

PRIVATE AND CONFIDENTIAL

Department of Health
**SUMMARY OF PRIVACY IMPACT ASSESSMENT
ON THE ELECTRONIC PRESCRIBING PROJECT**

7 December 2020

Contents

1.	Introduction	1
1.1	Overview of Electronic Prescribing	1
1.2	Purpose of the Privacy Impact Assessment	1
1.3	Scope of Privacy Impact Assessment	1
2.	Project Description	2
2.1	Background	2
2.2	Moving towards Electronic Prescribing	2
2.3	Collaborating agencies' role in implementing Electronic Prescribing	3
2.4	Broader health industry collaboration	3
2.5	Regulatory changes to support Electronic Prescribing	4
2.6	Technology underpinning Electronic Prescribing	4
2.7	Types of information collected, used and disclosed	7
3.	Summary findings and recommendations	9
3.1	Summary of findings — APP compliance	9
3.2	Summary of findings — community expectations	12
3.3	Summary of findings — States and Territory laws	14
Schedules		
	Schedule 1 — Information Flow Diagrams	15
	Schedule 2 — Glossary	19
	Schedule 3 — Source Materials	22

1. Introduction

1.1 Overview of Electronic Prescribing

The Commonwealth, States and Territories are collaborating to implement a solution which will enable the prescribing, dispensing and claiming of Pharmaceutical Benefits Scheme (**PBS**) and Repatriation Pharmaceutical Benefits Scheme (**RPBS**) medications in an electronic manner (**Electronic Prescribing**). Electronic Prescribing is being implemented to increase PBS compliance and efficiency, improve drug safety, and support better data collection.

Electronic Prescribing seeks to give effect to Australia's National Digital Health Strategy which provides that by 2022 '... all prescribers and pharmacists will have access to electronic prescribing and dispensing, improving the safety of our systems'.

1.2 Purpose of the Privacy Impact Assessment

The Commonwealth Department of Health (**Health**) is the lead agency in the project to implement Electronic Prescribing. Health has commissioned the Privacy Impact Assessment (**PIA**) to:

- assess the collection, use and disclosure of personal information by Health and Services Australia in connection with Electronic Prescribing; and
- more broadly consider the privacy impacts and risks associated with Electronic Prescribing including compliance with privacy law and alignment with community expectations.

To that end, the PIA:

- describes the information life cycle by considering how personal information is collected, used, stored and disclosed by Health and Services Australia in connection with Electronic Prescribing;
- considers Health's and Services Australia's compliance with the *Privacy Act 1988* (Cth) (**Privacy Act**), including the Australian Privacy Principles (**APPs**), in their collection, use and disclosure of personal information (specifically PBS claims information);
- considers how State and Territory privacy and drugs, poisons and controlled substances laws affect Electronic Prescribing; and
- seeks to identify any general privacy risks, that if not mitigated, could threaten the effective operation of Electronic Prescribing.

The PIA also includes a high level overview of State and Territory privacy and drugs, poisons and controlled substances laws to confirm that they do prohibit the implementation of Electronic Prescribing.

1.3 Scope of Privacy Impact Assessment

In addition to Health and Services Australia, the Department of Veterans' Affairs (**DVA**) will also collect, use and disclose personal information (specifically, RPBS claims information) in connection with Electronic Prescribing. Health will also collect, use and disclose RPBS claims information (as well as PBS claims information) in connection with Electronic Prescribing.

While the PIA includes details of the RPBS information that DVA and Health will collect from electronic prescriptions, the assessment of whether DVA's and Health's collection, use and disclosure of RPBS claims information is compliant with the APPs is outside the scope of the PIA.

The assessment of whether Health's proposed uses of personal information relating to Prescribers and Approved Suppliers that it collects in connection with Electronic Prescribing is compliant with the APPs is also outside the scope of the PIA.

2. Project Description

2.1 Background

Prescriptions for PBS and RPBS medicines are currently paper-based — a prescriber creates a paper prescription for a Subject of Care to present to a pharmacist, and the pharmacist sights the paper prescription to dispense and supply the prescribed medication to the Subject of Care.

The Australian Government has sought to encourage a move to Electronic Prescribing. On 1 July 2010, an Electronic Prescription Fee (**EPF**) was established to support the electronic transfer of prescriptions (**ETP**) between prescribers and dispensers. ETP involves a prescriber creating (in addition to a paper prescription) an electronic copy of a paper prescription, which is transmitted to a Prescription Exchange Service (**PES**). A dispenser can dispense a paper prescription using the ETP process by scanning a barcode on the paper prescription.

The use of the ETP reduces the chance of transcription and interpretation errors occurring and increases efficiency in the dispensing of prescriptions as the dispenser does not have to manually enter information from a paper prescription into their dispensing software. Although prescriptions that are processed through the ETP involve the use of electronic systems, the prescription itself remains paper-based as the electronic message which contains the prescription information and which is uploaded to the PES is not the legal instrument that authorises the dispensing of a medication. Rather, the legal instrument remains the paper prescription that is given to the Subject of Care by the prescriber.

2.2 Moving towards Electronic Prescribing

The establishment of the EPF payment from 1 July 2010 was done in contemplation of the later introduction of Electronic Prescribing — ETP was a mechanism to support the transition to Electronic Prescribing over time.

Health is leading the process to implement Electronic Prescribing nationally for both the PBS and RPBS.¹ Unlike ETP where the paper prescription is still the legal instrument that authorises the dispensing of a medication, under Electronic Prescribing the electronic prescription created by a prescriber using their prescription software will be the legal instrument that authorises the dispensing of a medication.

In the community context,² Electronic Prescribing will allow Subjects of Care to choose an electronic prescription as an alternative to a paper-based prescription. Under Electronic Prescribing as described in the PIA, paper prescriptions, ETP and full electronic prescriptions will all operate concurrently in the community context. Electronic Prescribing will not fundamentally change how current prescribing and dispensing processes operate — a patient's choice of pharmacy will remain central.

The objectives of Electronic Prescribing include:

- supporting the safety of Subjects of Care by reducing the risk of dispensing errors;
- assisting health practitioners by reducing unnecessary paperwork;
- improving data for health technology assessments, post market reviews, and broader health policy and planning;

¹ Electronic Prescribing can also be used for the prescribing and dispensing of non-PBS and non-RPBS medication (**private prescription**). As no Commonwealth payments are made in relation to private prescriptions, the Commonwealth does not collect any personal information relating to private prescriptions.

² Broadly speaking, the community context is where the Subject of Care is able to choose the supplier that will supply their prescribed medication. The community context includes primary care prescribing, community pharmacy dispensing, prescriptions made in outpatient settings or on discharge from hospital, and prescriptions made in residential care settings where the resident exercises their choice to manage their own prescription supply.

- providing choice for Subjects of Care in the new digital health world; and
- becoming a platform to enable digital health services and initiatives.

2.3 Collaborating agencies' role in implementing Electronic Prescribing

Health is the lead agency in a collaboration of Commonwealth, State and Territory agencies seeking to implement Electronic Prescribing. Health's role and the role of key Commonwealth agencies involved in the implementation or operation (or both) of Electronic Prescribing are outlined below.

Agency	Role
ADHA	<p>Health has contracted the ADHA to develop the technical framework applicable to all systems that facilitate Electronic Prescribing.</p> <p>The Agency will also be managing the implementation of Electronic Prescribing by:</p> <ul style="list-style-type: none"> • providing vendor support; • providing assistance for clinical change activities; and • undertaking quality assurance activities.
DVA	<p>DVA administers the RPBS and receives RPBS claim data from Health (which collects RPBS information from Services Australia).</p> <p>Health has consulted with DVA on changes to the RPBS claiming process to implement Electronic Prescribing including amendments required to the Repatriation Pharmaceutical Benefits Scheme Instrument.</p> <p>The drafting instructions for amendments to the <i>National Health (Pharmaceutical Benefits) Regulations 2017</i> (Cth) to implement Electronic Prescribing indicate that DVA will amend the instruments governing the RPBS as necessary to implement the framework for Electronic Prescribing.</p>
Health	<p>Health administers the National Health Act and is responsible for management of the PBS including policy development in relation to the supply of, and payment for, pharmaceuticals. Health is the lead agency in the project to implement Electronic Prescribing.</p>
Services Australia	<p>Services Australia administers the PBS and receives PBS claims from Approved Suppliers. Services Australia sends approved PBS and RPBS claim data to Health and DVA.</p> <p>Health has consulted with Services Australia on changes to the PBS claiming process to implement Electronic Prescribing including amendments required to the <i>National Health (Claims and under co-payment data) Rules 2012</i> (Cth) (Claims Rules).</p>

2.4 Broader health industry collaboration

To ensure Electronic Prescribing meets the needs of all participants, including prescribers, dispensers and Subjects of Care, and does not hinder existing mechanisms and business processes, Health has committed to a co-design approach to developing the technical framework.

Industry stakeholders who have been consulted include the Medical Software Industry Association, Australian Medical Association, the Royal Australian College of General Practitioners, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, consumer representative groups and medical software industry representatives. These stakeholders are represented on the ADHA's Electronic Prescribing Technical Working Group.

Health intends to undertake further change and communication activities to consult with and inform Subjects of Care, prescribers and dispensers. This will include the release of user guides and frequently asked questions relating to Electronic Prescribing in the lead up to its proposed implementation.

2.5 Regulatory changes to support Electronic Prescribing

Electronic Prescribing requires regulatory changes and the implementation of technical frameworks. Commonwealth legislation has been amended to describe the data fields to be included when prescribing, dispensing and claiming from an electronic PBS prescription.

State and Territory governments are responsible for regulating the prescribing of medicines in their jurisdictions. The States and Territories have worked with the Commonwealth to achieve a consistent approach to Electronic Prescribing across Australia which includes amending State and Territory laws to recognise Electronic Prescribing for the supply of medicines which are claimable, as well as medicines which are not claimable, under the PBS. Accordingly, amendments to the corresponding State and Territory legislation have already been made, or will be made, to enable the implementation of Electronic Prescribing in each jurisdiction.

The Commonwealth is working with the States and Territories to facilitate the required amendments through the Electronic Prescribing Working Group, which reports to the Health Services Principal Council (a sub-committee of the Australian Health Ministers' Advisory Council).

The technical framework for Electronic Prescribing has been developed by the ADHA. The technical framework documents indicate that the technical framework is intended to describe clinical software requirements that will ensure the software aligns with relevant Commonwealth, State and Territory legislative requirements concerning Electronic Prescribing matters such as claims rules and form of prescription instruments, as well as privacy and security principles concerning authentication and secure messaging. This technical framework applies to all systems that give effect to Electronic Prescribing which includes prescriptions for medicines which are claimable, as well as medicines which are not claimable, under the PBS and RPBS.

The organisations that develop these systems are required to complete a self-assessment against the technical framework. An organisation may only 'release' its system for Electronic Prescribing if the organisation has:

- self-assessed its system as complying with the technical framework's mandatory requirements; and
- provided its Conformance ID to the ADHA for inclusion on a Register of Conformance.

In essence, only Prescribers and Approved Suppliers using technology for which a Conformance ID has been issued and recorded on a Register of Conformance can generate and dispense an electronic prescription for the purposes of the PBS and RPBS.

2.6 Technology underpinning Electronic Prescribing

There are six key technology components that underpin Electronic Prescribing:

2.6.1 Prescribing System

A Prescribing System is a system which facilitates the authoring of an electronic prescription by a Prescriber. The Prescribing System must be capable of lodging the electronic prescription with a Prescription Delivery Service (**PDS**) such as a PES.

2.6.2 Dispensing System

A Dispensing System is a system which is capable of facilitating the dispensing of medications by an Approved Supplier. The Dispensing System must be capable of retrieving an electronic prescription from a PDS.

2.6.3 Prescription Delivery Service

A Prescription Delivery Service is a system through which an electronic prescription is communicated from a Prescribing System to a Dispensing System. There are two categories of PDS:

- *Open Prescription Delivery Service*

This is a PDS that accommodates choice of supply by the Subject of Care. Approved Suppliers can retrieve electronic prescriptions using a Token (**the Token model**) or by selecting an electronic prescription from an Active Script List (**the ASL model**).

Under the Token model, a Token is provided to a Subject of Care by a Prescriber (or, in the case of repeats or deferred supply, the Approved Supplier) in physical form (ie a barcode) or in electronic form (as information stored on their personal device). The Subject of Care provides their Token to their chosen Approved Supplier, who enters or scans the Token into a Dispensing System to retrieve the electronic prescription from an Open PDS.

Under the ASL model, Prescribers add electronic prescriptions to a Subject of Care's Active Script List and Approved Suppliers can retrieve an electronic prescription from an Open PDS by selecting the prescription from a Subject of Care's Active Script List. Where a Subject of Care has registered for an Active Script List, the ASL model becomes their default channel for electronic prescriptions.

Open Prescription Delivery Services are required to be interoperable — an electronic prescription that has been lodged with one Open Prescription Delivery Service must be capable of being retrieved by an Approved Supplier who uses another Open Prescription Delivery Service. The two current PES operators (eRx Script Exchange Pty Ltd and IP MDS Pty Ltd) are types of PDS operators and are currently interoperable.

- *Direct Prescription Delivery Service*

The Direct PDS communicates an electronic prescription directly to a nominated Approved Supplier. Accordingly, this Prescription Delivery Service does not accommodate choice of supplier by the Subject of Care. Additionally, electronic prescriptions that have been sent to a Direct PDS will not be added to a Subject of Care's Active Script List. A Direct PDS is only permitted in circumstances where the selection of the Approved Supplier is made by the Subject of Care before the prescription is issued (eg prescriptions issued during an admission to a residential care or hospital facility).

2.6.4 Active Script List Registry

The Active Script List Registry (**ASLR**) is a system that allows:

- a Subject of Care to register for an Active Script List either by themselves or via a Prescriber or Approved Supplier;
- Prescribing Systems and Dispensing Systems to view and add prescriptions/dispense records to a Subject of Care's Active Script List; and
- mobile application intermediaries to provide Mobile Applications that allow Subjects of Care to view their Active Script List and manage access permissions for their Active Script Lists.

Not all of the functionality listed above will be available when the ASL model is released. The ASL model will be implemented in two releases (Release 1 and Release 2), and in the first release Subjects of Care will only be able to register for an Active Script List through an Approved Supplier,³ and Mobile Applications will not be available.

³ It is possible that some Prescribers will also be able to register Subjects of Care for an Active Script List.

2.6.5 Mobile Applications

Mobile Applications may be used by the Subject of Care to manage their electronic prescriptions, manage authorised agents, forward prescription links to an online or bricks and mortar pharmacy, and allow the Subject of Care to present a Token to their chosen Approved Supplier. The Mobile Application may, through the use of a Mobile Intermediary, use a Token to retrieve information about an electronic prescription from the PDS.

In Release 2 of the ASL model, Mobile Applications will also allow Subjects of Care to:

- register for an Active Script List;
- view their Active Script Lists;
- manage access permissions for their Active Script Lists;
- create a Token for an ASL prescription item; and
- receive notifications relating to their Active Script List (eg prescriptions added to an Active Script List).

2.6.6 Mobile Intermediaries

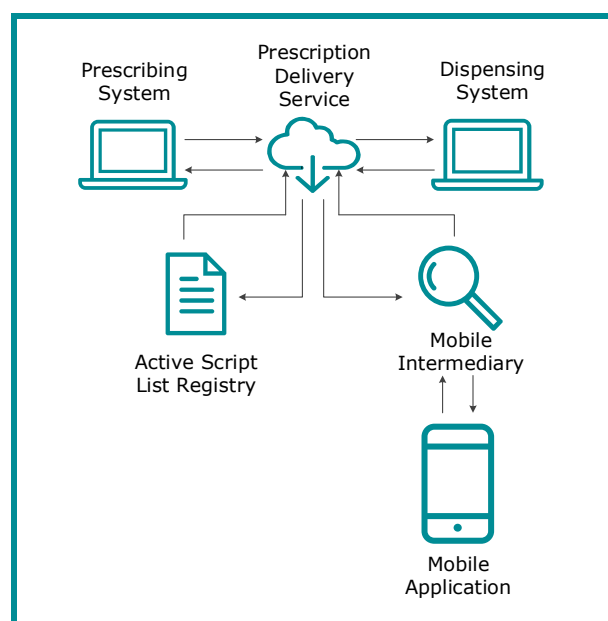
A Mobile Intermediary is software which manages communications between a PDS and a Mobile Application. The primary purpose of a Mobile Intermediary is to access prescription information contained in a PDS on behalf of the Mobile Application. A Mobile Intermediary may also perform other functions, such as user authentication and validation, and storing a Token on behalf of the Subject of Care. In most instances the Mobile Intermediary will be the server component of the Mobile Application.

2.6.7 Conformance IDs

All of the key technology components above must have a valid Conformance ID to participate in Electronic Prescribing.

Expressed at its highest level, the interaction between the technology components described above can be depicted as set out in Figure 1. The information flows are essentially the same for both the Open PDS and the Direct PDS. However, Mobile Applications and Active Script Lists cannot be used for electronic prescriptions that are sent to a Direct PDS and a Direct PDS will only release electronic prescriptions to the Dispensing System that is linked to the Prescribing System that generated the electronic prescription.

Figure 1



2.7 Types of information collected, used and disclosed

Personal information is used by Health and Services Australia in Electronic Prescribing to enable the subsidised supply of pharmaceutical benefits under the PBS.

Personal information from electronic prescriptions

An electronic prescription will include all fields required by the following sections of the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cth):

- section 40, which concerns prescriptions other than medication charts;
- section 41, which concerns medication chart prescriptions;
- section 41A, which concerns additional requirements for all electronic prescriptions; and
- section 41B, which concerns additional information that may be included in electronic prescriptions.

Notably, there are two additional pieces of personal information relating to the Subject of Care which may be included in an electronic prescription — date of birth and the reason why the pharmaceutical benefit is prescribed to the Subject of Care. The collection of this data is intended to assist in improving Subject of Care safety and PBS payment compliance. Additionally, an electronic prescription will also include (in its metadata) the individual healthcare identifier (**IHI**) of the Subject of Care and the healthcare identifier (**HPI-I**) of the Prescriber.

Personal information from claims information

After an electronic prescription is dispensed, Approved Suppliers will (as per the current procedure for paper prescriptions) send PBS and RPBS claims information to Services Australia in accordance with the Claims Rules and the Repatriation Pharmaceutical Benefits Scheme instrument. As part of the implementation of Electronic Prescribing, the Claims Rules have been amended by the *National Health (Claims and under co-payment data) Amendment (Electronic Prescriptions) Rules 2019* (Cth) to require Approved Suppliers to provide the following information to Services Australia as part of the claims process for an electronic prescription:

- the Subject of Care's date of birth and the reason for prescription where this information is included on an electronic prescription when the Approved Supplier uses the PBS Online Claiming system; and
- the PBS Prescriber's and Approved Supplier's HPI-I.

There are no other new collections, uses or disclosures of personal information by any Commonwealth Participants. The storage arrangements for Commonwealth Participants will also remain unaffected. Further, in accordance with the *National Health (Privacy) Rules 2018* (Cth), claims information obtained under the Pharmaceutical Benefits Program will continue to be stored in a separate database to claims information obtained under the Medicare Benefits Program.

Other personal information

Electronic Prescribing will require the disclosure of a Subject of Care's electronic address (such as SMS or email address) if the Subject of Care has opted to receive a Token electronically. The electronic address will not be required if the Token is given to the Subject of Care in paper form.

Where a Subject of Care wishes to have electronic prescriptions added to and dispensed from an Active Script List, the Subject of Care can register for an Active Script List through a Mobile Application (under Release 2) or with the assistance of a Prescriber (under Release 2) or Approved Supplier (under Release 1). The ASLR will need to collect the following information in order to register the Subject of Care for an Active Script List:

- the Subject of Care's:
 - IHI;

- first name;
- last name;
- date of birth;
- gender;
- if available, Medicare card number and individual reference number (IRN); and
- if available, DVA file number; and
- an email address for the primary point of contact for ASL notifications.

Once a Subject of Care is registered for an Active Script List, Prescribers can add electronic prescriptions to, and (if permitted by the Subject of Care under Release 2) view electronic prescriptions on, the Subject of Care's Active Script List by sending the Subject of Care's IHI and the healthcare identifier of the prescribing organisation (**HPI-O**) to the ASLR. Approved Suppliers can view the electronic prescriptions on a Subject of Care's Active Script List by sending the Subject of Care's IHI and the dispensing organisation's HPI-O.



3. Summary findings and recommendations

3.1 Summary of findings – APP compliance

Ashurst has assessed Health's and Services Australia's compliance with the APPs and believes that all privacy risks relating to Electronic Prescribing will be sufficiently mitigated by implementing the recommendations set out in *Table 1: Summary of APP Assessment*.

Ashurst has assessed other general privacy risks including alignment with community expectations and believes that, subject to the implementation of our recommendations in *Table 2: Community Expectations Privacy Assessment Recommendations*, these risks will be appropriately mitigated.

Table 1: Summary of APP Assessment

Privacy requirement	Status	Recommendation
APP 1 – Openness and transparency	<p>Health</p> <p>Compliant.</p> <p>However, the implementation of Recommendation 1 will achieve better privacy practice.</p>	<p>Recommendation 1</p> <p>Amend the following paragraph in the Health Privacy Policy as shown in underline below:</p> <p>For example, the sensitive information that we collect may include:</p> <ul style="list-style-type: none"> your health (including information about your medical history and any disability or injury you may have, or a family member's medical history) where relevant to assessing an application, making reasonable adjustments in a recruitment process or the management of staff; and <u>information about your health where relevant to ensuring PBS claiming compliance and to assist in research and analysis to support improved delivery of health programs.</u> <p>Health may address the issue of use of personal information for research purposes in its Privacy Policy in a variety of ways - the proposed mark-up is only one approach. Services Australia's Medicare and Health Programmes Policy (Health Programmes Policy), for example, has the effect of indicating that Services Australia discloses aggregated data to researchers and research bodies for Medicare and health program related purposes.</p>
	<p>Services Australia</p> <p>Compliant.</p>	No recommendations.
APP 2 – Anonymity and pseudonymity	<p>Health and Services Australia</p> <p>Does not apply.</p>	No recommendations.

Privacy requirement	Status	Recommendation
APP 3 — Collection of solicited information	Health and Services Australia Compliant.	No recommendations.
APP 4 — Dealing with unsolicited personal information	Health and Services Australia Does not apply.	Recommendation 2 Services Australia does not address how it deals with unsolicited personal information. Although it is not essential that the issue be addressed, Services Australia should consider whether there is value in amending its Privacy Policy to address the issue.
APP 5 — Notification of the collection of personal information	Health Compliant, subject to implementation of Recommendation 3. Services Australia Compliant, subject to implementation of Recommendation 3.	Recommendation 3 The proposed APP 5 collection notice for prescriptions should be amended from: <i>Privacy and your personal information</i> The privacy and security of your personal information is important to us, and is protected by law. We need to collect this information so we can process and manage your applications and payments, and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to servicesaustralia.gov.au/privacy To: <i>Privacy and your personal information</i> The privacy and security of your personal information is important to us, and is protected by law. We need to collect this information for the purposes of processing and managing your applications and payments, providing services to you, and undertaking research to improve service delivery and develop government policy. We only use or share your information with other parties for the same purposes, where you have agreed, or where the law allows or requires it. For more information, go to servicesaustralia.gov.au/privacy The amended notice should be included: <ul style="list-style-type: none"> • on any hard copy document on which a Token is printed/embedded or other hard copy document that is given to the Subject of Care in connection with an electronic prescription (eg Evidence of Prescription); or • in any electronic message that is sent to the Subject of Care in connection with an electronic prescription (eg an electronic message containing a Token or Evidence of Prescription).

Privacy requirement	Status	Recommendation
		Health and Services Australia should include in their frequently asked questions (which should be available on their website) an explanation of the personal information that is collected by Health and Services Australia and the purposes for which that information is collected.
APP 6 — Use or disclosure of personal information	Health and Services Australia Compliant.	No recommendations.
APP 7 — Direct marketing	Health and Services Australia Does not apply.	No recommendations.
APP 8 — Cross-border disclosure of personal information	Health and Services Australia Does not apply.	No recommendations.
APP 9 — Adoption, use or disclosure of government related identifiers	Health and Services Australia Does not apply. However, the implementation of Recommendation 4 will achieve better privacy practice.	Recommendation 4 Best privacy practice will be achieved if Health reminds non-government participants of their obligation under the Healthcare Identifiers Act to only use healthcare identifiers for the intended purposes of Electronic Prescribing. This can be done as part of the Registration of Conformance process for non-government participants. Before finalising the ASL model design, Health should confirm that all collections, uses and disclosures of healthcare identifiers are permitted by the Healthcare Identifiers Act.
APP 10 — Quality of personal information	Health and Services Australia Compliant.	No recommendations.
APP 11 — Security of personal information	Health and Services Australia Compliant.	No recommendations.
APP 12 — Access to personal information	Health and Services Australia	No recommendations.

Privacy requirement	Status	Recommendation
	Compliant, subject to implementation of Recommendation 5.	
APP 13 – Correction of personal information	Health and Services Australia Compliant.	Recommendation 5 To ensure ongoing compliance with APP 13 by Commonwealth agencies and non-government agency participants, Health should remind non-government agency participants by way of Electronic Prescribing Privacy guidelines (or a similar document) of their privacy obligations in relation to APP 13 and specifically that they should only amend a record if that entity has the authority to do so (ie a Prescribing System vendor can only change a record if instructed to do so by a Prescriber). This document should be made publicly available.

3.2 Summary of findings – community expectations

The PIA identified that members of the community:

- could be concerned about the privacy-related risks that arise from the involvement of a large number of private non-government entities in collecting, storing, using and disclosing sensitive information (the ADHA's Electronic Prescribing Conformance Scheme indicates at least 11 private non-government participants ranging from IT software providers to entities that host data); and
- are likely to assume that the Commonwealth Participants, through their role in the implementation of Electronic Prescribing, endorse the ability of these private non-government entities to protect their personal information.⁴

The PIA findings on the privacy risks associated with community expectations are summarised below.

Table 2: Community Expectations Privacy Assessment Recommendations

Privacy requirement	Recommendation
Meet Community Expectations Providing a general overview of Electronic Prescribing	Recommendation 1 Health is proposing to develop FAQs in relation to Electronic Prescribing. Health should ensure that the FAQs (or a general overview of Electronic Prescribing): <ul style="list-style-type: none"> • provide a high level description of Electronic Prescribing; • provide Subjects of Care with the ability to identify the Commonwealth Participants and non-government entities that are involved in Electronic Prescribing and thereby locate those entities' websites and privacy policies; • provide Subjects of Care with the ability to ask Health (or an Australian Government agency) by email or chat bot, privacy-related questions concerning Electronic Prescribing; and • are made available on the Commonwealth Participant's and ADHA's website.

⁴ The expectation that Subjects of Care will assume that the Commonwealth Participants endorse Electronic Prescribing is supported by the fact that a current Prescription Exchange Service operator, MediSecure, states on its website that 'MediSecure is one of two Commonwealth approved Prescription Exchange Services.'

Privacy requirement	Recommendation
	<p>Reflecting the above content in the FAQs will address survey findings in the OAIC Australian Community Attitudes to Privacy Survey 2017 report that 87 per cent of Australians considered a misuse of personal information to be providing their personal information to an organisation that '[they] haven't dealt with'.</p>
<p>Meet Community Expectations</p> <p>Waiting Room Brochure</p>	<p>Recommendation 2</p> <p>Health should consider producing a summary of the key points in the FAQs in a brochure form for health practitioners to make available, to Subjects of Care, in the practitioner's waiting rooms. Health has indicated that it expects that the Electronic Prescribing Communication Plan will recommend the production of such a brochure and that the AMA and RACGP would possibly support this.</p>
<p>Meet Community Expectations</p> <p>Quality assurance processes of system compliance with technical framework</p>	<p>Recommendation 3</p> <p>The technical framework for Electronic Prescribing is being developed by the ADHA. The organisations that develop Prescribing Systems, Dispensing Systems, PDSs, ASLRs, Mobile Intermediary systems and Mobile Application systems will be required to complete a self-assessment against the ADHA technical framework.</p> <p>The Electronic Prescribing Conformance Scheme document refers to ADHA providing ongoing Quality Assurance processes. However, these processes are not described in detail. Health, in consultation with ADHA, should implement a process for:</p> <ul style="list-style-type: none"> • notifying developers and supporters of solutions of technical framework updates to address emerging threats; and • periodic audit of ongoing compliance with the current approved technical framework.
<p>Meet Community Expectations</p> <p>Overseas disclosure or access to personal information</p>	<p>Recommendation 4</p> <p>Health should confirm whether it expects the Electronic Prescribing participants to not store or access the personal information overseas.</p> <p>If there is to be a restriction, the technical framework needs to be updated to articulate this requirement. If there is no restriction on overseas disclosure or access, Health should address this feature of the solution in the Electronic Prescribing Privacy guidelines (or a similar document). Addressing this feature would require each non-government party that will send or access data overseas to confirm that they comply with APP 8 in their own right.</p>
<p>Meet Community Expectations</p> <p>Participant compliance with privacy laws</p>	<p>Recommendation 5</p> <p>The non-government participants in Electronic Prescribing will be subject to, and required to comply with, all applicable Commonwealth, State and Territory privacy laws.</p> <p>The community would expect that the Australian Government is confident that those participants are aware of, and will comply with, their privacy obligations. To meet community expectations, Health should consider preparing and providing all non-government participants in Electronic Prescribing with a short document that reminds participants of their privacy obligations and highlights the key obligations related to their role in Electronic Prescribing. This 'reminder' could, for example, be incorporated into the declaration of conformance that software vendors will submit to the ADHA to be listed on the Register of Conformance.</p>

3.3 Summary of findings – States and Territory laws

Privacy Acts

The Privacy Act applies to all private sector health providers in every State and Territory. Additional obligations will be imposed on private sector health providers in NSW, Victoria and the ACT by health records legislation. This legislation does not prohibit Electronic Prescribing.

The Privacy Act does not apply to State and Territory public sector health providers, such as public hospitals. Most States and Territories have privacy legislation which will capture public sector health providers. In each case this legislation imposes similar, but not identical, obligations to the APPs. We have not identified any requirement that would prohibit public sector agencies from participating in Electronic Prescribing.

Drugs, Poisons and Controlled Substances Laws

These laws do not prohibit Electronic Prescribing. However, there are a variety of provisions concerning retention of prescriptions and requirements for signatures by hand. These requirements will need to be further reviewed to determine whether the State or Territory Acts will require amendment or the technical specifications for Electronic Prescribing can accommodate the requirements.



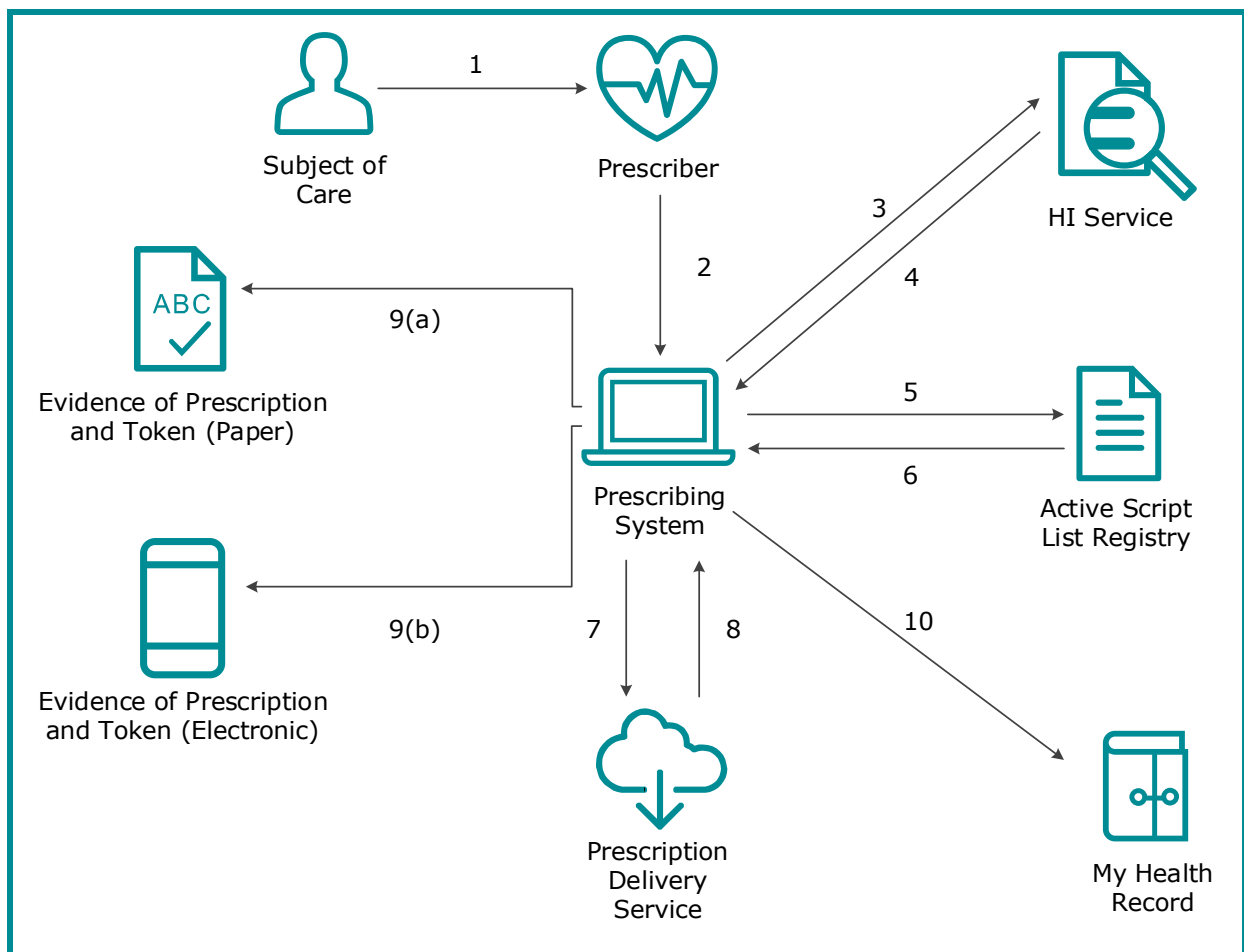
Schedule 1 — Information Flow Diagrams

INFORMATION FLOW 1 — SUBJECT OF CARE RECEIVES ELECTRONIC PRESCRIPTION UNDER THE TOKEN MODEL

Figure 2 below depicts a Subject of Care receiving an electronic prescription from a Prescriber under the Token model. The circumstances in which a Subject of Care is issued with an electronic prescription under the Token model rather than the ASL model include where:

- the ASL model has yet to be implemented;
- the ASL model is active but the Subject of Care has not registered for an Active Script List; and
- a Subject of Care has registered for an Active Script List but has elected to receive a Token instead (eg the Subject of Care has withdrawn their consent for electronic prescriptions to be added to their Active Script List).

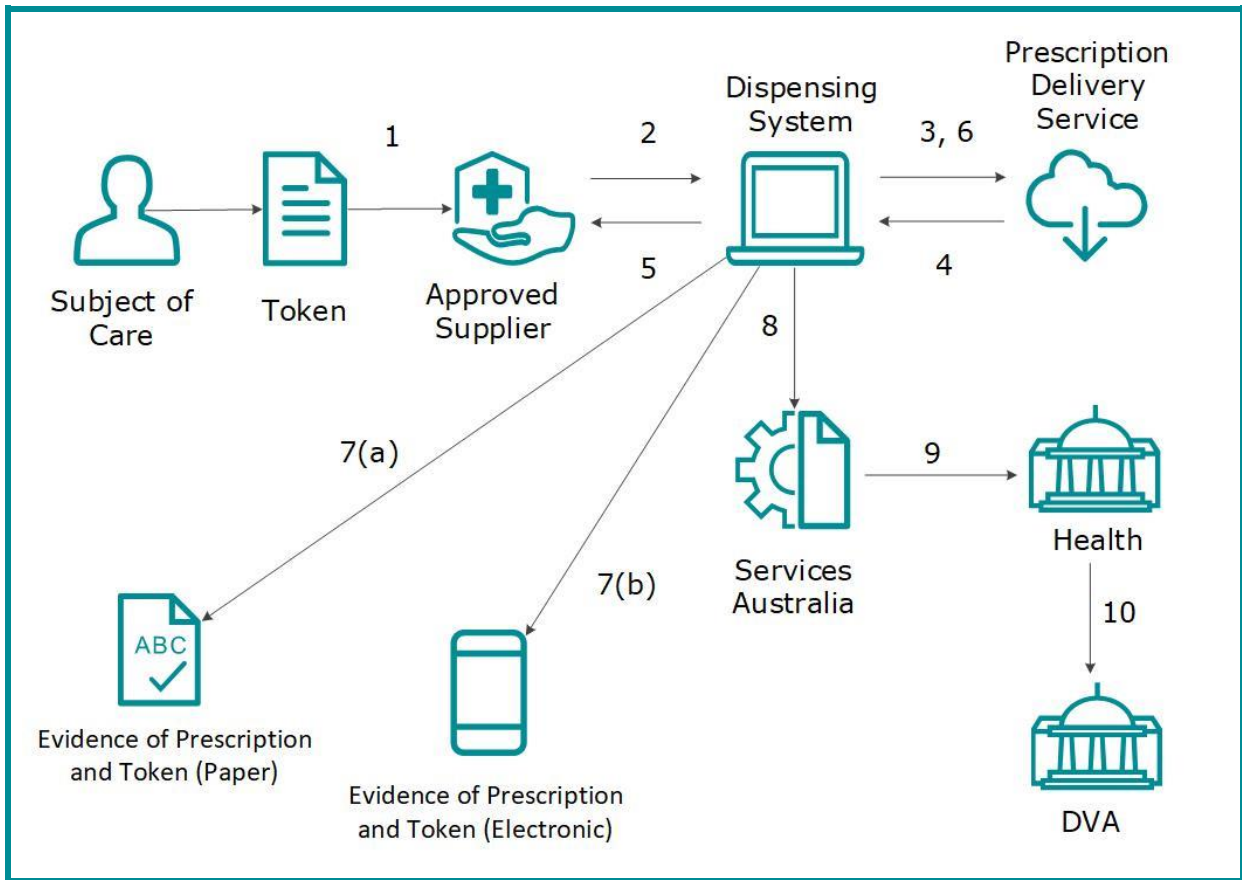
Figure 2 — Information Flow 1



INFORMATION FLOW 2 – APPROVED SUPPLIER DISPENSES PRESCRIBED MEDICATION TO SUBJECT OF CARE UNDER THE TOKEN MODEL

Figure 3 below depicts an Approved Supplier retrieving the electronic prescription from a PDS for the purpose of dispensing the prescribed medication to the Subject of Care under the Token model.

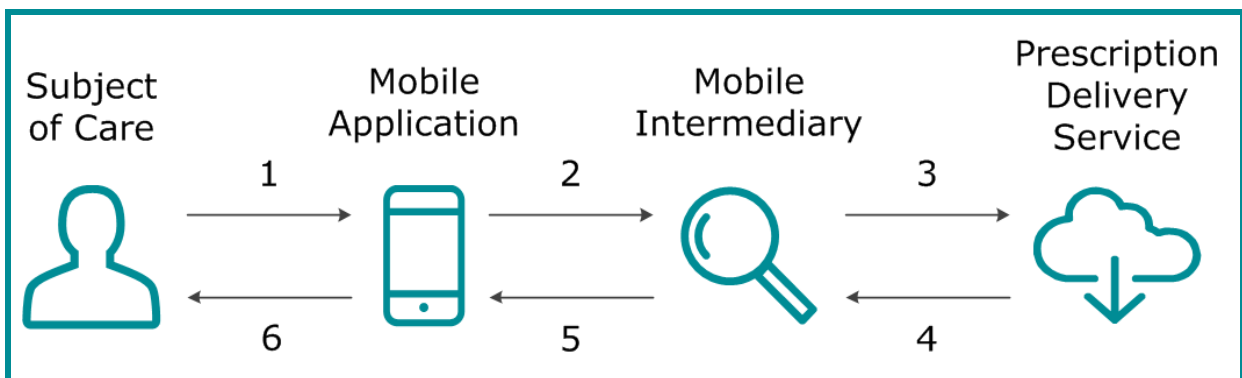
Figure 3 – Information Flow 2



INFORMATION FLOW 3 – SUBJECT OF CARE USES A MOBILE APPLICATION TO REVIEW ELECTRONIC PRESCRIPTION UNDER THE TOKEN MODEL

Figure 4 below depicts a Subject of Care who has received their Token in electronic form using a conformant Mobile Application to review their prescription.

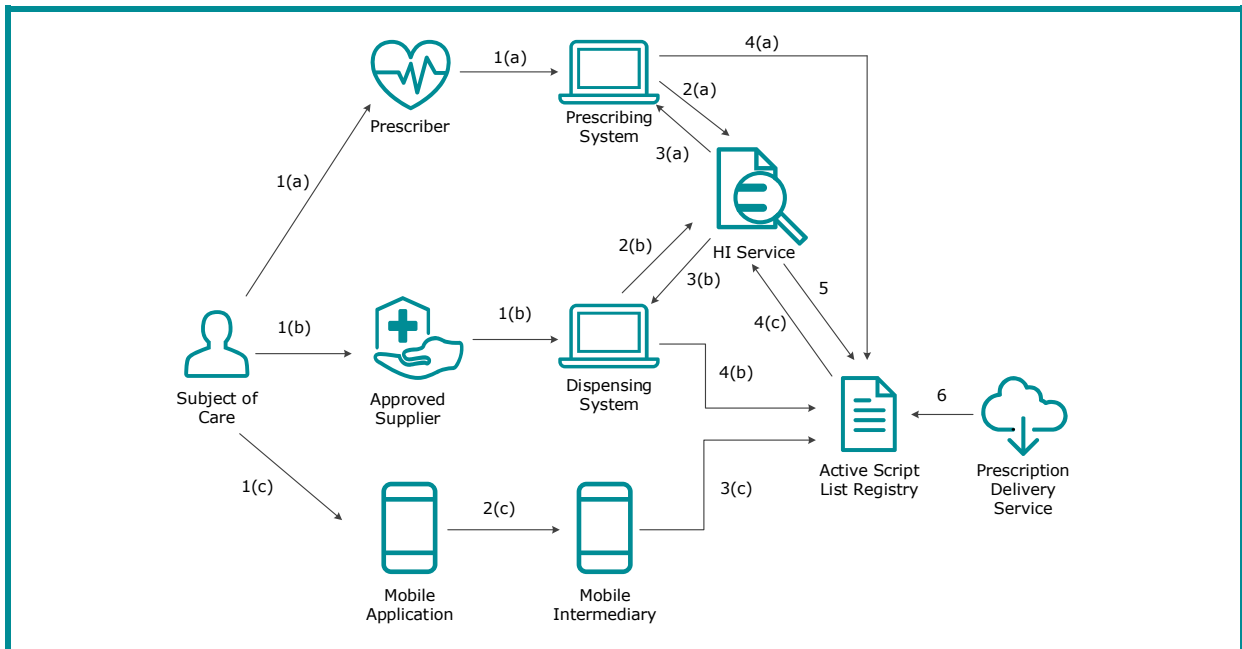
Figure 4 – Information Flow 3



INFORMATION FLOW 4 – SUBJECT OF CARE REGISTERS FOR AN ACTIVE SCRIPT LIST

Figure 5 below depicts the process in which a Subject of Care registers for an Active Script List either via assisted registration (ie with the assistance of a Prescriber or an Approved Supplier) or self-registration using a Mobile Application.

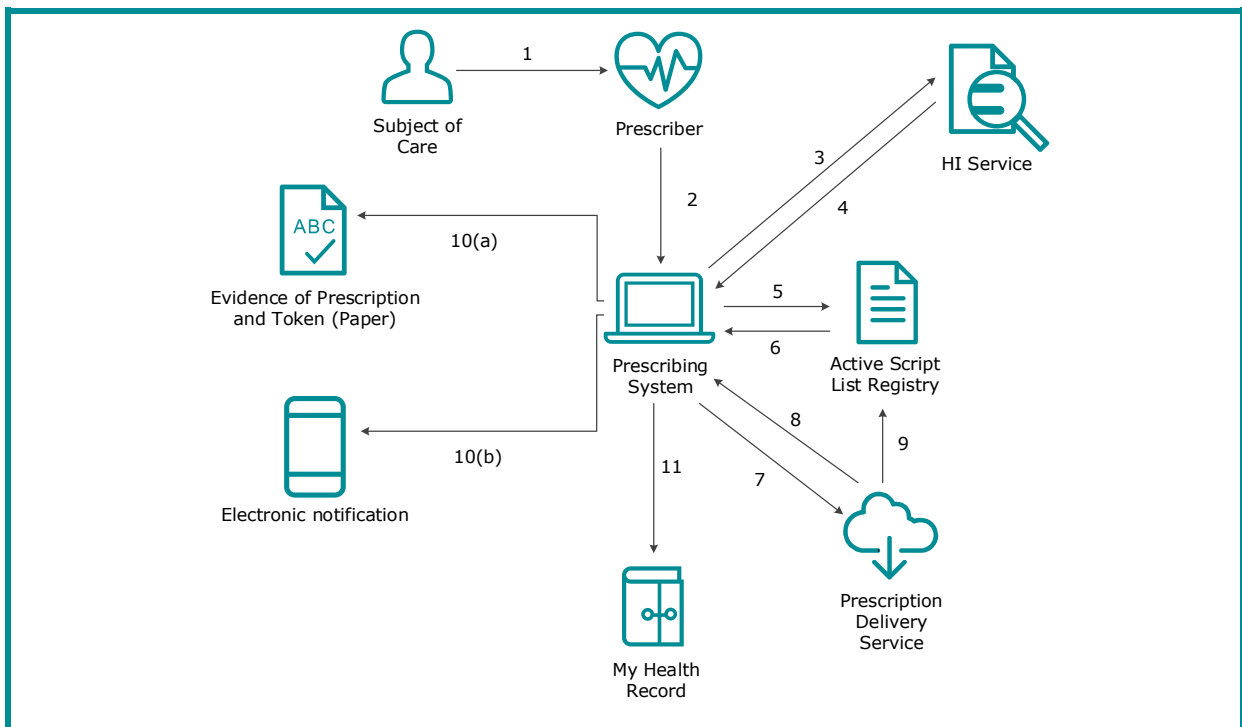
Figure 5 – Information Flow 4



INFORMATION FLOW 5 – SUBJECT OF CARE RECEIVES ELECTRONIC PRESCRIPTION UNDER THE ASL MODEL

Figure 6 below depicts a Subject of Care receiving an electronic prescription from a Prescriber under the ASL model.

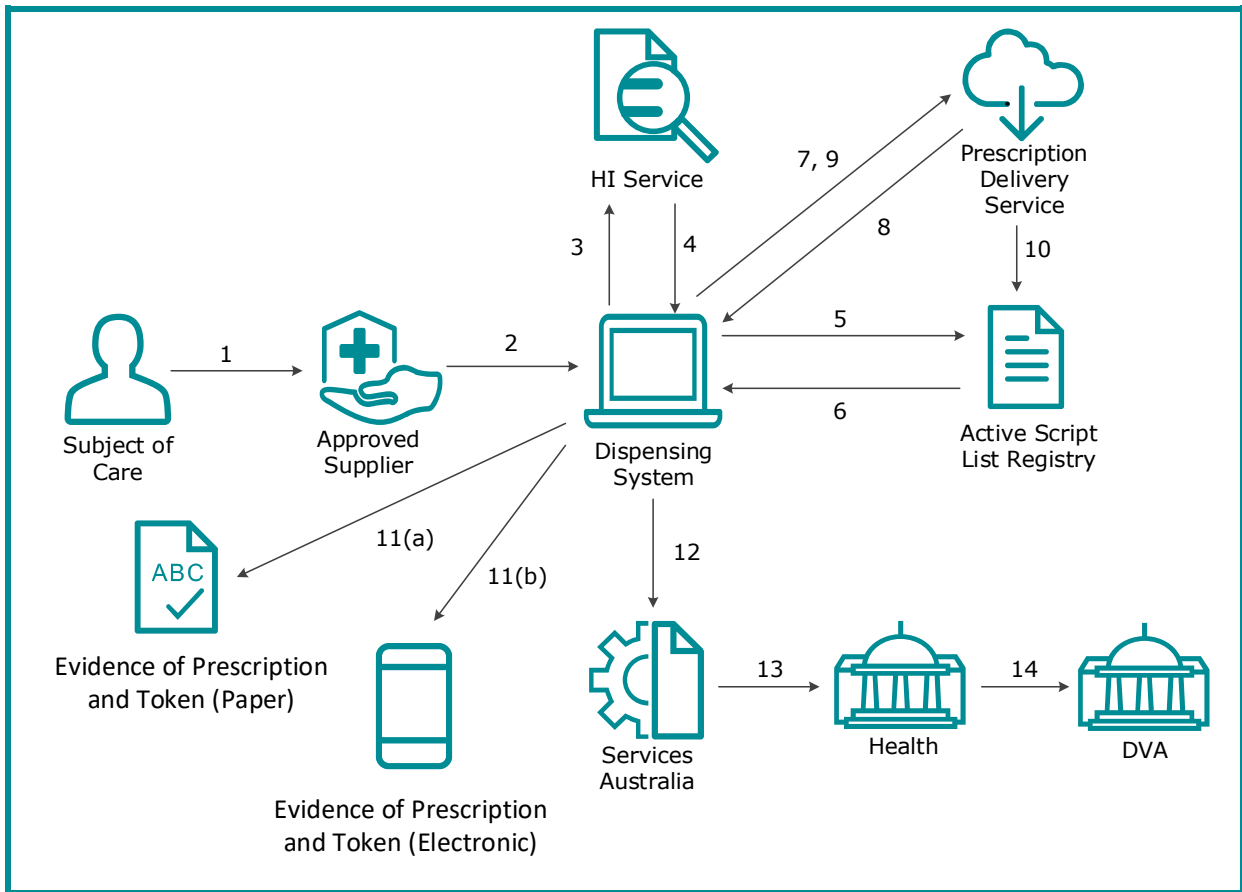
Figure 6 – Information Flow 5



INFORMATION FLOW 6 – APPROVED SUPPLIER DISPENSES PRESCRIBED MEDICATION TO SUBJECT OF CARE UNDER THE ASL MODEL

Figure 7 below depicts an Approved Supplier retrieving the electronic prescription from a PDS for the purpose of dispensing the prescribed medication to the Subject of Care under the ASL model.

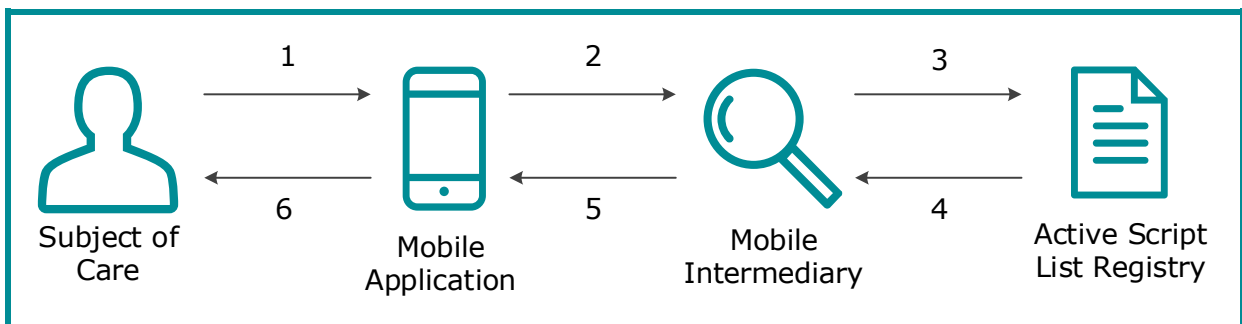
Figure 7 – Information Flow 6



INFORMATION FLOW 7 – SUBJECT OF CARE USES A MOBILE APPLICATION UNDER THE ASL MODEL

Figure 8 below depicts a Subject of Care using a conformant Mobile Application under Release 2 of the ASL model. This Information Flow assumes that the Subject of Care has already registered for an Active Script List as shown in Information Flow 4, and therefore this Information Flow will not address the Subject of Care using the Mobile Application to register for an Active Script List.

Figure 8 – Information Flow 7



Schedule 2 – Glossary

ACRONYM	FULL TERM
ADHA	Australian Digital Health Agency
AMA	Australian Medical Association
APP	Australian Privacy Principle
ASL	Active Script List
ASLR	Active Script List Registry
DVA	Department of Veterans' Affairs
ETP	Electronic transfer of prescriptions
IHI	Individual Healthcare Identifier
IRN	Individual reference number
OAIC	The Office of the Australian Information Commissioner
PBS	Pharmaceutical Benefits Scheme
PDS	Prescription Delivery Service
PES	Prescription Exchange Service
PKI	Public Key Infrastructure
RACGP	The Royal Australian College of General Practitioners
RPBS	Repatriation Pharmaceutical Benefits Scheme

TERM	DEFINITION
Active Script List	summary information associated with a Subject of Care's active electronic prescriptions (ie electronic prescriptions that are not expired, exhausted or cancelled), which includes the Delivery Service Prescription Identifier that enables an electronic prescription to be retrieved from an Prescription Delivery Service. The Active Script List does not contain the electronic prescriptions that are referred to in the Active Script List.
Active Script List Registry	a system that allows: <ol style="list-style-type: none"> a Subject of Care to register for an Active Script List; Prescribing Systems and Dispensing Systems to add prescriptions/dispense records to a Subject of Care's Active Script List; and Mobile Application Intermediaries to provide Mobile Applications that allow Subjects of Care to view their Active Script List and manage access permissions for their Active Script Lists.

TERM	DEFINITION
APP entity	has the meaning given to it under the Privacy Act.
Approved Supplier	has the meaning given to it under the <i>National Health Act 1953</i> (Cth).
Commonwealth Participants	the Commonwealth Department of Health, Department of Human Services and the Department of Veterans' Affairs.
Dispensing System	a system which is capable of facilitating the dispensing of medications by an Approved Supplier.
Evidence of Prescription	<p>evidence of a Subject of Care's prescription that is provided by a Prescriber or an Approved Supplier. The exact information that is provided in an Evidence of Prescription will vary depending on the circumstances in which it is given, but in general it may include:</p> <ul style="list-style-type: none"> (a) barcode/QR code; (b) Delivery Service Prescription Identifier (eg barcode/QR code number); (c) name of the Subject of Care (where the Evidence of Prescription is in paper form); (d) name of the prescriber; (e) name of the prescriber organisation; (f) contact details of the prescriber/organisation; (g) most recent dispenser (where the Evidence of Prescription is given by an Approved Supplier); (h) medicine name and strength; (i) date prescribed; (j) number of repeats available; and (k) a privacy notice relating to the collection of personal information by the Australian Government to support the assessment and administration of payments and services.
Healthcare Identifiers Act	<i>Healthcare Identifiers Act 2010</i> (Cth).
Mobile Application	a mobile application which can be used by a Subject of Care to manage their electronic prescriptions, manage authorised agents, forward prescription links to an online or bricks and mortar pharmacy and allow the Subject of Care to present an electronic Token to their chosen Approved Supplier.
Mobile Intermediary	software which manages communications between a PDS and a Mobile Application. In most instances the Mobile Intermediary will be the server component of the Mobile Application.
Open Prescription Delivery Service or PDS	a PDS that accommodates choice of supply by the Subject of Care.
Organisation	has the meaning given to it under section 6C of the Privacy Act.
PBS Prescriber	has the meaning given to it under the National Health Act.

TERM	DEFINITION
personal information	<p>information or an opinion about an identified individual, or an individual who is reasonably identifiable:</p> <p>(a) whether the information or opinion is true or not; and</p> <p>(b) whether the information or opinion is recorded in a material form or not.</p>
Prescriber	a PBS Prescriber or RPBS Prescriber.
Prescription Delivery Service	<p>a system through which an electronic prescription is communicated from a Prescribing System to a Dispensing System.</p> <p>There are two types of Prescription Delivery Services:</p> <p>(a) Open Prescription Delivery Service; and</p> <p>(b) Direct Prescription Delivery Service.</p>
Prescribing System	a system which facilitates the authoring of an electronic prescription by a Prescriber.
Project Description	the description of the Electronic Prescribing contained in paragraph 2 of the PIA.
RPBS Prescriber	has the meaning given to it under the Repatriation Pharmaceutical Benefits Scheme Instrument.
Sensitive Information	<p>(a) information or an opinion about an individual's:</p> <p>(i) racial or ethnic origin;</p> <p>(ii) political opinions;</p> <p>(iii) membership of a political association;</p> <p>(iv) religious beliefs or affiliations;</p> <p>(v) philosophical beliefs;</p> <p>(vi) membership of a professional or trade association;</p> <p>(vii) membership of a trade union;</p> <p>(viii) sexual orientation or practices; or</p> <p>(ix) criminal record;</p> <p>that is also personal information;</p> <p>(b) health information about an individual;</p> <p>(c) genetic information about an individual that is not otherwise health information;</p> <p>(d) biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or</p> <p>(e) biometric templates.</p>
Subject of Care	the intended recipient of the medicines described on a prescription.
Token	a piece of information (such as a barcode or Quick Response code) which is used to identify and retrieve the electronic prescription from a PDS, and which can be provided in either paper or electronic form.

Schedule 3 – Source Materials

DOCUMENT

Australian Competition and Consumer Commission Determination – Application for authorisation lodged by eRx Script Exchange Pty Ltd in respect of a Commercial Interchange Agreement with MediSecure Pty Ltd (7 March 2013).

Australian Competition and Consumer Commission Determination – Application for authorisation lodged by eRx Script Exchange Pty Ltd in respect of a Commercial Interchange Agreement with MediSecure Pty Ltd (27 September 2017).

Seventh Community Pharmacy Agreement (11 June 2020).

Australian Privacy Principles Guidelines (July 2019).

Commonwealth of Australia Administrative Arrangement Orders 5 December 2019. The Order commenced on 1 February 2020.

Australian Digital Health Agency Conformance Profile Active Script List Requirements (Draft 010).

Australian Digital Health Agency Electronic Prescribing Conformance Scheme, Version 1.4.

Australian Digital Health Agency Electronic Prescribing Participating Software Conformance Profile (Version 2.2.1).

Australian Digital Health Agency Electronic Prescribing Solution Architecture (Draft 026).

Department of Health Complete Privacy Policy (October 2020).

Department of Health Electronic Prescribing Fact Sheet.

Summary of Existing and New Regulatory Requirements for Electronic Prescriptions – *National Health (Pharmaceutical Benefits) Regulations 2017* (Cth) (prepared by the Department of Health).

Drafting instructions for amendments to the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cth) to implement Electronic Prescribing.

OAIC Guide to undertaking privacy impact assessments (May 2014).

OAIC Australian Community Attitudes to Privacy Survey 2017 (15 May 2017).

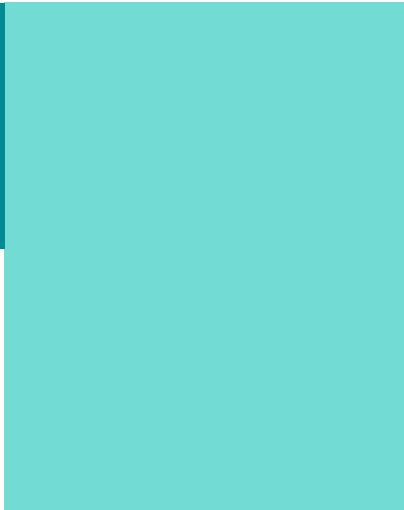
The Office of the Australian Information Commissioner, De-identification and the Privacy Act (Guide, March 2018).

Safe, seamless and secure: evolving health and care to meet the needs of modern Australia. Australia's National Digital Health Strategy.

Services Australia Privacy Policy as at 27 October 2020 including 'Collection, use and disclosure of personal information for Medicare and Health program related purposes' document.

Department of Human Services, *Healthcare Identifiers Service User Guide* (Guide, June 2016).

The Office of the Australian Information Commissioner, *Publication of MBS/PBS Data – Commissioner Initiated Investigation Report* (Report, 23 March 2018).



ashurst

www.ashurst.com