription Release 1.1 – e-Prescription Clinical Document Architecture Implementation Guide		
[ETP-DR_CDAIG2010]	Electronic Transfer of Prescription Release 1.1 – Dispense Record Clinical Document Architecture Implementation Guide		
[ETP-PR_CDAIG2010]	Electronic Transfer of Prescription Release 1.1 – Prescription Request Clinical Document Architecture Implementation Guide		

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The documents listed below are non-package documents that have been cited in this document.

Reference Documents			
[REF]	Document Name	Publisher	Link
[ADE2001]	'Adverse drug events as a cause of hospital admission in the elderly', Internal Medicine Journal, 31: 199-205, Chan, M., Nicklason, F. and Vial, J. H., 2001	Adult Medicine Division of The Royal Australasian College of Physicians (RACP)	http://onlinelibrary.wiley.com/doi/10.1046/j.1445-5994.2001.00044.x/references
[AHMC2008]	'National E-Health Strategy: Summary', Australian Health Ministers' Conference, December 2008	Australian Health Ministers' Advisory Council 2008	http://www.ahmac.gov.au/cms_documents/National%20E-Health%20Strategy.pdf
[APAC2005]	'Guiding principles to achieve continuity in medication management', July 2005	Australian Pharmaceutical Advisory Council 2005	http://www.health.gov.au/internet/main/publishing.nsf/Content/4182D79CFCB23CA2CA25738E001B94C2/$File/guiding.pdf
[COMAUS2010]	Portfolio Budget Statements 2010-11, Budget Related Paper No. 1.1, Health and Ageing Portfolio, Budget Initiatives and Explanations of Appropriations specified by Outcomes and Programs by Agency, May 2010, p.292	Commonwealth Government of Australia	http://www.health.gov.au/internet/budget/publishing.nsf/Content/2010-11_Health_PBS_sup2/$File/Department%20of%20Health%20and%20Ageing%20PBS.pdf
[IMS2002]	'Second National Report on Patient Safety: Improving Medication Safety', July 2002, p24 (69,766 adverse drug reactions associated with hospital admission for the year 1999-2000.)	Safety and Quality Council 2002	http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/F0FD7442D1F2F8DDCA2571C6000894FF/$File/med_saf_rept.pdf
[ISOBAR2007]	ISO/IEC 15417:2007 - Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification	ISO 2007	http://www.iso.org/iso/catalogue_detail.htm?csnumber=43896
[KPMG2008]	'Consultancy in Electronic Prescribing and Dispensing', p54	KPMG via DoHA 2008	http://www.health.gov.au/internet/main/publishing.nsf/Content/80B878329CD34C6ACA25715700229B28/$File/DOHA08-ePrescribing%20report-Final290708.pdf
[MJA2006]	Nelson MR, Reid CM, Ryan P, et al. 'Self-reported adherence with medication and cardiovascular disease outcomes in the second Australian National Blood Pressure Study (ANBP2)'. MJA 2006; 185: 487-489	Medical Journal of Australia 2006	http://www.mja.com.au/public/issues/185_09_061106/nel10178_fm.pdf
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[QUM2002]	'The National Strategy for Quality Use of Medicines', 2002	Department of Health and Ageing	http://www.health.gov.au/internet/main/Publishing.nsf/Content/nmp-pdf-natstrateng-cnt.htm

Related Reading

The documents listed below may provide further information about the issues discussed in this document.

Related Documents			
[REF]	Document Name	Publisher	Link
[AST5820]	ATS 5820—2010 -- E-Health Web Services Profiles	Standards Australia 2010	http://infostore.saiglobal.com/store/Details.aspx?ProductID=1391033
[AST5821]	ATS 5821—2001 -- E-Health XML Secured Payload Profiles	Standards Australia 2010	http://infostore.saiglobal.com/store/Details.aspx?productID=1391034
[IF2007]	Interoperability Framework v2.0	NEHTA 2008	http://www.nehta.gov.au/ (Home > Publications)
[NEHTAWEB]	NEHTA Web Site	NEHTA 2008	http://www.nehta.gov.au/ (Home > Publications)

Key Contacts

Contacts listed below will be able to clarify provide further information about the issues discussed in this document.

Contacts		
Contact name	Email Address	Phone Number
Toby Mathieson Program Manager, Electronic Medication Management, NEHTA	Toby.Mathieson@nehta.gov.au	+61 2 8298 2605

Appendix A: Privacy Principles

	Privacy Principles	General Requirements
1	Collection	Collection is necessary; and Consent is obtained or collection authorised by or under law; and Individuals are notified of the collection.
2	Use and Disclosure Primary Purpose	Allowed
	Use and Disclosure Secondary Purposes	Secondary purposes are directly related to primary purpose and within individual's reasonable expectations; or Consent is obtained; or Required or authorised by law; or Serious or imminent threat to any individual's life, health or safety.
3	Data Quality	Information is accurate, complete and up to date.
4	Data Security	Protection from misuse, loss and unauthorised access, modification and disclosure;
5	Openness	Provide a document that clearly sets out policies on handling personal information.
6	Access and Correction	On request and excluding certain circumstances, provide individuals with access to their personal and health information and/or; Where reasonable, correcting health information at the request of the individual.
7	Identifiers	Assignment of identifiers must be necessary and/or; Adoption of identifiers must be in accordance with prescribed circumstances.
8	Anonymity	Allow anonymity where lawful and practical.
9	Transborder Data Flows	Transfer if reasonable belief recipient is subject to comparable information privacy scheme; or Transfer with individual's consent; or Transfer is necessary for contract at the request of, or to benefit the individual.

Appendix B: Acknowledgements

B.1   Contributors

The following individuals were consulted on the development of the Electronic Transfer of Prescription (ETP) Concept of Operations.

NEHTA thanks those involved for the time and effort involved in developing and reviewing this document.

Participant	Organisation
Andrew Howard	Victorian Department of Human Services
Paul Hart	Medicare Australia
Coral Rizzalli	Consumer Health Forum
David Roffe	St Vincent's and Mater Health Sydney
Graham Bedford	Australian Commission on Safety and Quality in Health Care
James Reeve	National Prescribing Service
Janine Bevan	Department of Health and Ageing
Jennie McKay	Queensland Department of Health
John Bennett	General Practitioner/University of Queensland
Vimala Rajavelu	Medicare Australia
Paul McRae	Queensland Department of Health
Peter Slobodian	Department of Health South Australia
Ric Day	University of New South Wales and St Vincent's & Mater Health Sydney
Shane Carney	Royal Australasian College of Physicians
Stephen Moo	Northern Territory Department of Health and Family Services
Sue Page	Royal Australian College of General Practitioners
Suri Ramanathan	The Aged Care Industry IT Council
Tim Logan	Pharmacy Guild Australia
Yvonne Allinson	The Society of Hospital Pharmacists of Australia
Margaret Gerhig	Medical Software Industry Association
Necdet Varova	Department of Health and Ageing
Irwin Lowe	Pharmaceutical Society of Australia