Department of Health

PBS Pharmaceuticals in Hospitals Review

Final Report

December 2017

Australian Healthcare Associates
Australia's largest specialist health and community care consultancy

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List of abbreviations

Abbreviation	Definition
6CPA	Sixth Community Pharmacy Agreement
the Act	National Health Act 1953
ACPA	Australian Community Pharmacy Authority
AHA	Australian Healthcare Associates
AHCA	Australian Health Care Agreement
APAC	Australian Pharmaceutical Advisory Council
ARTG	Australian Register of Therapeutic Goods
CAR	Complex Authority Required
CATAG	Council of Australian Therapeutic Advisory Groups
CLEMM	Closed Loop Electronic Medication Management
CSO	Community Service Obligation
CTG	Closing the Gap
the Department	Australian Government Department of Health
DHS	Department of Human Services
DTC	Drugs and Therapeutics Committee
DVA	Australian Government Department of Veterans' Affairs
EFC	Efficient Funding of Chemotherapy
EPAS	Electronic Patient Administration System
F1	Formulary One
F2	Formulary Two
GP	General practitioner
HPOS	Health Professional Online System
HPV	Health Purchasing Victoria
HSD	Highly Specialised Drug
HSQ	Health Support Queensland
IHI	Indigenous Health Incentive
IHPA	Independent Hospital Pricing Authority
IVF	In-Vitro Fertilisation
LAM	List of Approved Medicines
NHCA	National Health Care Agreement
NIMC	National Inpatient Medication Chart
NMP	National Medicines Policy
ODTP	Opiate Dependence Treatment Program
PBAC	Pharmaceutical Benefits Advisory Committee

List of abbreviations

Abbreviation	Definition
PBS	Pharmaceutical Benefits Scheme
PBS HMC	PBS Hospital Medication Chart
PIP	Practice Incentives Program
PPP	Public Private Partnership
PRA	Pharmaceutical Reform Agreement
QHMAC	Queensland Health Medicines Advisory Committee
QUM	Quality Use of Medicines
RAAHS	Remote Area Aboriginal Health Services
RPBS	Repatriation Pharmaceutical Benefits Scheme
s85	Section 85 of the National Health Act
s90	Section 90 of the National Health Act
s94	Section 94 of the National Health Act
s100	Section 100 of the National Health Act
SAMAC	South Australian Medicines Advisory Committee
SAN	Sydney Adventist Hospital
SAS	Special Access Scheme
SHPA	Society of Hospital Pharmacists Australia
TGA	Therapeutic Goods Administration

Glossary

Term	Definition
Ancillary chemotherapy item	Ancillary chemotherapy items are medicines that are used in conjunction with chemotherapy agents and include items such as antiemetics, antinauseants, immunostimulants and detoxifying agents for antineoplastic treatment.
Antimicrobial	An antimicrobial is any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of microorganisms but causes little or no damage to the host. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics.
Antipsychotic	A medicine that is used if a patient with delirium is distressed and the cause of their stress cannot be addressed and non-drug strategies have failed to ease their symptoms
Antiretroviral	A medicine used in the treatment against viruses
Approved pharmacies	Pharmacies that are approved under the Act as either a s90 community pharmacy or a s94 hospital pharmacy
Authority Required	Generally, Authority required items require telephone approval via the DHS Authority Approval Telephone Line, or online via the Health Professional Online System (HPOS). These items are prescribed using a PBS authority prescription.
Authority Required (Streamlined)	Authority required (Streamlined) items do not require telephone or written approval prior to prescribing. Rather, prescribers must include a 4-digit streamlined authority code on the authority prescription.
Biological	A biological medicine is a medicine that comes from living cells
Biosimilar	A biosimilar medicine is a highly similar version of a biological medicine
CAR HSD program	CAR HSDs are medicines that require written authority applications before prescribing
Chemotherapy	A type of cancer treatment that inhibits the reproduction of cancer cells
Closing the Gap PBS Co-payment measure	One of 14 measures in the Indigenous Chronic Disease package established to reduce the cost of PBS medicines for eligible Aboriginal and Torres Strait Islander people living with, or at risk or, chronic disease
Community Access Arrangements	The HSD Community Access Arrangements allow authorised community-based practitioners to prescribe medicines without being affiliated to a hospital. Special HSD Community Access arrangements exist for Hepatitis B medicines, antiretrovirals for HIV/AIDs and clozapine for maintenance of schizophrenia.
Compounding	The compounding of chemotherapy medicines ensures that medicines are in a ready-to-use form for the patient. It requires a sterile environment and a high level of precision in the preparation process
Day-admitted patient	A patient who is admitted and discharged from the hospital on the same date
Discharge	When an inpatient leaves the hospital and returns home or is transferred to another facility such as a nursing home
Dispensing	Dispensing is the process whereby a pharmacist prepares and issues pharmaceutical items for a patient
Dispensing doctor	A general practitioner who is approved to supply PBS medicines to the public under section 92 of the National Health Act, where there is no pharmacist approved to do so in that particular area

Glossary

Term	Definition
Dual-listed	A drug that is listed under both s85 and s100 of the Act which allows it to be prescribed and dispensed in both a community and hospital setting
Excipients	An inactive substance that is used in the preparation of medicines for long-term stabilisation, to bulk up formulations or confer a therapeutic enhancement of the active ingredient
Formulary	A formulary is a list of medicines that are approved to be prescribed for use in a particular hospital or in a particular health system
Health technology assessment	Assesses the quality, safety, efficacy, effectiveness and cost effectiveness of new medicines
High-cost medicine	Highly individualised medicines such as biologics and chemotherapy drugs. Note that currently there is no agreed definition of what constitutes a high-cost drug in Australia
Highly Specialised Drugs program	The HSD program provides access to medicines for the treatment of chronic conditions that have restrictions on where they can be prescribed and supplied due to their clinical use and other special features
Imprest	A generic term that encompasses the medication supply kept in hospital wards for inpatient use
Inpatient	Patients that are formally admitted to a hospital for treatment
Medication chart	Prescribing of medication for inpatients of a hospital are written on these charts and can be supplied by Imprest or via the hospital pharmacy
Non-CAR drug	A HSD that is not a complex authority required drug
Outpatient	An outpatient sees a specialist who determines the most appropriate course of treatment
Patient co-payment	The portion of the bill for medication or services that a patient is required to pay out-of-pocket, determined by their level of private health insurance cover
Price disclosure	A component of the PBS reforms of August 2007 which progressively reduces the price of some PBS medicines which are subject to competition
Procurement	Procurement is the process of finding goods or services from an external source, often via a tendering process
s85	Most PBS medicines are dispensed by community pharmacies and used by patients at home. These are known as 'General Schedule' or 'section 85' medicines because they are dispensed under s85 of the National Health Act
s90	Under s90 of the National Health Act, community pharmacies require s90 approval to supply medicines
s94	Under s94 of the National Health Act, hospital authorities require s94 approval to supply medicines
s100	Under s100 of the National Health Act some PBS medicines are supplied through special arrangements where normal supply through community pharmacies is not suitable. For example, some medicines may require special storage or dispensing, specialist monitoring during treatment, or administration in a hospital outpatient setting. Such medicines are subsidised on the PBS under a number of 'Section 100' programs
Supply	Supply is the act of supplying or providing a good or service

1. Executive summary

1.1. Introduction

Australia's Pharmaceutical Benefits Scheme (PBS) provides reliable, timely and affordable access to a wide range of medicines for all Australians.

Over the past six decades, the PBS has evolved from supplying a limited number of 'life saving and disease preventing drugs' free of charge to the community to providing almost 1,000 subsidised drugs, available in more than 2,500 forms, and marketed under more than 5,500 different brands (Australian Government Department of Health 2017a).

The PBS has also expanded from providing subsidised medicines purely within the community pharmacy setting to delivering medicines in public and private hospital settings (Australian Government Department of Health 2017b). The proportion of PBS medicines that are used in hospitals has grown to be more than an estimated 20% of PBS expenditure, and is expected to continue to increase with the anticipated future listings of high-cost medicines. Not all high-cost medicines are Highly Specialised Drugs (HSDs), however, HSDs are of particular interest in this context, with more than $1.55 billion spent on HSDs in 2015-16. Of all HSD expenditure, 73% was spent in public hospitals, 21% in private hospitals and 6% in community pharmacies (Australian Government Department of Health 2017a).

The expansion and operation of the PBS is supported by a range of enabling laws, regulations, agreements, and policy frameworks. These include the *National Health Act 1953* (the Act) which lists medicines subsidised under the PBS and defines the pharmacies that can prescribe medicines. PBS benefits are provided for medicines listed in the Act under Section 85 (General) and Section 100 (Special Arrangements).

In Australian public and private hospitals, medicines are supplied by a hospital pharmacy (authorised under Section 94 of the Act), or a community pharmacy (authorised under Section 90 of the Act).

The Australian Government Department of Health (the Department) introduced bilateral Pharmaceutical Reform Agreements (PRAs) from 2001 to support the implementation of the PBS in hospitals, and these agreements are now in place with all states and territories except New South Wales and the Australian Capital Territory. The PRAs permit approved public hospitals to prescribe and dispense PBS-subsidised medicines, chemotherapy drugs and highly specialised drugs to day-admitted patients, outpatients, and patients upon discharge (Department of Human Services 2016).

1. Executive summary

1.1.1. Review objectives

In April 2017, the Department engaged Australian Healthcare Associates (AHA) to conduct a review of issues relating to PBS benefits in private and public hospitals.

The overall purpose of the review is to provide the Department with insight and understanding as to how the PBS and its sub-programs are used in the supply of medicines in public and private hospitals in Australia.

The specified aims of this review are to:

- Describe and profile the various arrangements used to procure, purchase, prescribe, dispense, and claim PBS benefits in public and private hospitals
- Report on operational issues faced by states and territories and private hospital operators in relation to PBS benefits in hospitals
- Assist in the preparation of options for alternative risk-sharing arrangements between the Commonwealth and public and private hospital operators to contribute to PBS sustainability.

1.1.2. Method

A mixed-methods approach was used to conduct the review and included:

- A literature and document review
- Stakeholder consultation, including in-depth interviews with:
  - Commonwealth and state and territory government representatives
  - Public hospital and private hospital pharmacy providers
  - Industry stakeholders
- Comparative analysis of the price paid by stakeholders for high-cost medicines
- Case studies from state and territory health departments and public and private hospital pharmacies.

1. Executive summary

1.2. Summary of key findings

1.2.1. PBS arrangements in hospitals are complex and varied

A range of factors affect how the PBS is utilised in any particular hospital, including:

- Type of pharmacy (Section 90 (s90) community pharmacy or Section 94 (s94) hospital pharmacy)
- Type of hospital (public or private hospital)
- Type of patient
- Presence/absence of a Commonwealth/state or territory PRA for public hospitals
- PBS rules
- Patient choice
- Co-payment issues.

The interplay of these factors means that there is considerable variability and complexity in the procurement and utilisation of PBS medicines in Australian hospitals. In particular, there is significant variation in approaches to procuring PBS medicines across hospitals; but there are also significant differences in prescribing, dispensing and claiming models.

1.2.2. A range of operational issues exist

Consultations with stakeholders identified a number of issues in key areas of focus. These are summarised below, with options for consideration that could improve the operation of the PBS in hospitals across Australia. Suggestions made by stakeholders are highlighted in boxes under each issue. AHA was not engaged to assess the feasibility or desirability of these suggestions but to identify the issues.

Issue 1: National supply shortages

Stakeholders considered medicine shortages a significant issue. While this is not a new issue, the consistent message was that supply shortages had worsened in recent years. Specifically, stakeholders noted that supply shortages negatively affect:

- Clinical care, through substitution of less effective medicines or changes in the route of administration
- Pharmacist time and resources in sourcing alternative supplies
- The cost of medicines to hospitals (increased)
- Patient quality use of medicines where the most suitable medicines for a patient were not available
- Rural and remote supply, particularly in delays in supply when normal supply chains cannot provide medicines.

1. Executive summary

Stakeholders suggested that supply shortage issues could be addressed through a national approach, potentially including a national medical stockpile of medicines with high domestic demand, or a model in which medicines are produced locally for use in Australia.

Issue 2: Medicine assessments and PBS listings

Based on an application from a sponsor, the Pharmaceutical Benefits Advisory Committee (PBAC) assesses a medicine's clinical effectiveness, safety and cost-effectiveness compared with other treatments, and advises the Minister for Health on its listing on the PBS. Stakeholders noted that in the hospital context, there are a range of medicines that are either not listed on the PBS, or are approved by PBAC under specific clinical guidelines, but used in hospitals in other ways. For example, in different dose levels, alternative routes of administration or in use with patients or conditions outside the PBAC information guidelines.

Some states also conduct health technology assessments for medicines to determine the use of these medicines in public hospitals. This may include health technology and/or cost effectiveness assessments for listed PBS medicines to approve their use in public hospitals.

States and territories saw value in greater consultation in the PBS assessment and listing process, particularly for high cost medicines. While states and territories have previously had greater access to PBAC assessment documents, more information is now being redacted for confidentiality reasons, reducing the usefulness of the available information. Further, the only current mechanism for state/territory input into PBAC review of future PBS listings is through general public access on the PBAC website.

Stakeholders suggested that to improve the process of assessing medicines, the Australian Government could consider developing:

- A dedicated and formal mechanism for state and territory input to PBAC decisions regarding new listings
- A national approach to horizon scanning for emerging medicines and to conducting medicine assessments for the acute sector.

Issue 3: Implications of new PBS listings

Stakeholders noted that hospitals sometimes had limited notice prior to a medicine listing on the PBS. This perceived lack of notice was reported to impact a hospitals ability to facilitate clinical and cost-effectiveness assessments, establish procurement and supply arrangements and consider the impact of changes on hospital administration, including IT processes and training for medical staff. Greater engagement with the hospital sector, as well as sufficient advance notice, would assist hospitals to make implementation arrangements.

1. Executive summary

Stakeholders reported that PBS prescribing indications generally matched standard treatment expectations. However, greater flexibility in prescribing indicators and quantity is an issue for many hospital patients, particularly those with serious health conditions.

Stakeholders suggested that to address these issues, the Australian Government could consider:

- Introducing a more systematic way to consider the implications of new PBS listings for hospitals
- Facilitating greater engagement between the Department and the states and territories, especially prior to new high-cost PBS listings, to inform the process of implementation.

Issue 4: Unwieldy PBS authority processes

PBS authority processes are difficult for hospital prescribers to navigate due to multiple listings of pharmaceutical items for different indications. Stakeholders reported that it is often difficult to know which streamlined authority code to use, and they are perceived to change frequently.

Stakeholders expressed concern over the relatively long turnaround timeframes (up to six weeks) for Complex Authority Required (CAR) medicines.

Stakeholders suggested that the Australian Government could consider a more streamlined approach to PBS authority processes.

Issue 5: Consistency of information technology infrastructure implementation

The perceived benefits of electronic prescribing include administrative efficiency and improvement in accuracy and medication safety (through the elimination of handwritten scripts).

As hospitals move towards implementing the PBS Hospital Medication Chart (PBS HMC), integration of electronic prescribing upon discharge is considered essential.

While stakeholders suggested that electronic medication charts would be beneficial for hospitals, they highlighted that end-to-end digitisation is a major piece of work requiring a regulatory framework to enable change as well as input from Commonwealth and state/territory governments.

Stakeholders suggested that the Australian Government could consider developing the regulatory electronic prescribing framework in consultation with the states and territories.

Issue 6: Differential PBS reimbursement fees

The review highlighted that public hospitals, private hospitals and community pharmacies receive different reimbursements for similar activities. This is due to a number of factors, including differences in s90 and s94 hospital pharmacy fees, compounding fees and hospital wholesaler mark-up

arrangements. For example, private hospital pharmacies are eligible to receive mark-ups and dispensing fees that public hospitals are not eligible for; community pharmacists receive a dispensing fee that is not provided to hospital pharmacists; and compounding preparation fees differ and can only be reimbursed for chemotherapy compounding.

Stakeholders noted that medicines that necessitate clinical services (e.g. patient review, interpretation of pathology results, managing treatment cycles, etc.) are often dispensed in a hospital setting and were concerned about the sustainability of these services.

Currently, public hospitals are remunerated for Section 85 (s85) dispensing at the ex-manufacturer price, plus a wholesaler mark up of 11.1%, but no dispensing or other fees. At the time of establishing the wholesaler mark-up, the 11.1% was the community rate. For many low-cost medicines, this percentage on-cost is small. However, this has caused concern for the Australian Government for high-cost medicines such as dispensing s85 scripts for high cost Hepatitis C treatments.

Stakeholders perceived that the differentials in fees can result in a lack of fairness, equity and provides for potential gaming of the system.

Stakeholders made a range of suggestions to improve fairness, equity and system efficiency and address the variation in PBS reimbursement fees to that the Australian Government could consider. These included:

- Aligning the mark up and dispensing fees
- Further discussing the issue of hospital wholesaler mark-up of 11.1% with relevant stakeholders
- Considering tiered fees that reflect the complexity of pharmacy services to ensure the sustainability of delivering cognitive medication review and appropriate access to medications.

Issue 7: Script transferability and confusion about where scripts can be filled

The approval status of pharmacies in public hospitals (s94 hospital authority or s90 community pharmacy) determines what scripts can be dispensed. Hospitals face issues where patients present with scripts that they cannot dispense. For example, s94 approved hospital pharmacies cannot dispense community scripts for PBS items or PBS scripts from another hospital if the patient is not a patient of that hospital. Section 100 (s100) HSD non-CAR scripts that are written in an approved public hospital can only be filled by an approved public hospital s94 pharmacy and are not transferrable to s90 community pharmacies or s94 private hospital pharmacies. s100 HSD non-CAR private hospital scripts can be claimed by either a s94 private hospital pharmacy or s90 community pharmacy.

This limits medicine access for patients, and causes confusion and frustration for patients as it inhibits patient-centred care.

Public hospitals encouraged discharge patients and outpatients to have their scripts dispensed in a community pharmacy as part of a strategic decision which reflected their clinical priorities. Public hospitals also reported that even if they were permitted to dispense community scripts, they did not

have the capacity to dispense community scripts. Some public hospitals, however, saw a potential benefit to dispensing community or general practitioner (GP) scripts in specific circumstances, including:

- Rural and remote communities where there are no private pharmacies in the area
- Where local pharmacies do not stock high-cost drugs because of the financial risk to the pharmacy and where these medicines are only available at the hospital
- Where residential aged care beds are co-located within a public hospital, but scripts written by a visiting GP are unable to be dispensed at the s94 hospital pharmacy and had to be taken off-site to a community pharmacy, creating an unnecessary delay.

Stakeholders suggested that the Australian Government could consider streamlining approval arrangements to facilitate transferability of scripts and improve access for patients.

Issue 8: No direct access to required Medicare information

Hospitals who access PBS Online valued the efficiencies that PBS Online has provided. However, both public and private hospitals reported administrative time, complexity, and cost in accessing required patient information to prepare a PBS claim, including checking a patient's Medicare card number and retrieving information on a patient's PBS safety net limit.

The current lack of access to patients' PBS safety net information causes problems in determining patient co-payments to enable correct billing.

Stakeholders suggested that as PBS claiming is now completed online, information on patient safety net limits and the amount spent on medications could be linked to a patient's Medicare card to determine if a patient is eligible for a concession.

Issue 9: Complexity of PBS arrangements

Decisions affecting the operations of the PBS (including the number of medicines, the range of medicines, the number of brands on the PBS) reportedly put considerable pressure on hospitals. New PBS listings or changes in PBS business rules impact on clinical prescribing, hospital pharmacy and administration arrangements.

Stakeholders are concerned about the overall complexity of arrangements related to meeting the different business rules associated with the various PBS subprograms, including but not limited to the s100 HSD Program and the s100 Efficient Funding of Chemotherapy (EFC) special arrangements.

The dual listing of some medicines under both s85 and s100 of the Act creates complexity, as the same medicine may have different authorised prescribers or prescribing requirements depending on the program through which it is prescribed and can create claiming errors where medicines should have been dispensed at the s85 or s100 remuneration rate.

1. Executive summary

To reduce complexity, stakeholders suggested simplifying business rules and arrangements particularly in relation to the HSD Program and the EFC special arrangements.

In relation to the dual listing of items, stakeholders suggested removing s100 medicines as a category and to review the listing of medications on s85 to ensure it covers the clinical conditions and uses currently specified under s100. Alternatively, to remove the dual listing of items, s100 medicines could be re-categorised as high cost, high risk and/or medicines requiring specialist input to prescribe.

Issue 10: Funding of Chemotherapy

Generally, stakeholders considered the EFC program to be valuable in ensuring equitable patient access to chemotherapeutic agents across the public and private sectors. Two key issues related to chemotherapy in the context of the PBS were raised.

No chemotherapy agents are eligible for subsidy under the PBS for inpatients, as inpatients are state/territory funding responsibility. Public hospitals indicated that they are sometimes unable to fund treatment with expensive medicines without PBS support. States and territories would find it helpful for PBS support for expensive medicines, such as blinatumomab.

Ancillary chemotherapy items are medicines that are used to manage the side effects of chemotherapy. They include items such as antiemetics, antinauseants, immunostimulants and detoxifying agents for antineoplastic treatment. Some ancillary chemotherapy items represent a significant expense to hospitals. Patients usually receive their treatments as part of a treatment regime. Same-day prescribing is particularly prevalent in practices that use a computerised oncology management system. The management system stores details of chemotherapy regimes which may involve multiple days of treatment in each cycle (e.g. days 1, 8 and 15 in a 21 day cycle). The entire cycle will be prescribed on one occasion, and when day 8 and day 15 are dispensed) but can be claimed only for the day of prescribing as they are precluded from the same-day prescribing rules. This means that subsequent dispensing of these ancillary chemotherapy items from the first day of prescribing within a course of treatment is not funded under the PBS. Hospitals reported that some inexpensive ancillary chemotherapy items are dispensed as non-PBS items. However, there are other ancillary items that carry significant value.

The suggestion is for same day ordering of ancillary items which means that the date of administration, rather than the date of prescribing, should be what is entered in to the dispensing software. This would allow for claiming of second and subsequent doses of ancillary items in a course of chemotherapy treatment.

There is evidence of a shift away from public hospital chemotherapy services, towards private hospital and day procedure centres. Public hospitals reported that this raised long term sustainability issues for public chemotherapy services. Notwithstanding the public hospital issue, private hospitals also reported the long-term funding of chemotherapy medicines as important.

1. Executive summary

Stakeholders suggested that to improve access to chemotherapeutic agents and ancillary items, the Australian Government could consider revisions to the EFC program to:

- Expand the range of eligible chemotherapy agents
- Facilitate same-day ordering for ancillary chemotherapy items to facilitate PBS claiming.

Issue 11: Inconsistent access rules for the Aboriginal and Torres Strait Islander population

Aboriginal and Torres Strait Islander people can receive health care through Aboriginal Health Services and may be eligible to access more affordable medications through the Closing the Gap (CTG) PBS co-payment measure or s100 Remote Area Aboriginal Health Services (RAAHS) program.

Hospital-based prescribers are unable to provide CTG prescriptions unless they are a specialist treating a patient who has been referred by a GP working out of a general practice participating in the Indigenous Health Incentive (IHI) under the Practice Incentives Program (PIP).

Under the RAAHS Program, Aboriginal Health Services in remote locations are approved to provide free PBS medicines without a prescription to their patients (see *Section 6.5.1* for more details). Stakeholders reported that issues arise when patients require hospitalisation, receive outpatient treatment, or visit locations which are away from their community. In such circumstances, clients are expected to obtain a PBS prescription, attend a community pharmacy, and pay the PBS patient co-payment for their medicine. This can be very confusing for RAAHS clients and may result in poor medication compliance when a patient cannot afford the co-payment amount.

Stakeholders suggested that to improve access to PBS medicines for Aboriginal and Torres Strait Islander people, the Australian Government could consider:

- Extending the ability for all hospitals to prescribe under the CTG program to discharge patients and outpatients
- Facilitating registration of patients' CTG eligibility through their Medicare or Centrelink cards.

Issue 12: Lack of prisoner access to the PBS

Prisoners are generally the responsibility of states and territories; however, a provision has been made for prisoners to access s100 HSDs under the PBS. The provision of medical services and health care to prisoners is possible under state and territory enacted legislation that facilitates the administration of corrective service facilities. A number of care models provide treatment for prisoners, including being an outpatient of state public hospital clinics; being an inpatient of on-site corrective service health clinics or being supplied medicines via State/territory-operated services.

There are reports that private operators of prisons cannot claim s100. An example was given whereby a private hospital has to claim on behalf of the private operator and then be reimbursed later. Another issue that was noted by stakeholders was the initial listing of the new treatments of Hepatitis C under s85 only. As prisoners only have access to s100 HSD medications, this created concern that the prison

population would not have access to treatment. Stakeholders noted that the listing of new expensive medications requires consideration of the administrative and financial burden on health care providers in all settings.

> Stakeholders suggested that inconsistencies with current arrangements that limited access to s100 HSDs in prison populations be reviewed.

Issue 13: Costs associated with the involuntary admitted mental health patient population

Each state and territory in Australia has a Mental Health Act that enables detainment of people with severe mental health conditions for care and treatment, without their consent. Stakeholders reported that considerable cost is associated with supplying medications for the treatment of these patients. Public hospitals reported that as these patients are classified as inpatients, they cannot claim under the PBS.

The view of one state was that the reimbursement of inpatient costs is a barrier to treatment for forensic mental health patients with Hepatitis C. This patient population was contrasted to prisoners who are able to access the s100 HSD program.

> Stakeholders suggest that the Department consider facilitating access to the s100 HSD program for the involuntary admitted mental health patient population.

Issue 14: Review of Pharmaceutical Reform Agreements needed

The bilateral PRAs were introduced as a variation to the Australian Health Care Agreement (AHCA) between the Australian Government and states and territories, with the objective of reforming pharmaceutical services available to patients of public hospitals and improving the continuum of care for patients leaving hospital.

The PRA states and territories are strong supporters of the PRA and its continuation in their jurisdictions. However, two jurisdictions (NSW and ACT) have not agreed to sign the PRA. Some stakeholders noted that this may have resulted in inadequate care for patients living in non-adopter states of PRAs who require EFC medicines, or who are discharged with smaller supplies of medication (usually for seven days) compared to PRA states who are able to prescribe up to 28 days of medication.

Overall, stakeholders perceived key benefits of PRAs to include:

- Access to the PBS for non-admitted patients and admitted patients upon discharge from public hospitals
- Supply of s100 chemotherapy medications to day admitted and non-admitted public hospital patients
- Adoption of the Australian Pharmaceutical Advisory Council (APAC) guidelines on the continuum of pharmaceutical care between hospitals and the community, enabling hospitals to prescribe up to 28 days of medications under the PBS for the discharged patient and to ensure the quality

use of medicine and clinical pharmacy activities an improved continuum of care for patients and patient-centred care

- Improved quality use of medicines
- Hospital access to the PBS, employment of clinical pharmacists and the provision of clinical pharmacy services.

PRAs were progressively signed with states and territories between 2002 and 2010. Variations exist in the agreements across states and territories. Over time, Agreements were changed to clarify that hospitals can both prescribe and dispense PBS medicines to public hospital patients (other than in-patients).

States and territories felt that the agreements were now outdated, and it was timely to review and update the PRAs. The value of the risk sharing ceiling included in current PRAs (designed to set a level of expenditure at which risk-sharing arrangements between the state/territory and the Australian Government would be activated) was questioned with the exclusion of Hepatitis C medications from the calculations. States noted that Department of Health reporting on risk sharing levels is delayed and received well after hospital budgets are finalised, making it difficult to adjust budgets if required. There were some misconceptions that have arisen from different definitions of the PRA arrangements that exist in the PRAs and the National Health Reform Agreement.

All stakeholders considered that a forum which involved health department representatives and chief pharmacists would be beneficial, given the increasing use of the PBS in the hospital setting. States and territories are keen to engage with the Department prior to the implementation of PBS listings, where these listings have a direct impact on hospitals.

Public hospital stakeholders noted that the dual funding of medicines by the Commonwealth and state/territory governments creates duplication in systems and some suggested that a single funder model could reduce this duplication. Stakeholders acknowledged that this is part of a larger reform discussion.

Stakeholders suggested that to improve the implementation of the PBS in public hospitals, the Australian Government could consider:

- Facilitating timely review and update of existing PRAs
- Facilitating a forum involving states and territories and hospital pharmacists
- Developing a single funder model of medicines in public hospitals. Stakeholders acknowledged that this is part of a larger reform discussion and an alternative could be to provide the opportunity to utilise the PBS inside hospitals (without the duplication of payments) thereby leading to safety and financial improvements.

2. Background

2.1. Introduction

This chapter provides the background context for the review of access to PBS medicines in public and private hospitals in Australia. It presents an overview of:

- The evolution of the PBS
- Legislation that supports PBS operation
- Policies that support PBS operation
- Agreements that support PBS operation
- The PBS in practice
- Financing the PBS.

This background is based on:

- Documents provided by the Australian Government Department of Health, state and territory health departments, hospitals, and industry organisations
- An environmental scan and literature review
- Interviews and hospital case studies.

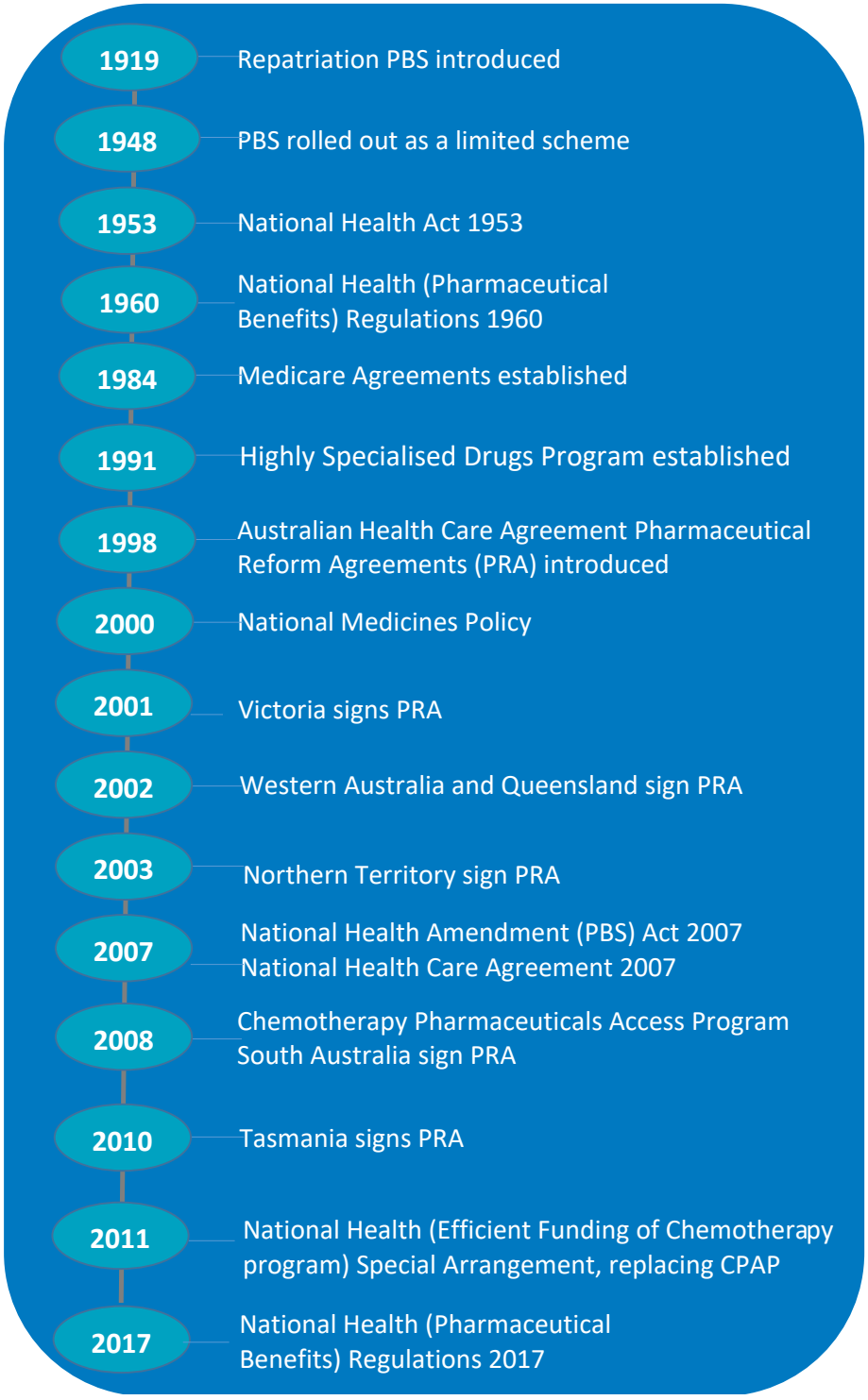
Following the background context, a description of the review method is provided.

2. Background

2.2. Evolution of the PBS

The supply of subsidised prescription medicines through the PBS is a fundamental component of Australia's National Medicines Policy (NMP), designed to provide timely access to medicines for the Australian community. A summary of legislative and policy instruments relevant to this review is presented in *Figure 2-1*.

Figure 2-1: PBS timeline – legislative and policy instruments summary



2. Background

Over the past six decades, the PBS has evolved from supplying a limited number of 'life saving and disease preventing drugs' free of charge to the community, to providing almost 1,000 subsidised medicines, available in more than 2,500 forms, and marketed as over 5,500 different brands (Australian Government Department of Health 2017a).

The PBS has also expanded from providing subsidised medicines purely within the community pharmacy setting to delivering medicines in public and private hospital settings (Australian Government Department of Health 2017b). This expansion has been supported by a range of enabling laws, regulations, agreements, and policy frameworks, including:

- *National Health Act 1953* (the Act)
- *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations)
- *Private Health Insurance Act 2007*
- *National Medicines Policy 2000* and guiding principles to achieve continuity in medication management
- National Health Reform Agreements and the bilateral PRAs
- PBS Special Arrangements under s100 of the Act, including the HSD and EFC programs
- *Sixth Community Pharmacy Agreement* (6CPA), which funds a range of community pharmacy programs.

Benefits are provided under the Act for 'the provision of pharmaceutical, sickness and hospital benefits, and of medical and dental services'. The PBS currently operates within the framework of the Act, together with the Regulations made under the Act and the *Private Health Insurance Act 2007.*

For the purposes of this review, a further discussion of several of these pieces of legislation is included, to provide background for some of the issues raised by stakeholders in later chapters of the report. The legislation discussed is:

- The Act, with specific focus on Part VII—Pharmaceutical benefits
- National Health (Highly specialised drugs program) Special Arrangement 2010, established under s100 of the Act
- National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011, established under s100 of the Act.

2. Background

2.3. Legislation that supports PBS operation

2.3.1. *National Health Act 1953*

Part VII—Pharmaceutical Benefits includes sections which detail the type of:

- PBS medicine listings that exist
- Pharmacies approved to supply PBS medicines.

Listing of medicines on the PBS

Benefits are provided for PBS medicines listed under s85 (General Schedule) and s100 (Special Arrangements) of the Act:

- **s85 items** are medicines that are mainly dispensed by community pharmacies and include commonly used medicines such as those for the treatment of diabetes, asthma, depression and infections (Harvey & de Boer 2015). These medicines make up the majority of expenditure (approximately 75%) on the PBS (Australian Government Department of Health 2016a).
- **s100** details alternative arrangements for the provision of a range of PBS medicines, when alternative arrangements are deemed appropriate, e.g. for people living in isolated areas, people receiving treatment in circumstances in which the pharmaceutical benefits are inadequate for the diagnosis, or where the pharmaceutical benefits can be more conveniently or efficiently supplied under a special arrangement (Australian Government 2015).

Key arrangements relevant for this Review include the following programs:

- HSD
- EFC
- Botulinum Toxin
- Growth Hormone
- In-Vitro Fertilisation (IVF)
- Opiate Dependence Treatment Program (ODTP)
- RAAHS.

Note that a medicine may be dual listed under both s85 and s100, that is, it may be prescribed and dispensed in both a community and hospital setting. Dual listing can occur where there is a difference in how the medicine is used and/or the maximum quantity or number of repeats allowed when dispensed in a community setting (s85) and a hospital or community access setting (s100).

Before being listed in either s85 or s100, a medicine must first be registered on the Australian Register of Therapeutic Goods (ARTG) and available for sale in Australia. In order to be registered on the ARTG, a medicine sponsor must apply to the Advisory Committee on Prescription Medicines, a committee of the Therapeutic Goods Administration (TGA), and the medicine must be assessed for its safety, quality and efficacy. Criteria for consideration for registration are specified in the *Therapeutic Goods Act 1989.*

2. Background

Sponsors are usually the pharmaceutical companies that manufacture the medicines, but can also be medical bodies, health professionals, private individuals, and their representatives.

Once a medicine is listed on the ARTG, the sponsor may also apply to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS. Criteria for listing a medicine on the PBS are specified in the Act, including a requirement to provide Cost of Goods Information at the time of submission to PBAC. Listing medicines on the PBS can be a lengthy and costly process and not all sponsors elect to do so.

The PBAC assesses the evidence on the medicines effectiveness for a particular condition, including its cost effectiveness, and advises the Minister for Health if the medicine should be listed on the PBS. In some cases, high-cost medicines may also require Cabinet approval. Once the Minister approves the medicine, it is then listed on the PBS. PBS listings include approved product information that specify the uses of that medicine as recommended by PBAC.

In circumstances where patients need access to therapeutic goods that are not on the ARTG, or where medicines cannot be sourced in Australia, medical practitioners may apply to the TGA Special Access Scheme (SAS) for approval to import and/or supply unapproved medicines for individual patients on a case-by-case basis. The SAS includes a notification pathway that allows hospitals to supply goods without prior approval where these medicines are deemed to have an established history of use. The Australian Government does not provide funding for medicines supplied through the SAS.

Approved pharmacies

All pharmacies in Australia must be approved under the Act as either:

- s90 community pharmacies
- s94 hospital authorities.

Section 90 community pharmacies approval

Under s90 of the Act, approved pharmacists are permitted to supply pharmaceutical benefits to consumers with a valid PBS prescription and a Medicare card at particular premises (Australian Government 2015). Section 90 pharmacies are predominantly community based; however, some provide hospital pharmacy services under contract to private hospitals (Ryan 2011). Some public hospitals also have community pharmacies on site as well as a s94 hospital pharmacy.

The location of community pharmacies is determined by the Minister for Health in a legislative instrument made under s99L of the Act (the Pharmacy Location Rules). The Pharmacy Location Rules reflect the agreement reached between the Commonwealth and the Pharmacy Guild of Australia under the 6CPA. Location-based criteria must be met prior to approval of a pharmacist (Australian Government Department of Health 2015). Approval is required:

- To establish a new pharmacy
- To relocate an existing pharmacy
- To expand or contract the size of an existing pharmacy
- To change the address of an existing pharmacy, even if the premises have been renumbered

- To change the ownership of an existing pharmacy, including changes resulting from the death of an owner.

The Australian Community Pharmacy Authority (ACPA) advises the Secretary of the Department of Health on whether approval should be given to a pharmacist in relation to an application to establish a new pharmacy or relocate an existing pharmacy. The ACPA meets once a month to consider applications against the Pharmacy Location Rules. The process of approval for s90 pharmacies is shown in *Figure 2-2.*

Section 94 hospital pharmacies approval

Under s94 of the Act, approvals are provided to hospital authorities rather than individual pharmacists. Approved hospital authorities can supply pharmaceutical benefits only to patients receiving treatment in or at the hospital (Australian Government 2015).

In order to be approved, a hospital must be deemed a hospital under subsection 121-5(6) of *the Private Health Insurance Act 2007*. Each hospital campus is required to have its own s94 approval.

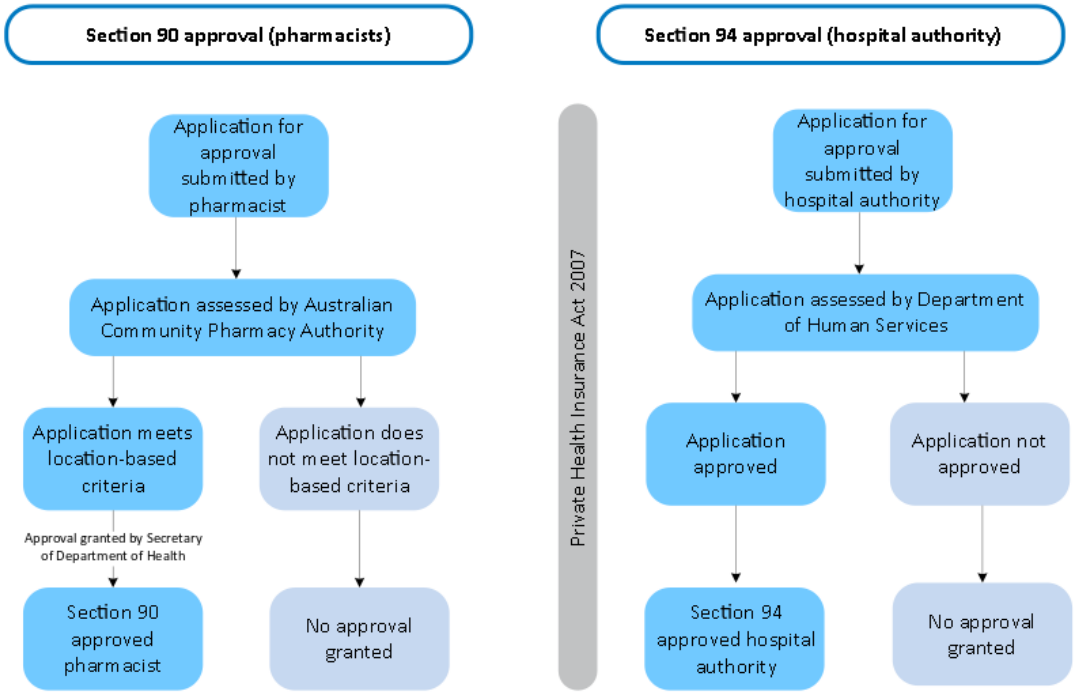
Section 94 approvals are managed by the Department of Human Services (DHS) and are not subject to the Pharmacy Location Rules. Before a public hospital pharmacy applies to DHS for s94 approval, they must first be approved by the relevant state or territory health department. Similarly, private hospital pharmacy departments need to be approved by the relevant statutory body in their state or territory, e.g. the Victorian Pharmacy Authority.

A common arrangement for private hospitals is to gain s94 approval and engage a contracted pharmacy service provider to operate the pharmacy. The pharmacy then uses the s94 approval to claim payment from the DHS for pharmaceutical benefits supplied to patients (Ryan 2011).

Figure 2-2 compares the approval process for s90 and s94 pharmacies.

2. Background

Figure 2-2: Summary of approval processes under s90 and s94 of the National Health Act



PBS Reform 2007

In June 2007, a significant restructure of PBS pricing arrangements under the Act was implemented to ensure the long-term sustainability of the PBS (Australian Government Department of Health and Ageing 2010). This restructure was termed the 'PBS reform' under the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*. The PBS reform involved a number of measures that shape current PBS operations, including:

- The creation of two separate formularies on the PBS:
  - Formulary One (F1) for medicines with only one brand
  - Formulary Two (F2) for medicines that have two or more brands listed on the PBS
- The introduction of a system of price disclosure for all F2 medicines
- A change to the pharmacy mark-up structure
- An increase to the Community Service Obligation (CSO) funding pool for pharmacy wholesalers.

2.3.2. National Health (Highly specialised drugs program) Special Arrangement 2010

The *National Health (Highly specialised drugs program) Special Arrangement 2010* provides the legislative framework for the HSD Program. HSDs are subsidised through the PBS under s100 of the *National Health Act 1953*. The program provides access to medicines for the treatment of chronic conditions that have restrictions on where they can be prescribed and supplied due to their clinical use and other special features (Australian Government Department of Health 2017c).

2. Background

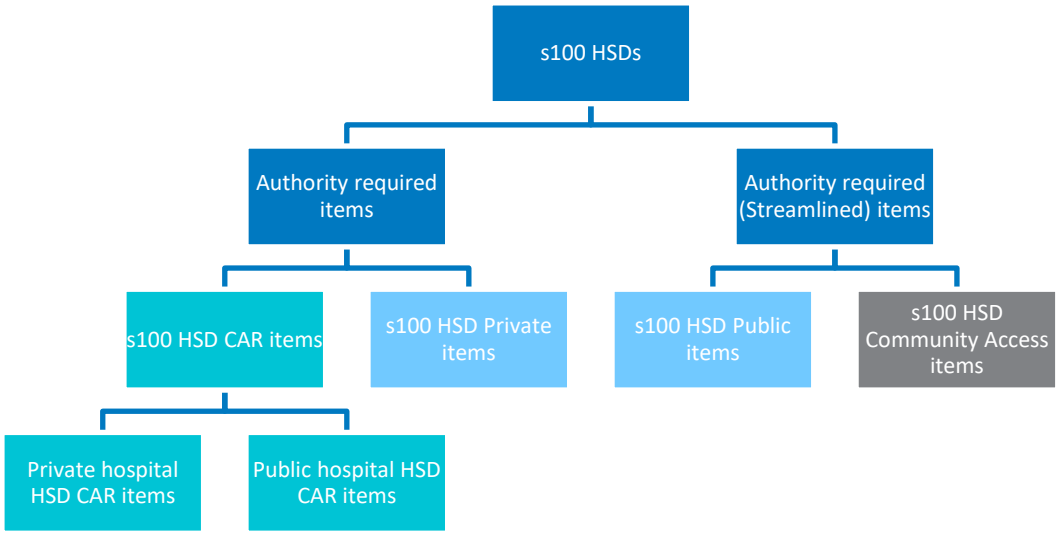
There are different requirements for gaining authority approval and dispensing, depending on the medicine and the setting of the prescriber.

HSDs are classified as Complex Authority Required (CAR) medicines or non-CAR medicines. CAR medicines require written authority approval from DHS Tasmania. Non-CAR HSDs are listed under the PBS Schedule as Authority required items, or Authority required (Streamlined) items:

- Generally, **Authority required items** require telephone approval via the DHS Authority Approval Telephone Line, or online via the Health Professional Online System (HPOS). These items are prescribed using a PBS authority prescription.
- **Authority required (Streamlined) items** do not require telephone or written approval prior to prescribing. Rather, prescribers must include a 4-digit streamlined authority code on the authority prescription.

The listing determines the type of approval that is required and varies depending on the type of HSD program the medicine falls under (see *Figure 2-3*).

Figure 2-3: PBS Schedule listings under the HSD program



HSD Sub-Programs

As discussed, HSDs are listed as Authority required items or Authority required (Streamlined) items. HSDs are also listed in the PBS Schedule under the following programs (see *Figure 2-3*).

- HSD Program (Private Hospital), identified in the Schedule as s100 HSD Private items
- HSD Program (Public Hospital), identified in the Schedule as s100 HSD Public items
- HSD Program (Community Access), identified in the Schedule as s100 HSD Community Access items.

2. Background

It should be noted that some items are dual listed under the HSD program and in the general Schedule (as s85 items). In some cases, these dual items may be for the same medication but listed with different restriction criteria (see *Section 6.2*).

The complex arrangements for PBS HSD program listings in the PBS schedule, approval processes and dispensing are summarised in *Table 2-1*.

Table 2-1: Summary of PBS HSD programs

	Authority required items		Authority required (Streamlined) items	
HSD listing	**S100 HSD items (CAR)**	**s100 HSD items (Private hospital)**	**s100 HSD items (Public hospital)**	**S100 HSD items (Community Access)**
Approval process	• Written application to DHS • Authority Approval Telephone Line (limited circumstances)	• Authority Approval Telephone Line • HPOS	• 4-digit streamlined authority code • For quantities and/or additional repeats, item treated as an Authority required item	• 4-digit streamlined authority code • For quantities and/or additional repeats, item treated as an Authority required item
Type of PBS stationery	• PBS authority prescription • PBS public hospital prescription	• PBS authority prescription	• PBS authority prescription • PBS public hospital prescription • Approved hospital medication chart	Public hospital: • PBS authority prescription • PBS public hospital prescription • Approved hospital medication chart Private hospital/ Community setting: • PBS authority prescription
Dispensing	Public hospital HSD CAR items: • s94 approved public hospital authorities • s90 approved pharmacists Private hospital HSD CAR items: • s94 private hospital authorities • s90 approved pharmacists	• s94 approved private hospital authorities • s90 approved pharmacists	• s94 approved public hospital authorities	Public hospital script: • s94 approved public hospital authorities • s90 approved pharmacists Private hospital script: • s94 approved private hospital authorities • s90 approved pharmacists Community script: • s90 approved pharmacists • Dispensing doctor

2. Background

HSD Program (Public Hospital) and HSD Program (Private hospital)

There are differences in the authority approvals processes between public and private hospitals for non-CAR medicines (see *Figure 2-3*). HSDs prescribed through public hospitals are Authority required (Streamlined) items, whilst HSDs prescribed in private hospitals are Authority required items.

These differences are primarily to enable DHS claiming systems to differentiate whether the prescription originates from a public or private hospital, which correlates to the level of remuneration provided to the pharmacy dispensing the medicine. The dispensed price for the supply of HSDs by a s94 public hospital authority is the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity. In comparison, the remuneration rates for HSDs prescribed through private hospitals comprise the normal PBS ready-prepared dispensing fee plus a mark-up.

HSD Program (Community Access)

The HSD Program (Community Access) was introduced on 1 July 2015 to align the existing HSD program with current clinical practice and models of care. HSD Community Access arrangements exist for Hepatitis B medicines, antiretrovirals for HIV/AIDs and clozapine for maintenance of schizophrenia. It allows authorised community-based practitioners to prescribe medicines without being affiliated to a hospital. The arrangement allows for patients to have greater choice about where they access their medicines, through either a s90 community pharmacy or a s94 hospital authority.

HSD prescribing

Prescribing for Authority required items

Generally, Authority required items need telephone approval via the DHS Authority Approval Telephone Line, or online via the Health Professional Online System (HPOS). These items are prescribed using a PBS authority prescription.

However, **s100 HSD CAR items** require a written application and prescription to DHS in Tasmania. In limited circumstances, CAR items may receive approval via the Authority Approval Telephone Line. CAR items can be prescribed using a PBS authority prescription, or on a PBS public hospital prescription.

Prescribing for Authority required (Streamlined) items

The streamlined authorities were introduced on 1 July 2007, to reduce the administrative burden on prescribers. Authority required (Streamlined) items do not require telephone or written approval prior to prescribing. Rather, prescribers must include a four-digit streamlined authority code on the authority prescription. If the medicine is prescribed for quantities and/or additional repeats above those specified in the PBS schedule, the item is treated as an Authority required item.

These items can be prescribed using a PBS authority prescription, a PBS public hospital prescription, or from an approved hospital medication chart (if supply occurs within the public hospital).

2. Background

Prescriber eligibility

To prescribe HSD public, HSD private and HSD CAR items, a medical practitioner must be:

- A staff hospital specialist or visiting/consulting hospital specialist affiliated with the public or private hospital the patient is receiving treatment from
- An accredited prescriber of medication for the treatment of:
    - HIV/AIDS
    - Hepatitis B
    - Hepatitis C
    - Schizophrenia.
- A medical practitioner prescribing maintenance therapy when it is impractical to get a prescription from the treating affiliated specialist medical practitioner and the specialist has agreed to the prescription
- A medical practitioner whom the Commonwealth and the state or territory government has agreed may prescribe medication for maintenance therapy, under the guidance of a treating specialist.

To prescribe HSD Community Access Arrangement medicines, a medical practitioner may be community or hospital based. The practitioner must be an accredited prescriber of HIV antiretroviral therapy, clozapine maintenance therapy or chronic hepatitis B therapy.

2.3.3. National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

The *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* provides the legislative framework for the EFC program. In 2011, the revised EFC arrangements for the provision of PBS subsidised medicines used for the treatment of cancer replaced the Chemotherapy Pharmaceuticals Access Program.

The intention of the EFC program was to achieve greater efficiency in the use of injectable and infusible chemotherapy medicines. The changes included:

- Dose-specific prescriptions using milligrams (in most situations)
- Approval to pay suppliers or a pharmacist for the combination of vials that most cost-effectively makes up the required patient dose
- Patients only pay for one PBS co-payment for each original prescription but not for repeat prescriptions.

These changes assisted the government to reduce expenditure on EFC medicines by minimising wastage and associated costs.

Under the EFC Arrangement, eligible patients can access EFC medicines if they are:

- An eligible person, or are treated as an eligible person, within the meaning of the *Health Insurance Act 1973*

- Receiving treatment from an authorised prescriber.

In the public hospital setting, patients can only access the EFC if they are receiving treatment as a non-admitted patient, day-admitted patient, or patient on discharge at or from a public hospital that is participating in a PRA.

In public hospitals, an infusion medication chart may be prepared. In addition, for certain chemotherapy drugs and EFC medicines, including trastuzumab and bortezomib, an infusion prescription is also required (*see Figure 2-4*).

Many chemotherapy medicines require compounding before they can be administered to a patient, which involves special equipment and expertise. Given the specialist nature of chemotherapy compounding, this may be undertaken by:

- TGA-licenced compounders (Slade Health, Baxter Healthcare and The Wesley Pharmacy)
- Non-licenced TGA compounders. All public hospitals who compound chemotherapy in Australia operate as non-licenced TGA compounding suppliers. A number of smaller, non-licenced compounders also exist, including community pharmacies.

2. Background

Figure 2-4: Sample PBS Authority Approval EFC Prescription

PBS-RPBS authority prescription
Not valid unless authorised by delegate
23758031

Dr. A Practitioner M.B.B.S.
1 Main Street
Brisbane QLD 4001
Ph: (99) 999 99999
Prescriber no: 000000

Patient's Medicare no. 6900 82317 1 Patient's Ref no. 1
Patient's full name Mary Citizen
Patient's address 22 Smith Street
Tick for return to patient
Cityside QLD Postcode 4333
Entitlement no.
Safety Net entitlement cardholder
Concessional or dependant, RPBS beneficiary or Safety Net concession cardholder

Authorisation is requested for the following:
(Tick appropriate boxes)
PBS prescription from state manager, Medicare Australia
RPBS prescription from the authorised delegate of the Repatriation Commission
Brand substitution not permitted

Only one item per form

Cetuximab

Pharmacist/patient copy

Dosage directions: Inject 300mg IV on day 1 week 1 and day 1 week 5
Quantity: 300mg
No. of repeats: 1
Prescriber's signature: A. Practitioner
Date: 01/01/201X

Medicare Australia/DVA use | Quantity | Repeats | Phone/Delegate approval: Z1234AB

I declare that I have received this medicine and the information relating to any entitlement to a pharmaceutical benefit is correct.
Patient's or agent's signature
Date of supply / /
Agent's address

Privacy note: The information recorded on this form, including your Medicare, Centrelink and/or Department of Veterans' Affairs numbers will be used to assess your entitlement to benefits under the Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme and to determine payments due to pharmacists. With your consent the pharmacist or doctor may store your Medicare number for use on future prescriptions. The collection of this information is authorised by the National Health Act 1953 and may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law. This information may also be disclosed to doctors and pharmacists.
4006_10/09

SAMPLE

Review of Chemotherapy Funding Arrangements 2013

Following the 2007 PBS reform, some stakeholders expressed concern that 'reductions in the ex-manufacturer price of some chemotherapy medicines would make chemotherapy services unviable' (Australian Government Department of Health 2013). In 2013, the Australian Government commissioned a review of the funding arrangements which aimed to identify options for a long-term and sustainable funding model that identifies and appropriately manages all components of chemotherapy dispensing and supply (Australian Government Department of Health 2014). The review found that:

- There are a range of costs, as pharmacies and hospitals have complex business models
- There was significant administrative and regulatory red tape which meant that health care workers could not devote as much time to patient care
- Previous fees for compounding and dispensing chemotherapy infusions are not sufficient to meet the cost of providing the medicines

- The average cost of supplying chemotherapy infusions was $144.90 per infusion and includes the preparation costs, dispensing/processing costs, other business costs and clinical services.

Following the review, manufacturing and dispensing fees were adjusted (see *Table 2-2*) and efforts were made to simplify the administrative processes involved. These included:

- Removing the double handling of prescriptions where both a medication chart order and a PBS prescription were required for the same medicine, so that doctors could prescribe directly off the standardised medication chart
- Allowing pharmacies to make a single electronic claim for payment of chemotherapy medicines dispensed off a medication chart
- Removing the requirement for authorisation to prescribe some medicines for patients and introducing streamlined approval processes.

Table 2-2: Fees per approved provider type

Fee	Community pharmacy	Private hospital	Public hospital (reforms)
Section 85 medicines			
Ex-manufacturer price	Yes	Yes	Yes
Wholesaler mark-up1	7.52%	11.1%	11.1%
Pharmacy mark-up	No	1.4%	No
Administrative, Handling and Infrastructure fee	Yes	No	No
Dispensing fee	Yes	Yes	No
Section 100 Medicines (HSDs)			
Ex-manufacturer price	Yes	Yes	Yes
4-tier pharmacy mark-up	Yes	Yes	No
Dispensing fee	Yes	Yes	No
Section 100 Medicines (EFC)			
Calculated base price of dose2	Yes	Yes	Yes
Ready-prepared dispensing fee	$7.15	$7.15	No
Preparation fee3	$83.22	$83.22	$83.22
Distribution fee	$26.28	$26.284	No
Diluent fee	$5.21	$5.21	No
6CPA			
Indexed annually to Consumer Price Index	Yes	N/A	N/A
MedsChecks	Yes	N/A	N/A
Home medicines review programs	Yes	N/A	N/A

Source: Australian Government Department of Health (2017b)

[1] Capped at $69.94

[2] Based on the most cost-efficient combination of PBS-listed strengths which make up the patient dose

[3] Additional $20 fee when compounding was undertaken at a TGA-licensed site

[4] Not payable where the drug is trastuzumab.

2.4. Policies that support PBS operation

The legislative basis of PBS supply is supported by a range of policies that govern the safe and effective use of medicines by the community, often broadly referred to as Quality Use of Medicines (QUM). QUM is defined as 'selecting management options wisely, choosing suitable medicines if a medicine is considered necessary and using medicines safely and effectively' (Australian Government Department of Health 2011). The key policy documents that impact this Review are summarised below.

2.4.1. National Medicines Policy 2000

The PBS operates under the framework of the National Medicines Policy (NMP) established in 2000. The NMP was launched as an endorsed framework with whole-of-government support involving Commonwealth, state and territory governments. The NMP aims to 'improve positive health outcomes for all Australians through their access to and wise use of medicines' (Australian Government Department of Health and Ageing 2000). Under the NMP, the term 'medicines' covers both prescription and non-prescription medicines, including complementary healthcare products (Australian Government Department of Health and Ageing 2000).

The four main goals of the NMP are:

- Timely access to medicines
- Medicines meet appropriate quality, safety and efficacy standards
- Quality use of medicines
- A responsible and viable medicines industry.

The NMP recognises that there are a number of partners that are required to promote these four main agendas, including government, health practitioners, health educators, other healthcare providers and suppliers, the medicines industry, healthcare consumers and the media (Australian Government Department of Health and Ageing 2000).

Guiding principles to achieve continuity in medication management

The APAC produced the *Guiding principles to achieve continuity in medication management* (the Guiding Principles), ten principles that aim to achieve quality use of medicines in medication management.

All hospital sites participating in PRAs must implement and report on progress and milestones against six of the ten Guiding Principles (see analysis in *Section 7.1.3)*. The nature and scope of the PRAs are discussed further in *Chapter 7*.

2. Background

2.5. Agreements that support PBS operation

While the enabling legislation and the NMP provides the overarching framework for the PBS, the framework is also enabled across the public sector by multilateral and bilateral health reform agreements established between the Australian Government and state and territory governments, including:

- AHCA and subsequent National Health Care Agreement (NHCA)
- *National Health Reform Agreement* in 2011
- Bilateral Pharmaceutical Reform Agreements, which have been established with all states and territories except NSW and the ACT.

2.5.1. Australian Health Care Agreement and National Health Care Agreement

The five-year AHCA, was introduced in 1998 and replaced the Medicare Agreements established in 1984. From 1 July 2009, the NHCA replaced the AHCA and a new agreement is refined every year.

The objective of the AHCA 1998-2003 was to continue the Medicare program, to increase Commonwealth funding and to increase the accountability for states and territories for hospital activity level changes (Duckett 2004). The 2003-2008 AHCA continued with the Medicare program, but slowed Commonwealth funding and aimed to increase the accountability of states and territories through improved reporting and a new requirement for states to match Commonwealth funding increases. The AHCAs were shaped by political objectives with the orientation, emphasis and priorities of the agreements changing over time (Duckett 2004).

The objective of the NHCA is to improve health outcomes for all Australians and the sustainability of the Australian health system. Over subsequent years, the objectives of the NHCA have been redeveloped to align with the *National Health Reform Agreement 2011*.

2.5.2. National Health Reform Agreement 2011

In 2011, the Australian Government and all state and territory governments agreed to the introduction of a multilateral *National Health Reform Agreement* introducing a range of major health system reforms designed to 'improve health outcomes for all Australians and ensure the sustainability of the Australian health system' (Council of Australian Governments 2016). This included improvements in the financing and sustainability of public hospital funding (Council of Australian Governments 2011) and the replacement of the CPAP by the EFC program.

2.5.3. Pharmaceutical Reform Agreements

The Australian Government introduced bilateral PRAs under the AHCAs to support the implementation of the PBS in hospitals. Over subsequent years, the objectives of the PRAs have been redeveloped in alignment with the *National Health Reform Agreement*.

The PRAs permit approved public hospitals to prescribe and dispense medicines up to the PBS maximum quantity (which is most commonly up to one month's supply of PBS s85 medications), as well as those listed through the s100 EFC program (Australian Government Department of Human Services 2016). Prior to these arrangements, public hospital patients received between two and seven days of non-PBS subsidised medication and were required to visit their GP for additional prescriptions soon after discharge from hospital. The PRAs provide a smoother transition from hospital into the community setting by ensuring that patients received appropriate quantities of medications when discharged.

States and territories that have signed bilateral PRAs may charge the PBS for pharmaceuticals for specific categories of patients as provided for in the arrangement. However, participating public hospital pharmacies are reimbursed differently from approved community pharmacies for this supply (see *Section 2.6.2*).

The timeline for implementing these changes varied greatly, with states and territories progressively signing on to the agreements. The first jurisdiction to sign a PRA was Victoria in 2001, while the most recent was Tasmania in 2010. Currently, all states and territories except for NSW and the ACT have agreed to participate in bilateral PRAs (King et al. 2016); however, not all hospitals within eligible states and territories are approved to supply PBS medicines (King et al. 2016).

2.6. The PBS in practice

These enabling pieces of legislation, policies and agreements combine to prescribe and regulate the operation of the PBS across the community and hospital pharmacy sectors. A brief overview of how medicines are supplied via the PBS and how the remunerations arrangements work is provided in the subsequent sections.

2.6.1. Medicine supply

Medicines are usually supplied to community pharmacies by pharmaceutical wholesalers that participate in the CSO arrangements, which are detailed in the 6CPA. In some instances, community pharmacies deal directly with manufacturers (for example, Pfizer supplies its medicines directly to community pharmacies) or non-CSO wholesalers.

For public and private hospitals, medicines can be supplied by a:

- Section 94 approved hospital authority
- Section 90 pharmacy under contract to a hospital. Community pharmacies under contract to the hospital may be co-located on the hospital premises or as retail pharmacies in the community.

2. Background

It is not uncommon for hospitals to have an s94 hospital pharmacy located in the hospital supplying patients, with a retail community pharmacy, independent of the hospital, co-located on the same premises or nearby the hospital. Whilst there may be no formal arrangements between these pharmacies, from a patient perspective, this provides pharmacy options for filling scripts.

In the private hospital sector, ownership of the community pharmacy differs from the authorised hospital authority. State and territory pharmacy ownership and approval laws must also be recognised prior to any PBS approval. In addition to the s94 private hospital pharmacies, s90 pharmacies may be owned and operated by:

- Local community pharmacists
- An independent retail community pharmacy chain under contract to the hospital.

In 2017, there were 6,054 agencies registered to provide PBS medicines (Productivity Commission 2017). Of these:

- 92.3% (5,588) were community pharmacies
- 4.7% (283) were hospitals, of which:
  - 161 were public hospitals
  - 122 were private hospitals
- 2.7% (164) were Aboriginal Medical Services operating under s100
- 0.3% (19) were dispensing doctors.

2.6.2. Remuneration

The type of pharmacy model (as detailed above) has a direct impact on which programs may be remunerated under the PBS and on the remuneration fees available (see *Table 2-2).* Public hospitals are reimbursed at a lower rate than community pharmacies and private hospitals. Issues in relation to pharmacy models and remuneration are discussed in more detail in *Chapter 3.*

2. Background

2.7. Financing the PBS

While the remuneration rates paid to pharmacies for PBS medicines are relatively straightforward, who ultimately pays for medicines (both PBS and non-PBS) and how much, is more complex. The cost of implementing the PRAs and other agreements is shared between the Australian Government and state/territory governments. In relation to the PBS, under these agreements, states and territories are responsible for:

- Management and delivery of public hospital services
- Funding of public hospital pharmacies and pharmacists
- Funding of pharmaceuticals for patients, subject to reform agreements with the Australian Government
- Funding of medicines for prisoners, with the exception of s100 HSD medicines.

In turn, the Australian Government is responsible for funding of PBS subsidies and the administration of the PBS program, with the Australian Government Department of Health responsible for:

- PBS policies
- TGA and PBAC administration
- Listing of PBS medicines and associated guidelines.

The payment of benefits under the PBS is the responsibility of the DHS.

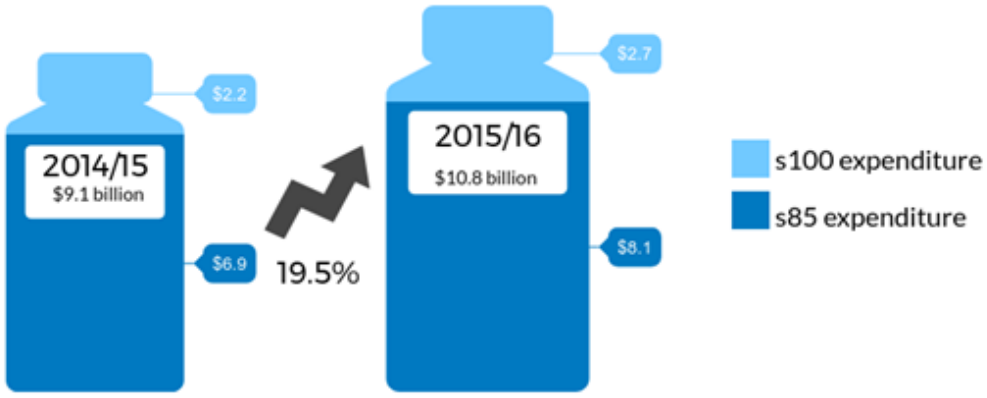
2.7.1. How much does it cost?

The total PBS government expenditure increased from $9.04[1] billion in 2014-15 to $10.8 billion in 2015-16 as illustrated in *Figure 2-5*. This represents an increase in spending of 19.5%, largely due to the listing of Hepatitis C medicines. Of the $10.8 billion spent during 2015-16, the majority was directed towards s85 medicines (74.8%), with the remainder on s100 medicines (25.2%). This is broadly comparable to the distribution of PBS expenditure during 2014-15 for s85 (76.2%) and s100 (23.8%) medicines.

[1] Excludes spending on Doctors' Bag and Safety Net Cards.

2. Background

Figure 2-5: PBS Expenditure for 2014-15 and 2015-16

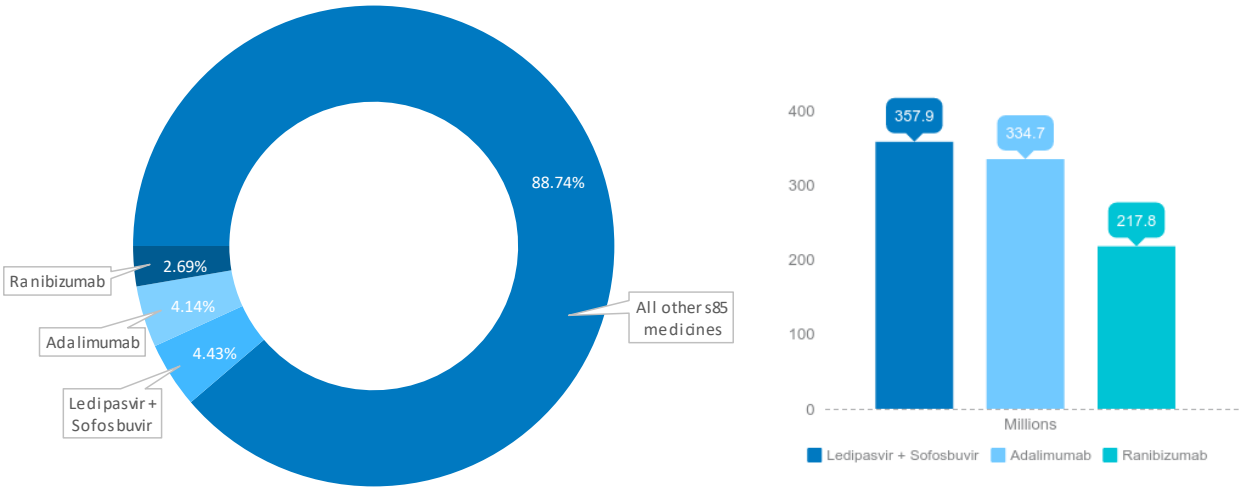


Source: Department of Health (2016)

Although there have been efforts to reduce prices of PBS medicines through the policy of price disclosure, it is anticipated that PBS expenditure will continue to rise with nominal growth of 5.4% per year projected from 2013-14 to 2023-24 (Australian Government National Commission of Audit 2014). The drivers of this increase in PBS expenditure can be attributed to a range of factors including the listing of new PBS medicines, the emergence of new technology creating complex and expensive biologic medicines, and the rise in the incidence of chronic conditions due to an ageing population (Australian Government National Commission of Audit 2014).

The three drugs with the highest cost to government during 2015-16 were Ledipasvir + Sofosbuvir, Adalimumab and Ranibizumab, which together cost over $900 million and represented over 10% of the cost of s85 medicines (Australian Government Department of Health 2016a), see summary at . All of these medicines are prescribed in both the community and hospital setting.

Figure 2-6: Medicines with the highest cost to Government in 2015-16, cost per medicine and percentage of all s85 cost



Source: Department of Health (2016). Note that the calculation for the Hepatitis C drugs (Ledipasvir + Sofosbuvir) was introduced in March 2016 and does not represent a full-year cost.

2. Background

Section 100 special arrangements program

In terms of funding sustainability, some medicines supplied under s100 of the *Act* are of particular interest (Department of Health 2017a, King et al. 2016), as some s100 programs include a number of medicines of very high value (Australian Government Department of Health 2017b).

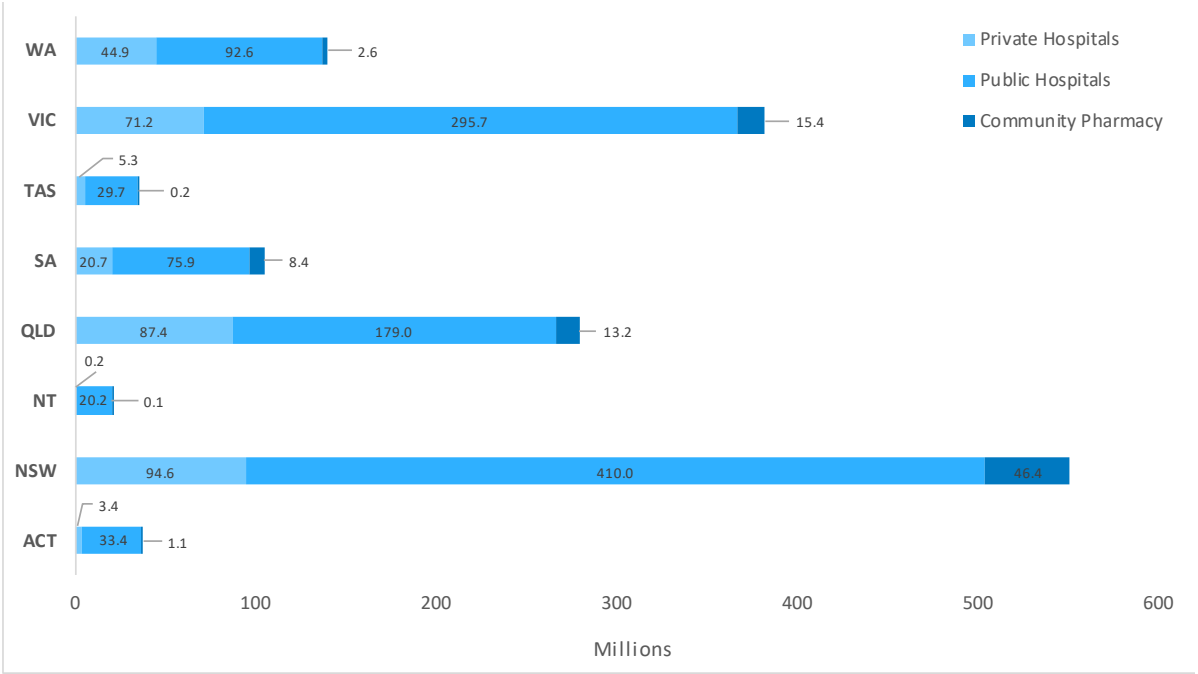
Although there is no agreed definition of what constitutes a high-cost drug in Australia, this Review will define it as highly individualised medicines such as biologics and chemotherapy drugs. The HSD program is the largest program and the majority of expenditure on this program occurs in public hospitals (Harvey & de Boer 2015).

HSD expenditure

Department of Health PBS data indicates that in 2015-16, more than $1.55 billion was spent on HSDs in Australia. *Figure 2-7* outlines expenditure by states and territories and pharmacy type, showing:

- Of all HSD expenditure, 73% was expended in public hospitals, 21% in private hospitals and 6% in community pharmacies
- Some states and territories varied markedly from this average – in the NT 98.9% of HSDs were dispensed by public hospitals, while in Qld this represented only 64% of supplies. Conversely, private dispensing in Qld represented 31.1%, see *Figure 2-7*.

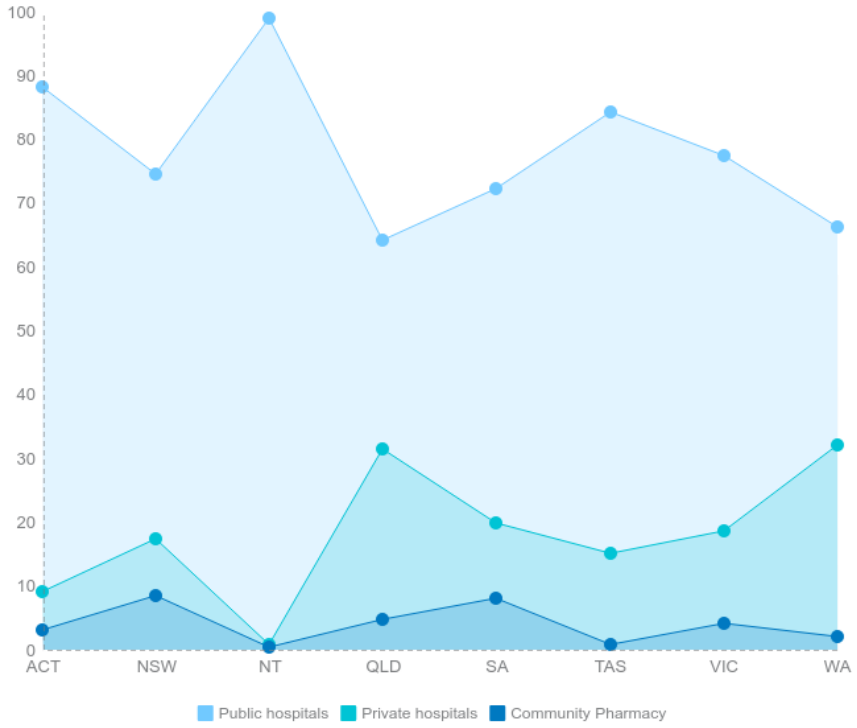
Figure 2-7: Millions spent by states/territories on HSD medicines, in 2015-16, by dispensing type*



Source: (Australian Government Department of Health 2017d)

2. Background

Figure 2-8: Percentage breakdown of HSD dispensing type, by state/territory 2015-16



Source: Australian Government Department of Health (2017e)

PBS and Non-PBS expenditure

Public hospitals currently report annual hospitals expenditure to the Independent Hospital Pricing Authority (IHPA). Table 2-5 reports on the average cost of average cost per separation by jurisdiction for Round 19 (2014-15). PBS and Non-PBS expenditure is reported according to the following categories:

- Acute expenditure
- Emergency department
- Non-admitted expenditure
- Sub-acute expenditure.

Data is based on data reported to IHPA by states and territories. It is important to note that:

- This data does not reflect total expenditure as it does not include all hospitals, and the number of hospitals included for reporting purposes varies from year to year
- NSW does not report on any PBS expenditure.

Nevertheless, the data indicates that overall on average, non-PBS expenditure is greater than PBS expenditure in all categories.

Table 2-3: Average cost per separation, actual, by jurisdiction ($) - Round 19, 2014-15

	Acute		Emergency Department		Non-Admitted		Subacute	
Jurisdiction	PBS	Non PBS	PBS	Non PBS	PBS	Non PBS	PBS	Non PBS
NSW*	0	135	0	7	0	14	0	244
Vic	69	126	1	8	0	17	52	266
Qld	0	166	0	9	0	20	0	215
SA	34	126	2	9	0	23	26	130
WA	87	157	4	7	0	26	120	198
Tas	98	124	2	10	0	29	121	141
NT	21	91	0	5	0	32	8	901
ACT	90	124	3	8	0	35	57	183
National	33	139	1	8	0	38	23	230

*NSW did not report PBS expenditure

2.7.2. Patient co-payments

To support the sustainability of the PBS, the Australian Government shares the cost of most prescriptions with the consumer. A fixed co-payment is applied to the prescription cost by the pharmacy, with the balance reimbursed to the approved pharmacist by the PBS.

Patients pay a maximum co-payment per dispense of no more than $6.40 for concessional patients (pensioners and health care card holders) and up to a maximum of $39.50 for general patients, until an individual or family reach their applicable safety net threshold.

Under this Scheme, administered by the DHS, consumers are protected by “safety nets” where expenditure is subsidised or free once a certain threshold is met. The general patient safety net threshold is currently $1521.80 for the calendar year. When patients and/or their families meet this threshold, the safety net patient contribution is $6.40 per item for the rest of the calendar year. For concessional patients, the threshold is $384.00. Once patients and/or their families reach the concessional safety net threshold, they can apply for a Safety Net Entitlement Card (issue fee $9.91) and receive items free of charge for the rest of the calendar year.

2. Background

2.8. Purpose of the Review

In April 2017, the Department of Health contracted AHA to undertake a Review of PBS Pharmaceuticals in Hospitals.

The overall purpose of the Review is to provide the Department with insight, understanding and clarity about how the PBS and its sub-programs are used in the supply of medicines in public and private hospitals in Australia. The specified aims of the Review are to:

- Describe and profile the various arrangements used to procure, purchase, prescribe, dispense, and claim PBS benefits in public and private hospitals
- Report on issues in relation to PBS benefits in hospitals including operational issues faced by states and territories and private hospital operators
- Assist in the preparation of options for alternative risk sharing arrangements between the Australian Government and states and territories, public and private hospital operators to contribute to PBS sustainability.

The key questions to be explored centre on the following:

- What are the current procurement arrangements for medicines in hospitals?
- What are the current prescribing arrangements for medicines in hospitals?
- What are the current dispensing arrangements for medicines in hospitals?
- What are the specific issues faced by hospitals in relation to PBS operations?

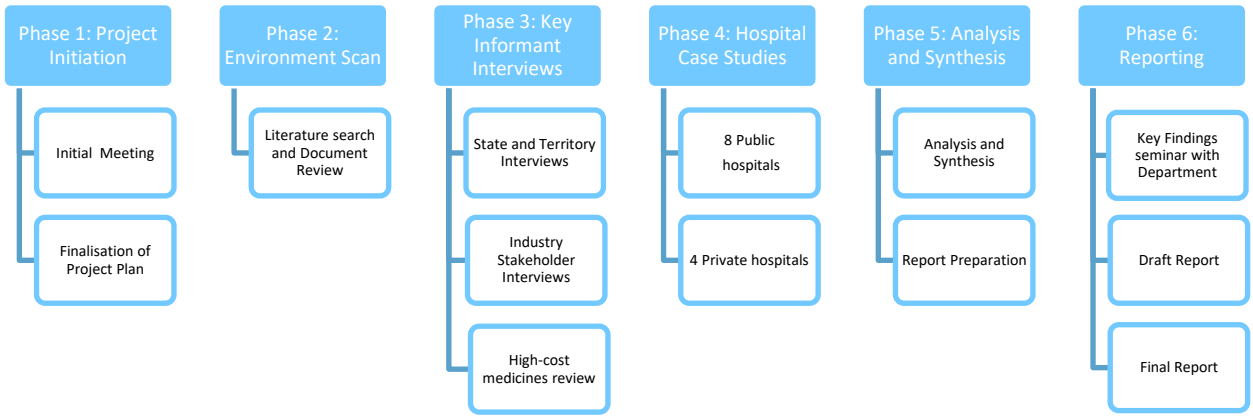
Whilst every effort was made to obtain information in all areas, the Review was not intended to be an exhaustive examination of PBS arrangements in all public and private hospitals in Australia. The Review is designed to provide the Department with insight into how the supply of PBS medicines is delivered in private and public hospitals and by states and territories.

2.9. Review method

The Review was conducted between May and October 2017 and involved a six-phase methodology, as illustrated in *Figure 2-9.* A summary of the key activities undertaken in each of these six phases is

provided in the following sections. It should be noted that while the stages are represented as distinct activities, in reality, the stages overlap, as described in the following sections.

Figure 2-9: Review Phases



2.9.1. Project initiation

AHA met with key departmental personnel for a project briefing and subsequently provided a project plan, detailing project activities, timeframes, milestones, and risk management and communications plans.

2.9.2. Environment scan

An environmental scan was undertaken of the Australian and international literature relating to the PBS in hospitals. The environmental scan informed the development of stakeholder consultation tools, and key findings are presented throughout the report.

A literature search and document review involved a Review of:

- Literature, publicly available information and data
- Relevant agreements and guidelines including the NHRA and PRAs
- Background reports and relevant data
- Details of any additional information that may be of relevance to the development of the interview and case studies.
- Relevant documents collected from states and territories and key informants in Phase 3
- Websites of research institutes, peak bodies and other relevant government and non-government organisations
- Key submissions made to the Department of Health Review of Pharmacy Remuneration and Regulation
- Online reports and documents on comparable projects/processes, including those published in the 'grey literature'

- Online databases containing peer-reviewed published research (e.g. Wiley Blackwell, Taylor & Francis, ProQuest)
- Reference lists of papers retrieved through the search were used to identify additional material of relevance.
- State and territory health department websites.

2.9.3. Stakeholder consultations

The Review involved extensive stakeholder consultation, including in-person and telephone interviews with key informants identified by the Department and in discussion with key stakeholders. *Table 2-4* provides a summary of stakeholders interviewed. These included representatives from:

- All eight states and territory health/state purchasing authorities
- 12 hospital sites (eight public and four private).
- Industry stakeholders including:
  - Pharmacy Guild of Australia National Body and the Pharmacy Guild of Australia (NSW branch)
  - Society of Hospital Pharmacists of Australia (SHPA)
  - Australian Private Hospitals Association
  - The Council of Australian Therapeutic Advisory Groups (CATAG).

Note that all industry stakeholders consulted with their members prior to discussing issues with AHA, thereby capturing views and issues across the relevant stakeholders.

Table 2-4: Summary of stakeholder interviews

Stakeholder group	Organisations contacted	Organisations consulted	Participants in interviews
State and territories (Pharmacy and Medicines procurement personnel)	8	8	23
Public hospitals	6	6	13
Private hospitals	5	4	11
Both public and private hospital	1	1	1
Industry bodies	5	4	21
Government representatives	1	1	3
Total	26	24	72

A list of stakeholders who were consulted is included in *Appendix B.*

2. Background

Industry stakeholder interviews

The objective of the interviews was to gain an understanding of the industry stakeholders' perspectives on the PBS and its use in hospitals. Those interviewed were given the opportunity to provide reports and documentation such as key position or research papers of relevance to this project.

2.9.4. High-cost medicines price review

The Department is seeking to understand costs of medicines particularly for a select sample of high-cost medicines.

AHA invited state, territory and hospital representatives to provide information on the price of a select group of medicines. This includes Hepatitis C, biologic, biosimilar, chemotherapy, antipsychotic and antiretroviral medicines. This list includes the most commonly prescribed form of the medicine.

Four responses were received from hospitals. AHA established a data portal to protect the confidentiality of information provided. This included the option of lodging the information anonymously, and the option of providing a price on a basket of F1 and F2 medicines to protect confidentiality.

The results of the high-cost medicines review is detailed in *Section 3.5*.

2.9.5. Case studies

AHA conducted case studies with hospital pharmacies on the supply and use of PBS medicines. This involved investigating in further detail, the supply chain, impact, issues, and costs of PBS medicines. Case studies were undertaken with all states and territories as well as a range of hospital pharmacies.

AHA consulted state and territory health departments regarding public hospital case study sites. Following consultations with ACT Health, Canberra Hospital declined to participate. This was replaced by another public hospital.

Criteria for the selection of hospitals/hospital networks included as far as practicable, a mix of:

- Public, private and not-for-profit hospital providers
- Hospital providers that operate both private and public hospitals
- Hospitals with differing dispensing models used (including hospital pharmacies and community pharmacies)
- Hospitals that support populations with special access needs, such as Aboriginal and Torres Strait Islanders and prison populations.

State and territory procurement models are detailed in *Appendix A.*

2. Background

2.9.6. Analysis and synthesis

A staged approach to data analysis was taken comprising the following:

- Qualitative analysis of:
  - Literature review findings
  - State / territory interviews
  - Industry stakeholder interviews
  - Comparative analysis of hospital case studies and consultations.
- Quantitative analysis of PBS data and information submitted as part of the High-cost Medicines review.

Findings were triangulated to address the Review objectives. This included:

- *Data triangulation* - Feedback and information obtained from different stakeholders was compared to identify areas of agreement and divergence
- *Investigator triangulation* - Several different consultants were involved in the analysis process, thus ensuring a breadth of knowledge, observation and experience is applied to the interpretation of findings
- *Methodological triangulation* - The mix of quantitative and qualitative approaches used in the study included interviews, consultations, and existing data sources
- *Environmental triangulation* - Comparisons will were made based on different states and territories and hospitals settings.

Quantitative data was analysed using Microsoft Excel, and tailored to the type of data obtained. Qualitative data derived from the stakeholder consultations, interviews and case studies were thematically analysed. AHA utilised NVivo (version 11) to conduct the qualitative analysis.

2.9.7. Reporting

AHA has provided regular telephone updates to the Department. A seminar was held with the Department and state and territory representatives in Canberra to present and discuss key issues from this report.

2.9.8. Methodological limitations

In preparing this report, the following methodological limitations are noted:

- The agreed method for the PBS Pharmaceuticals in Hospitals Review is not intended as an exhaustive study of public and private hospitals but was designed to provide insight into the issues.

- Some stakeholders did not agree to participate in the hospital case studies. This included Canberra Hospital and NSW public hospitals. The report does not include public hospital case studies from these two non-PRA reform states. However, some limited feedback on the operation of hospitals in these states was provided through broader industry stakeholder consultations that included pharmacy representatives from ACT hospitals and NSW Health.
- Detailed analysis could not be conducted for high-cost medicines as only a small sample (four) of responses were received. Data supplied was self-reported and therefore was not able to be verified.

3. Findings: Procurement and supply

3.1. Introduction

This chapter describes and profiles:

- Key elements of procurement in hospitals (public and private)
- Procurement in public hospitals
- Procurement in private hospitals
- High-cost medicines analysis
- Procurement and supply issues.

Case studies on state and territory procurement and supply models are detailed in *Appendix A*.

Discussion in this chapter is based on:

- Stakeholder feedback (including interviews and consultations)
- Hospital case studies
- The literature review
- PBS program documentation.

3.2. Key elements of procurement in hospitals

> An effective procurement process ensures the availability of the right drugs in the right quantities, available at the right time, for the right patient, at reasonable prices and at recognisable standards of quality
>
> (World Health Organization 2001).

While the PBS remuneration rates are relatively straightforward, the question of who ultimately pays for medicines (both PBS and non-PBS) through the supply chain and how much they pay is more complex.

> Procurement encompasses the whole process of procuring goods and services. It begins when a need has been identified and a decision has been made on the procurement requirement. Procurement continues through the processes of risk assessment, seeking and evaluating alternative solutions, the awarding of a contract, the delivery of and payment for the goods and services and, where relevant, the ongoing management of the contract and consideration of disposal of goods (Australian Government Department of Finance 2014).

3. Findings: Procurement and supply

Figure 3-1 outlines key elements of the procurement process identified in the Review. These include:

- Medicine management, including assessment and approval processes for medicines to be used in hospitals
- Formulary use and medicine listings
- Procurement methods, including:
  - Role and function of procurement agencies
  - Scope of procurement, such as procurement for whole state or territories, hospital groups, or individual hospitals.
- Supplier selection processes, including:
  - Tender processes or standing arrangements
  - Price negotiation responsibilities.
- Contract management
- Purchasing of supplies
- Supply and distribution arrangements for national or international distributors, wholesalers or manufacturers, including whether medicines are supplied by government wholesale pharmacies, directly to hospitals by distributors, wholesalers or manufacturers or via community pharmacies.

Figure 3-1: Elements of the procurement process for medicines in hospitals

3. Findings: Procurement and supply

3.3. Procurement in public hospitals

All states and territories, with the exception of the ACT, operated central procurement processes for their public hospitals. The ACT has an arrangement to buy from the NSW tender. The elements of each jurisdiction's process are summarised in *Table 3-1,* with each element described in the following sections.

Table 3-1: State and territory public hospital procurement and supply

Jurisdiction	Formulary type	Procurement agency	Central tender process?	Purchasing	Distribution
ACT	Hospital-based	Access to NSW contracts	Access to NSW contracts	Direct by hospital	Distributors/wholesalers/manufacturers
NSW	Hospital-based	HealthShare NSW	Yes	Direct by hospital	Distributors/wholesalers/manufacturers
NT	State-wide	NT Dept of Health	Yes	Direct by hospital	Distributors/wholesalers/manufacturers
QLD	State-wide	Health Support Qld	Yes	Direct by hospital Procurement agency	Central government warehouse
SA	State-wide	SA Health	Yes	Direct by hospital	Distributors/wholesalers/manufacturers
TAS	State-wide	Tas Dept of Health and Human Services	Yes	Direct by hospital	Distributors/wholesalers/manufacturers
VIC	Hospital-based	Health Purchasing Vic	Yes	Direct by hospital	Distributors/wholesalers/manufacturers
WA	State-wide	WA Health	Yes	Direct by hospital	Distributors/wholesalers/manufacturers

3. Findings: Procurement and supply

3.3.1. Formularies

Public hospitals in all states and territories used formularies that specified an approved list of medicines commonly used for inpatients, emergency departments, discharged patients, day-admitted patients, and outpatients. Formularies provided a key mechanism to achieve patient outcomes and manage hospital medication costs by listing the medicines for use in hospitals.

Each state or territory used one of the following models:

- A state- or territory-wide formulary, overseen by a state or territory drug and therapeutic committee with oversight of the medicines management system and formulary within that jurisdiction
- A hospital- or local health district-based formulary, overseen by a local drug and therapeutic committee that operates within overarching state or territory health department policies and guidelines.

State-wide formularies operated in Queensland, South Australia, Tasmania, Northern Territory and Western Australia, while hospital- or district-based formularies operated in Australian Capital Territory, New South Wales and Victoria.

Features of public hospital formularies

Public hospital formularies had a number of features that are common across jurisdictions:

- Formularies typically comprised a list of medicines by drug, form and strength, i.e. brands are not specified
- Formularies included both PBS and non-PBS medicines. PBS items are a smaller subset of formularies, both in number and dollar value
- The brand of medicines to be purchased was a decision made either as part of the state tender or by the hospital pharmacy
- In the case of therapeutically equivalent drugs, the (single) most cost-effective brand of each medicine listed on the formulary is purchased. Where brands are not interchangeable (e.g. Coumadin and Marevan, two brands of warfarin), hospitals may purchase both brands.

3.3.2. Medicine management

Each state or territory operates within a state-wide framework of medicine management and governance. This framework includes:

- **State or territory legislation, policies and guidelines** on the approval and use of medicines in public hospitals. In general, these covered:
  - Pharmaceutical preparation in public hospital pharmacies
  - Medication handling
  - Drugs, poisons, and controlled substances legislation
  - Medicine use for research purposes
  - Processes for approving and listing medicines on formularies.
- **CATAG guidelines** developed by representatives from all Australian state and territory therapeutic advisory groups or their equivalents. Guidelines include:
  - *Achieving effective medicines governance: Guiding principles for the roles and responsibilities of drug and therapeutics committees in Australian public hospitals* (CATAG 2013a)
  - *Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals* (CATAG 2016)
  - *Re-thinking medicines decision-making in Australian Hospitals: guiding principles for the quality use of off-label medicines* (CATAG 2013b)
  - *The use of complementary and alternative medicines* (CATAG 2015).
- **Medicine governance and the operation of drug and therapeutic committees** that conduct clinical cost-effective assessments of medicines. The purpose of these committees is to list medicines on hospital formularies and to advise procurement agencies on medicines to be included in state or territory purchasing arrangements.
- **Accreditation of hospitals** to meet the National Safety and Quality Health Service Standards. This includes meeting Standard 4: Medication Safety Accreditation, which requires health service organisations to implement systems that reduce the occurrence of medication incidents and improve the safety and quality of medicines use (Australian Commission on Safety and Quality in Health Care 2011).

Approvals for use of medicines not on formulary

Hospital doctors are required to apply to drug and therapeutic committees for approval in circumstances where they are seeking to:

- Use medicines not listed on the ARTG
- Trial new medicines in hospitals. Large hospitals reported that manufacturers would approach hospitals to arrange to introduce or trial medicines, usually well before medicines are listed on the PBS

- Apply for an exemption to use off-label medicines (TGA-approved medicines used in other ways than specified in TGA product information). Off-label medicines are used when the approved use of the registered medicine does not address the clinical needs of patients. They are prescribed or administered:
  - For another indication not specified in the product information
  - At a different dose
  - Via an alternate route of administration
  - For a patient of an age or gender outside the registered use.

  Under the PBS, hospitals are not reimbursed for the costs of off-label medicines.

Typically, approvals are granted for:

- Routine use, where high quality evidence supports the use of the medication
- Conditional use, where the evidence is low to moderate and where there is reasonable justification for use with certain groups of patients
- Exceptional use, where there is low or very low-quality evidence and where approval is patient specific.

Listing new PBS items on formulary

Not all new PBS items are automatically added to hospital formularies, but are assessed by the relevant state, territory or hospital drug and therapeutic committee for inclusion in the formulary. High-cost drugs, in particular, are carefully considered. Some stakeholders noted that PBS listing did increase demand to add items to the formulary.

Assessment criteria commonly used for considering the addition of new items to formulary included:

- Best available patient-based research evidence to support inclusion
- Objective of the drug, and listed indications
- Medicine costs, including associated costs for resources
- Potential harms and benefits of the new medicine
- Medicine protocol requirements
- Training, qualifications, skills or competencies required to prescribe, dispense or administer the medicine
- Organisational and electronic medicine safety requirements where relevant.

Most PRA states and territories considered safety, efficacy and cost-effectiveness of drugs when listing on formularies. However most operated streamlined approval processes for general PBS items, given that these medicines had already been through the PBAC process for listing on the PBS. For example, the Western Australian Drug Evaluation Panel only considers submissions for high-cost drugs that cost:

- More than $10,000 annually for an individual patient
- More than $100,000 annually for an individual health service

- More than $300,000 annually within the state public health system.

If the medication falls below the above thresholds and is to be used in accordance with the approved PBS indication, then the Streamlined Formulary Application Form is submitted to hospital drug and therapeutic committees.

Some states noted that PBAC assessments of PBS medicines with confidential information redacted had been made available to the states for use in medicine evaluation processes. However, given that key confidential information was not included, stakeholders viewed the usefulness of this information as limited.

Public hospital uses of medicines not on formulary

All public hospitals purchased medicines not included in their formulary, provided the medicines had been through appropriate approval processes.

In consultations, hospital pharmacists consistently reinforced the role that clinical decisions play in determining whether medicines are prescribed from the formulary. One common example was when a patient admitted to hospital was already using medications that are not on the formulary. To avoid confusion for patients and possible side-effects from changing brands, doctors would, as far as practicable, prescribe the non-formulary medicine unless there was a clinical reason to change medications during the hospital stay.

3.3.3. Procurement methods

All state and territory governments had central purchasing arrangements for medicines for public hospitals, with the exception of the ACT public hospital which accesses NSW state contract arrangements with suppliers.

While states and territories differed in their approaches to procurement of medicines, they are all designed to:

- Source and supply medicines needed by public hospitals and health services to deliver high quality patient care
- Improve the collective purchasing power for public hospitals in that state or territory
- Provide a central hub for procurement activities.

In addition to central state and territory procurement, hospitals are also involved in directly procuring medicines.

State and territory procurement models

Table 3-2 summarises the approaches used by states and territories. This table includes information on:

- Procurement agencies and approach
- Tender and contracting processes.

3. Findings: Procurement and supply

Further detail is provided in state and territory procurement and supply case studies in *Appendix A.*

In summary, the overall approaches to procurement included:

- **Central pharmacy model.** Queensland is the only state government that operates a central pharmacy model. Health Support Queensland (HSQ), a division of Queensland Health, manages the procurement of medicines as well as operating a central wholesale pharmacy, which supplies all Queensland public hospitals.
- **Central health support procurement agencies.** New South Wales and Victoria have established central health support procurement agencies. HealthShare NSW is a semi-independent government agency with its own board and Health Purchasing Victoria is an independent government statutory authority. These agencies are responsible for sourcing and procurement contracts for all public hospitals supplies, including medicines, in their state.
- **Health department procurement units.** State or territory health departments are responsible for sourcing and procurement contracts for public hospital medicines and other supplies in the remaining jurisdictions (except the ACT, which has access to NSW arrangements).

3. Findings: Procurement and supply

Table 3-2: State and territory procurement, contracts and suppliers

State/ territory	Procurement agency and approach	Tendering arrangements	Tender period
Qld	**Health Support Qld (HSQ)** Procurement is undertaken by HSQ, a division of Qld Health. HSQ is responsible for tender and contract management. Medicines are purchased by HSQ and stored at an HSQ-operated central pharmacy, which acts as a warehouse for Qld public hospitals. Hospitals order directly from HSQ via the iPharmacy system and medicines are distributed from the pharmacy to hospitals.	Open tender leading to standing offer arrangements with suppliers	**4 years** 1 Jan 2014 - 21 Dec 2018
Vic	**Health Purchasing Victoria (HPV)** Procurement is undertaken by HPV, an independent statutory authority. HPV works in partnership with public hospitals and health services to understand their requirements, facilitate large-scale tenders and manage common-use contracts with suppliers on behalf of the state. Advice is provided to HPV on medicine procurement by a committee of state health representatives and chief pharmacists. Public hospitals order and purchase supplies based on the common use contracts directly from suppliers.	Open tender for *Pharmaceutical products and IV Fluids* for Victorian health services. Supplementary tenders are issued for new medicines e.g. Dec 2017 tender for Infliximab	**2 years** 1 Sept 2016 - 31 Aug 2018 + 2 x 2-year options
Tas	**Tasmanian Department of Health and Human Services** DHHS is responsible for managing procurement of pharmaceuticals for Tasmanian public hospitals. The Tasmanian government conducts a state-wide tender process for three major contracts for: (1) Pharmaceuticals, (2) Compounding and (3) Fluids and Other Long-term Items. Common use contracts with suppliers are managed by the Department. Public hospitals order and purchase supplies based on common use contracts directly from contracted suppliers.	Open public tender for *Pharmaceutical products* for Tasmanian health services.	**2 years** 1 Aug 2016 - 21 Jul 2018 + 1 x 2-year option
SA	**SA Department of Health and Ageing** South Australia conducts procurement of pharmaceuticals and other materials through a single tender to contract a panel of suppliers. Each public hospital pharmacy purchases directly from one of the two major wholesalers. Price negotiation is undertaken with the provider of the medicine. Wholesalers then supply at that price, with a mark-up.	Open public tender for *Supply and distribution of Pharmaceuticals and Large Volume Fluids* for South Australian health services	**6 years** 1 Oct 2012 - 30 Sep 2018

3. Findings: Procurement and supply

State/ territory	Procurement agency and approach	Tendering arrangements	Tender period
NT	**Northern Territory Department of Health** The NT DH operates a three-year purchasing contract with multiple contractors (both wholesalers and manufacturers) for the procurement of pharmaceuticals. Chemotherapy is also part of the tender and all compounding is done externally. The NT has arrangements in place where patients from North Western Australia can be treated in the NT and similarly there are arrangements with SA patients. The NT does not utilise for patients on discharge as these arrangements (need to charge co-payments and no funding for DAAs) does not meet the clinical requirements of the majority of patients in NT hospitals. This results in a high administrative burden to ensure patients receive medicines through the closing the gap and Remote Area Aboriginal Health Services programs.	Open public tender for *Supply and delivery of Pharmaceutical Products, Intravenous Fluids and Compounding services* for Alice Springs, Darwin, Katherine, Nhulunbuy and Tennant Creek.	**3 years** 4 Oct 2016 - Oct 2019
NSW	**HealthShare NSW** Medicines are procured for NSW public hospitals under state-wide contracts administered by HealthShare NSW. Centrally-negotiated contracts provide competitive pricing arrangements for high volume items used in all public hospitals. If a required pharmaceutical is not available as a HealthShare NSW contract item, Local Health Districts and/or individual hospital pharmacy departments are responsible for purchasing that pharmaceutical. This procurement process applies to all medicines, irrespective of whether they are PBS or non-PBS medicines. NSW contracts are made available to other authorised health services. This includes not-for-profit hospitals in NSW and ACT Health for access in ACT hospitals.	Open public tender for Drugs and *Pharmaceutical Products* for NSW health services. Standing Offer arrangements in place	**2 years** 1 Aug 2016 - 30 July 2018
ACT	**ACT Health** ACT Health does not conduct purchasing for territory hospitals. Canberra and Calvary hospitals have an agreement with NSW Health which enables ACT hospitals to access the NSW hospital contracts with suppliers.	Not applicable	Not applicable

3. Findings: Procurement and supply

State/ territory	Procurement agency and approach	Tendering arrangements	Tender period
WA	**Health Support Services, WA Health** The Government Drug Procurement Office tenders to establish the supplier and price for each item, but the government does not store and distribute medicines from a central location. Rather, medicines are delivered directly by suppliers to hospitals. Newly added items are issued in Supplementary tenders.	Open public tender for *Drugs and Pharmaceutical products* for WA Health services. Issued as two tenders: (1) Sole supply drugs (2) Competitive market drugs. Standing Offer arrangements in place	**3 years** 5 Dec 2016 - 4 Dec 2019
	WA Country Health Tenders are also issued by WA Country Health for the provision of drugs and pharmaceutical products for specific Remote Area Aboriginal Health Centres.	Tenders are also issued by WA Country Health for the provision of drugs and pharmaceutical products for specific Remote Area Aboriginal Health Centres.	**3 years** Oct 2017 - Oct 2020 + 2 x 1-year options

Source: State and territory tender websites and online contract registers sourced between 13 and 15 September 2017. Information was also obtained from consultations.

3. Findings: Procurement and supply

Contracting and price negotiation processes

All state and territories, with the exception of the ACT, issue tenders for the provision of pharmaceuticals for public hospitals. Tenders lead to either:

- **Contracts** with selected suppliers for a fixed period at fixed conditions and prices, which expire at the end of the contract period (2-4 years); or
- **Standing offers** which are agreements with a supplier to allow the purchase of medicines at a predetermined price for a certain period on an 'as and when' required basis. This is an irrevocable offer that is automatically renewed after the expiration of the closing date. New South Wales, Queensland and Western Australia operate under standing offer arrangements.

States and territories commonly issued tenders on the basis of either category groups of pharmaceuticals (e.g. chemotherapy) or a detailed list of the pharmaceuticals to be supplied. In some state and territories, procurement was limited to a single brand of a generic medicine. In other cases, multiple brands of generic medicines are available under contract arrangements and the local hospital pharmacy was able to procure medicines at the lowest price.

Some states and territories also issued tenders for the provision of pharmaceutical services and supplies to specific remote locations, e.g. the provision of pharmacy services and pharmaceuticals for specified remote locations in Western Australia, and the provision of pharmaceutical services to RAAHS in the Northern Territory. Successful suppliers included local s90 community pharmacies as well as wholesalers or manufacturers.

3.4. Procurement in the private sector

Compared to the public sector, there are some key differences that have driven different procurement approaches in the private hospital sector. This is in part due to the different pharmacy models in operation in the private sector, as well as the wider use of the PBS, including for inpatients.

3.4.1. Private corporate hospitals

Three pharmacy models predominate in private hospitals. These are:

- s94 private hospital operated pharmacies
- s94 private hospital pharmacies contracted to s90 community pharmacies
- Private hospital operated s90 pharmacies.

Private hospitals predominantly tender or contract out pharmacy services rather than coordinate operations internally. Based on DHS pharmacy data in 2015 it was estimated that approximately 19% of

private hospitals pharmacy services were delivered by s94 pharmacies[2]. However, this also includes s94 hospital pharmacies contracted to community pharmacies.

The majority of private hospital pharmacies are operated by s90 community pharmacies owned by community pharmacists, retail pharmacy chains or under franchise to private hospitals.

Across the private hospital sector, there is evidence of increased corporatisation of pharmacy, greater integration with the community pharmacy sector, as well as evidence of more supply chain vertical integration.

Stakeholders advised that the private hospital pharmacy market is dominated by three major pharmacy providers. These are:

- **HPS Pharmacies** provide dispensing, imprest management, compounding, pharmaceutical product supply and clinical pharmacy accreditation support services for private hospitals. HPS operates both s94 and s90 hospital pharmacies, including the majority of the 45 HealthScope hospitals across Australia. In addition to private hospitals, HPS Pharmacies also provides outsourced pharmacy services to public hospitals, correction facilities and cancer centres. In May 2017, the international health care group, the EBOS Group, which owns Symbion, a national pharmaceutical wholesaler, acquired HPS Pharmacies.
- **Slade Health** is part of the Icon Group. Slade provides hospital, community and compounding pharmacy services to Icon Cancer Care, Epic Pharmacies, the greater Slade Group as well as public hospital pharmacy services. Icon Cancer Care has seven-day hospitals in Queensland and SA, and Epic Pharmacies have 24 pharmacies across Australia. Slade provides a range of hospital services including ward pharmacy services, clinical reviews, compounded medications, tender management and drug supply.
- **Ramsay Health Care** operates 70 hospitals and day surgeries across Australia including public/private partnerships hospitals. Ramsay Health Care also owns Ramsay Pharmacy which are independently-owned community pharmacies which operate as a franchise member of the Ramsay Pharmacy network. Ramsay Pharmacy currently provides pharmacy services to 44 Ramsay Health Care facilities in Australia. At their 2017 annual general meeting, Ramsay reportedly announced their intention to increase the number of community pharmacies to 55 in the Ramsay Pharmacy group in the next year.

In a similar manner to some large state and territories, these larger private sector pharmacy groups, such as HPS and Ramsay Pharmacy, are perceived by some stakeholders to hold considerable market power in negotiating preferential procurement arrangements with suppliers.

[2] Unpublished DHS data indicates there were 117 s94 hospital pharmacies in 2015. AIHW data indicates that there were 624 private hospitals in Australia in 2014-15 (Australian Institute of Health and Welfare 2016).

3.4.2. Not-for-profit private hospitals

The not-for-profit hospital sector is a comparatively smaller sector, comprising small groups of hospitals. Not-for-profit hospitals operate private and some public hospitals including:

- St Vincent's public hospital and St Vincent's private hospital in Melbourne
- Cabrini hospitals
- Sydney Adventist Hospital
- Epworth Group
- St John of God hospitals in regional Victoria and Western Australia
- Other independent not-for-profit hospitals.

Similar to other private hospitals, not-for-profit hospitals also operate s94 hospital pharmacies or contract out their pharmacy services to s90 pharmacy providers.

In NSW, approved not-for-profit private hospitals, also have access to NSW state standing offer arrangements with suppliers.

3.4.3. Procurement processes in private hospitals

A key difference in the operation of private hospitals compared to public hospitals is the use of the PBS for inpatient emergency departments, as well as discharged, day-admitted patients and outpatients.

Formulary

In many private hospitals, the PBS operates as a 'defacto' formulary. Prescribing decisions by clinicians drive medicine procurement decision making in hospitals. In relation to a hospital formulary, stakeholders advised that private hospitals in the not-for-profit sector predominantly operated hospital-based formularies. These hospitals also had drug and therapeutic committees in place for medicines management purposes.

However, decisions on what to add to the list of medicines to be purchased was primarily driven by clinicians and the PBS. Not surprisingly, as a result of the wider use of the PBS, in dollar value terms, private hospitals pharmacists indicated that a greater proportion of medicine expenditure was attributed to PBS medicines.

Hospitals noted however, that private health insurance funds do cap expenditure on patient medicines, which also impacts the medicines prescribed in private hospitals.

Procurement models and processes

Consultations revealed that procurement of medicines was either:

- Conducted by corporate private hospital procurement units for a group of hospitals
- Outsourced to community pharmacies or third-parties.

3. Findings: Procurement and supply

Similar to public hospitals, private hospitals also directly procured medicines. The following two case studies provide an insight into differing approaches to procurement in private hospital pharmacies.

Private sector case studies

The following provide two case studies of private sector hospital approaches to procurement and supply:

Case study: HPS

About HPS

HPS is the major supplier of pharmacy services for HealthScope hospitals, St Vincent's Private hospitals, Calvary hospitals and some St John of God hospitals as well as public hospitals.

As the successful tenderer, HPS is responsible for the provision of pharmacists, pharmacy services and procurement of medicines for their hospital contracts. They supply and operate both s90 and s94 pharmacies in hospitals.

s90 and s94 pharmacies

HPS advise that where they can, they are rolling all s94 hospital pharmacies that comply with s90 location criteria to s90 hospital pharmacies. This is because these hospitals can better manage the transitions of care of patients coming to the hospitals. They can also access the 6CPA which enables these hospitals to:

- Undertake medicine reconciliations which has the biggest impact on pharmacists' time
- Provides patients with access to pharmacy services which they would normally be entitled to under the 6CPA.

Procurement contracting

In relation to the contracts with hospitals, HPS advised that they have a standard level agreement that is very descriptive and prescriptive of the services that they provide, which includes key performance indicators, quantitative and qualitative measures.

HPS does not operate a formulary. They have a national procurement team who also source their own pharmaceutical drugs from manufacturers and wholesalers. This includes generic medicines, PBS medicines, private medicines, and medicines that they only dispense on imprest.

Ordering, billing, and supply

When ordering medicines, pharmacies will order through HPS. The order will identify who pays for these medicines, i.e. whether it is the PBS, the patient, the health insurer or the Government. HPS monitors drug usage over a period of time. In deciding what they want as a contract line, HPS will consider what is best value for HPS and their clients and what the demand is from prescribers. HPS

has an internal process for analysing usage week-to-week, month-to-month. HPS is aware of medicine usage and demand. The firm identifies trends, the ups and downs, which are aggregated at pharmacy level and national level. HPS does not have a contract on patent lines where there are no biosimilars.

In operating hospital pharmacies, HPS advised that decisions as to whether imprest medicines are brought from the pharmacy or tendered out is determined by:

- Pricing
- If the medicine is covered under the PBS or not
- Availability of storage.

In general, if it is a PBS item, then HPS will buy the item. HPS monitors stock holding in all of their pharmacies with regard to KPIs and expiry dates. In the private sector, the pharmacies are small and as a result, stock management can be challenging.

HPS advised that their vendors/suppliers advise that there is ongoing pressure due to price disclosure, resulting in suppliers leaving the Australian market. This affects both PBS lines and non-PBS lines. HPS noted that there is a lot wasted staff time in seeking medicines and concern for patients.

Case study: Sydney Adventist Hospital

About Sydney Adventist Hospital (SAN)

Sydney Adventist Hospital, known as the SAN, is a not-for-profit health care facility employing 2,200 staff and 700 accredited medical officers who provide services for more than 50,000 inpatients and over 160,000 outpatients annually. The Pacific Division of the Sydney Adventist hospital operates the hospital and the pharmacy. The Pharmacy Director is the 'owner' on behalf of the Sydney Adventist group. As a not-for-profit charitable hospital, profits are reinvested into the hospital.

s94 and s90 licence

The SAN was one of the few private hospitals in the country to have had both an s90 and s94 licence. At one stage, the hospital used both pharmacy licenses at the same time, using s94 for inpatients and s90 for outpatients. Due to changes in relative remuneration rates, the hospital shifted to using just the s90 license. As a result, the DHS asked SAN to withdraw their s94 license given it was redundant, which the hospital did.

The pharmacy

SAN now operates as an s90 pharmacy, with health funds covering the cost of the patient co-payment as part of the health fund agreements with the hospital. SAN patients therefore have the same access to subsidised PBS medicines as do patients in public hospitals. Currently the SAN is operating the National Inpatient Medication Chart (NIMC) but are in transition to the PBS Hospital Medication Chart system to enable paperless on-line claiming in real time. Unlike public hospitals, which have been supported in the implementation of new IT systems, these costs are borne by the hospital. The

introduction of PBS online has been a major improvement for the hospital with the automatic approval process and reducing the need for a manual claim.

As with many hospitals, a large proportion of the medicines prescribed are non-PBS medicines, however a lot of decisions and processes are made with the PBS primarily in mind. Non-PBS medicines are charged or bundled directly to the ward and are funded out of the health fund bundle for that patient. Patients are provided with the PBS quantity of medicines on discharge.

As a pharmacy, SAN tries to maximise the PBS because it represents 'real dollars' coming in to the pharmacy budget, in addition to the hospital patient budget.

Procurement

SAN now outsources the administrative and negotiating part of its procurement to Slade.

Slade has a buying model based upon the timing of price disclosure, running down stocks at the end of the Price Disclosure Cycle, and will forecast expected adjustments in prices based on publicly available information. The market is adjusting much more quickly to price disclosure than it used to, adjusting in six days now instead of six months.

Unusually, as a charitable not-for-profit hospital, the pharmacy is also eligible to access the NSW public tender.

SAN goes to the manufacturers for the odd stock keeping unit but in the main, they source Slade lines through the wholesaler. Chemotherapy infusions are ordered in through Slade. Prices have stayed the same, but competition has reduced with a reduction in the number of compounders. SAN order twice a day using an adjustment system and have $400,000 medicines sitting on their shelf at any one time. There is not sufficient margin to run inventories. SAN cannot afford to stockpile expensive stock and closely monitors inventory ratios such as stock turnover.

Medicine shortages

The pharmacy has a significant problem with medicines shortages and now has approximately one full time equivalent having to source medicines in short supply. Finding a medicine can involve dozens of telephone calls. The pharmacy produces a weekly TGA shortage report for hospital clinicians on the drugs in short supply. This is done to manage clinician expectations, who do not understand the complexities of the market supplying the prescribed medicines. Given that the SAN market share is small, SAN perceives that it does not have the cash-flow to match providers such as Ramsay or HPS, in buying medicine stock. SAN was of the view that one consequence of large tenders such as the NSW Health tender, was that if a product is not on the tender contract list, unsuccessful companies would run down non-contract lines because they could not sell them. This impacts alternative brands available for medicines when the market is in short supply.

In managing shortages in supply, SAN advised that some suppliers are not transparent on supply timeframes. As a result, this caused problems for the pharmacy in managing expectations with clinicians in the hospital. Suppliers who are transparent on supply timeframes and who had very good supply and demand forecasting models are highly valued. Along with other private hospital stakeholders, SAN held the view that medicine and brand choice has been impacted by price

disclosure, as companies see the Australian market as less profitable and there is a shortage of medicines as a result.

Where a replacement medicine was not on the PBS, SAN would be required to cover the full cost of the medication and could not claim a PBS reimbursement. Sourcing overseas product is also expensive, and this is a cost borne by the hospital, not the patient.

3.4.4. Direct hospital procurement

All hospitals advised that a key component of their activities involved sourcing and procuring drugs directly from the manufacturer or supplier. This may include sourcing from overseas or within Australia. Hospitals directly procured and sourced medicines, including:

- Bulk intravenous fluids and other pharmaceuticals with a short shelf life
- Medicines where central pharmacies could not complete hospital purchases
- Medicines in short supply
- Medicines not on the formulary
- Rare medicines.

All state and territories and hospitals reported increasing pharmacist workloads in sourcing medicines in short supply. Sourcing medicines in short supply was a considerable challenge for hospitals. This is discussed further in *Section 3.6.1.*

3.5. High-cost medicines analysis

State and territory governments and hospitals consulted were asked if they could provide a summary of the purchase price of drugs for a sample of PBS medicines.

Lists were received from four hospitals (which included a mix of private and public hospitals) for a sample of 12 high-cost medicines and one low cost, high use medicine (esomeprazole).

Table 3-3 details the average price of the medicines paid by these four hospitals compared with the PBS Price to Pharmacy price. Where more than one Price to Pharmacy was available for a drug under the PBS, the highest price was chosen for comparison. The drugs listed are indicated for a range of conditions including Hepatitis C, gastroesophageal reflux disease, multiple myeloma and schizophrenia.

Caution should be taken in applying this data given that it is self-reported and based on a very small number of cases (4). Nevertheless, the table indicates that in comparison to the PBS price:

- The high-cost medicines, across different categories of medicine, had average savings per pack ranging up to $1334.69.
- The low cost, high volume medicine, esomeprazole, had an average saving of 54%.

3. Findings: Procurement and supply

Table 3-3: Sample of medicines – Average cost

Formulary	Medicine	Form and Strength	Pack size	PTP*	Average Hospital price	Difference between Hospital price and PTP ($)	Difference (%)
CDL	Ledipasvir and Sofosbuvir	400mg tablet	28	$22,136.61	$22,089.98	$46.63	0.21%
F1	Adalimumab	40mg/0.8 mL injection	2	$1,349.80	$1,279.86	$69.94	**5.18%**
F1	Ranibizumab	1.65 mg/0.165 mL injection	1	$1,105.94	$1,077.32	$28.62	2.59%
F1	Sofosbuvir	400mg tablet	28	$19,367.69	$19,321.06	$46.63	0.24%
F1	Aflibercept	4mg/0.1 mL injection	1	$1,105.94	$1,065.48	$40.46	**3.66%**
F1	Lenalidomide	25mg capsule	21	$6,587.49	$6,587.49	$0.00	0.00%
CDL	Tenofovir and Emtricitabine	300mg+200mg tablet	60	$1,453.70	$1,337.40	$116.30	**8.00%**
F2	Esomeprazole	20mg enteric tablet	30	$10.98	$5.06	$5.93	**54.0%**
F2	Etanercept	Injection 50mg in 1mL	4	$1,009.19	$939.25	$69.94	6.9%
F2	Infliximab	Powder for I.V. infusion 100 mg	1	$574.85	$505.72	$69.13	**12.0%**
F2	Pegfilgrastim	6 mg/0.6 mL injection	1	$1,250.00	$1,250.00	$0.00	0.0%
F2	Azacitidine	Powder for injection 100 mg	14	$5,172.16	$3,837.47	$1,334.69	**25.8%**
F2	Clozapine (clozaril)	200mg tablet	200	$484.76	$277.29	$207.47	**42.8%**

*PTP = Price to Pharmacy on 1 July 2017. Note: Where more than one Price to Pharmacy was available for a medicine, the highest price was chosen for comparison

Some hospital stakeholders considered that the perception that the hospital pharmacy sector has access to more commercially advantageous medicines pricing compared to other stakeholders was incorrect, given that up to 80% of PBS medicines expenditure is in the community pharmacy sector.

In consultations, SHPA advised that:

> *"To ensure quality, and manage cost, hospital pharmacies must ensure adherence to formularies when procuring medicines. There is variation between state and territories to how formularies are established, maintained and operated, and the resulting procurement practices. The prices achieved by these processes are not necessarily greatly favourable to those negotiated by large community pharmacy providers. In addition, they are often more restrictive with a greater dependence on generics, no*

guarantee of supply, no support for ensuring manufacturer compliance for timely delivery such as occurs with the Community Service Obligation and no alternative medicine options when stock is unavailable."

The high cost sample data does indicate that there may be cost savings being made in the hospital sector compared to the PBS, which would be returned to the hospital, as the difference between the price to the hospital and the PBS reimbursement. However, the extent to which is this reflects large state or territory tenders or savings delivered by s90 community pharmacy is difficult to determine and the sample size is too small to draw any definitive conclusions.

3.6. Procurement and supply issues

The following section outlines the key procurement and supply issues emerging from the Review. These outline issues in relation to:

- National supply shortages
- Health technology assessments
- New PBS listings.

3.6.1. National supply shortages (Issue 1)

National shortages in supply of medicines was raised by all stakeholders consulted. Whilst stakeholders acknowledged that there havealways been shortages in supply, the consistent message provided was that the supply shortages of medicines has worsened.

"Supply shortages have gotten worse recently. It certainly has been a huge impact. Even simple drugs are experiencing shortages. We have to import our own products from overseas to keep the stocks up. This causes confusion with patients when multiple brand changes occur to work around these shortages. Significant pharmacy time being taken up finding and sourcing alternative medicines. It is probably taking 2-2.5 days a week to deal with this. We are treating simple infections with broad spectrum agents now due to shortage of antibiotics" - (State public hospital).

The extent of medicine shortages in hospitals was recently quantified in a survey of 280 Australian hospitals and healthcare facilities. In their report, SHPA found that:

- 100% of respondents experienced supply shortages, totalling 1,577 individual shortages across all major therapeutic groups (SHPA 2017)
- Whilst the majority of shortages were not PBS medicines, eight out of the top 12 were PBS-listed medicines and those that were not PBS listed were the same medicine in different form.

Stakeholders considered that the impact of medicine shortages had been significant, impacting on:

- Pharmacist time and resources
- Cost of medicines to hospitals
- Patient quality use of medicines

- Rural and remote supply.

Hospital pharmacies universally confirmed they are dedicating considerable pharmacy resources to source alternative medicines:

> *"We spend an awful amount of time chasing around to source medicines. Medication shortages has been a big issue (especially antibiotics), but to the credit of the manufacturers they have managed their shortages relatively well, by drip feeding their supply out. They're maintaining supply so they can continuously supply the market. Communication with suppliers is better than what it was, but is not ideal. The number of shortages and recalls are huge. It takes up a lot of time and wastes a lot of money. These drugs are readily available overseas which is frustrating. The drip-feeding method isn't done through the usual supply channels. The burden is on the hospital to ring up and speak to the manufacturers and wholesalers individually. We are also experiencing preferential drip feeding as well, which has had a massive impact. Hospitals are absorbing the cost of supplying non-PBS brands to patients when the PBS listed brands for that drug are not available" – (Private hospital).*

> *"There is a reasonable amount of cooperation until it is really important. Wholesalers have been managing the stock-outs on a much fairer basis- in the past, some hospitals would panic-buy but the wholesalers are rationing now, provide everyone with a small amount on a regular basis within the contract framework as well as outside the contract framework. We do get told if there is going to be a shortage which gives us time to talk to clinicians about alternatives" – (Private hospital).*

Hospitals indicated that they were very reliant on correct pharmaceutical company forecasts:

> *"We have found that when pharmaceutical companies merge or when new tenders start-up they don't get their forecasts right. If these two things happen at the same time, then this creates shortage and quality control issues. Forecast issues can be a hidden cost of a contract. So, if there are three brands of a particular drug, and two are unsuccessful, those two scale down their production and may be promised to other states with a preferential supply to other contracts" – (Private hospital).*

Many viewed that price disclosure also contributed to the supply shortages, and this view is being reported to hospitals by suppliers:

> *"Price disclosure has pushed the price so far down that companies decide to pull out of the market and leave a gap. The global market is playing into this, it is on a knife edge, and there is no back up stock, one little supply chain. [Jurisdiction] is remote so we will be affected by shortages. We spend a lot of money for bulk-standard drugs coming from all over the world just to meet standard drugs. The normal supply chain does not work, so have to look elsewhere" – (Public hospital).*

Whilst the sustainability of the supply chain was seen as a global problem, Australia is not a comparatively big consumer and therefore was considered to be 'at the end of the chain'. Hospitals are increasingly reliant on sourcing medicines from overseas, either directly by the hospital through TGA SAS or by suppliers directly sourcing from overseas. Stakeholders considered that there was a disconnect because of the size of the Australian market, PBS reforms and globalisation which was contributing to medicine shortages.

3. Findings: Procurement and supply

Preferential contracting arrangements may be protecting some states and large private hospital networks from medicine shortages to some extent, but all those consulted expressed issues with shortage in supply.

Some manufacturers are seen to be responding to this by rationing supply. However, public hospitals in particular considered that the public hospitals needed greater protection in supply from manufacturers.

Impact on clinical care

> *"Major disruptions of the supply of PBS medicines impedes every hospital's ability to achieve the aims of the PBS program and Australia's National Medicines Policy and risks patient safety (SHPA)"*

Of the PBS-listed medicine shortages, 50.9% were antimicrobials. Other examples of shortages included shortages of water in vials and sodium chloride.

SHPA noted that:

> *"The threat of widespread antimicrobial resistance is well documented and rising. A significant risk with using second and third line medicines is undoing antimicrobial stewardship efforts with respect to educating doctors, particularly junior doctors, about best practice antimicrobial prescribing and the preferred first line antimicrobials for infectious diseases. Not surprisingly antimicrobial medicines were also reported as the most likely to be stockpiled. Stockpiling of essential resources can negatively affect the capability of less well-resourced facilities to obtain essential medicines when required, most commonly regional and rural services."*

Shortages of medicines did mean that clinicians are required to change patient treatment plans. SHPA reported 32% of all medicines in short supply have a significant impact on patient care, either by being substituted by less effective medicine or changes in the route of administration.

> *"These 'workarounds' are extremely problematic. Using a less efficacious medicine means taking more time to treat the same condition, thus potentially increasing the length of a hospital admission. Using less efficacious medicines may also mean exposing patients to adverse effects which incur extra costs to monitor and treat. These workarounds also may negatively impact patient quality of life during care episodes" – (SHPA).*

Impact on hospital budgets

Medicine shortages are seen to have a significant impact on hospitals from a cost point of view in sourcing alternate medicines.

> *"At the moment 2 hours every day are spent on sourcing antibiotics, fentanyl, chemotherapy, critical out-of-stock drugs. We have increased stockholding over last 6 months by $100,000 to $200,000. We buy from companies that we know and that have a good reputation. We have had a wholesaler licence for 15-16 years so we can buy overseas, as long as there is no parallel buying. It is frustrating because the silver-lining between what we pay and what we get back is disappearing – the hospital does*

not pay for hospital pharmacists, we do. We are funding pharmacists from the margin on what we supply on invoice and PBS revenue from private patients." – (s94 private hospital)

"If we get something from the (Public hospital) or [Public Hospital], we can't borrow it and we must buy it and they charge a 25% mark-up and some 'amazing' service fee. We try not to use them except as a last resort. We would tend to borrow from [Private hospital] or [private hospital} or one of the local community pharmacies if we can, rather than public hospitals." – (Private hospital).

Rural and remote supply issues

Northern Territory, Western Australia and Tasmania reported additional challenges with supply, due to the remoteness of their locations or remoteness from suppliers.

For example, in the Northern Territory, the bulk of medicines come from SA creating issues of timeliness. Medicines come via road-freight and take a week to arrive. Urgent orders need to be flown in at considerable additional freight costs. It was reported that chemotherapy compounding does not occur at Alice Springs hospital. Chemotherapy infusions need to be transported to Alice Springs. If doses need to be changed, then the hospital has to delay treatment. Cold-chain issues can also occur because of the heat, especially once it lands on the ground as temperature is important to some medicines and can impact on safety.

In rural and remote areas, where a particular medicine is not in stock, some jurisdictions (e.g. NSW) have prior arrangements with the local s90 community pharmacy to supply the medicine to the hospital.

NSW advises that these arrangements must incorporate appropriate safety and accountability considerations and meet compliance requirements. Relationships with community pharmacies are important in regional and remote areas where a comprehensive pharmacy service is not available, however, these relationships often do not operate on a strict, contract basis.

Shortages in supply of medicines added additional challenges for rural and remote hospitals, who are further impacted by supplier delays.

TGA Medicines Shortage Information Initiative

Stakeholders discussed the TGA Medicine Shortages Information Initiative. Under this initiative, sponsors voluntarily list prescription medicine shortages.

Feedback from hospitals indicated that they are aware that the shortage list was not necessarily kept up-to-date. Pharmacists considered that suppliers are reluctant to list medicines if this impacted on market share or for commercial-in-confidence reasons. Timeliness and accuracy of information was seen by hospitals to be critical in effectively managing shortages in supply.

National medical stockpile

Australia has a National Medical Stockpile which is a strategic reserve of drugs, vaccines, antidotes, and protective equipment for use in the response to a public health emergency. In addressing supply

shortages, a number of stakeholders suggested the further development of a distributive national stock pile of essential medicines.

Stakeholders suggested that the stockpile be increased to include medicines in high domestic demand to ensure continuity of supply. Stakeholders considered that even if this is bought at a premium, it would create more resilience in the Australian market. Some stakeholders however saw the potential for the creation of perverse incentives and issues in determining what would go on the list and how a crisis would be defined.

3.6.2. Medicine assessments and PBS listings (Issue 2)

With the growth in expenditure on new technologies in hospitals, health technology assessments are conducted by PBAC and state and territory health technology assessment bodies to assess the quality, safety, efficacy, effectiveness, and cost effectiveness of new medicines.

In information forwarded to the review, CATAG noted that:

> *"Innovation in health technologies has seen remarkable advances in healthcare, however these come at significant cost, with an expected cost of AUD $460.4 billion in the global market by 2021. Health technologies are the main drivers of healthcare expenditure, rising from $50.3 billion in the 1990 to $154.6 billion in 2014 (Australia Institute of Welfare and Health). Almost 50% of annual hospital cost increases are due to new technologies or the intensified use of old ones. A significant portion of this increase arises from new high-cost medicines.*
>
> *High-cost medicines are a significant cost driver both nationally and to state and territory governments. The ageing population and increasing consumer and clinician demands have resulted in more new medicines being prescribed and over a much longer timeframe than previously. In the coming years, there are expected to be unprecedented increases in the costs of medicines arising from the availability of new biological medicines, immunotherapy and targeted therapies.*
>
> *All new medicines require assessment prior to introduction and funding, this involves complex safety, quality and cost effectiveness considerations."*

Public sector stakeholders noted that the only mechanism for input into PBAC review of future PBS listings is through general public access on the PBAC website. From a state and territory perspective this was not seen as an ideal format to make submissions. It was noted previously that state and territories have had greater access to public PBAC assessment documents, but now more information is being redacted for confidentiality reasons reducing the usefulness of this information. Moreover, cost-effectiveness analyses are not included in the PBAC assessment documents, which states and territories view as being useful.

CATAG was of the view that there is an absence of a nationally coordinated approach to horizon scanning and health technology assessments for medicines. CATAG noted:

> "At the national level the PBAC undertakes assessments for new medicines considered for national subsidy. New and emerging medicines, which are utilised in hospitals are outside of the Pharmaceutical Benefits Advisory Committee's remit.

> CATAG has identified that there is a gap in a national approach to horizon scanning to support preparedness for availability of new medicines. In addition, there is lack of coordinated technology assessments for medicines, which are specifically used in the acute care settings leading to inequity of access between and within state and territories.
>
> Lack of capacity to undertake such assessments and actively horizon scan in some individual state and territories. This leads to variation in preparedness, equity of access to medicines and medicines utilisation between states and territories and within states and territories.
>
> There is a significant opportunity to build on the existing models to collaborate and develop a national approach to medicine assessments for the acute sector.
>
> An operational international example includes the UK National Institute for Health Research Horizon Scanning Centre, which aligns with the function of other medicines HTA bodies internationally."

As a result, stakeholders suggested that:

- The Department considers developing a dedicated and formal mechanism for states and territories input to PBAC decisions regarding new listings
- A national approach to horizon scanning and medicine assessments for the acute sector be developed.

3.6.3. Implications of new PBS listings (Issue 3)

The origins of the PBS are in its development as a community based scheme. Stakeholders noted that in hospitals there are a range of medicines that are not listed on the PBS and should be listed.

Examples provided by stakeholders included:

- Daunorubicin – the standard of care in acute lymhoblastic leukaemia, not on the PBS
- Topotecan – standard of care in neuroblastoma, only covered on the PBS for ovarian cancer
- Temozolamide – in quantities greater than 5, only covered on the PBS for Glioblastoma multiforme, but temozolamide is recognised internationally to be standard of care in many types of brain tumours
- Gabapentin for neuropathic pain – it is only covered on the repatriation PBS but is used as standard of care for neuropathic pain in paediatrics
- Aciclovir for prophylaxis – currently it is only covered for genital herpes and not other types of HSV (i.e. recurrent cold sores)
- Cyclizine – currently not on the PBS
- Movicol Junior – currently only Movicol is on the PBS but not Movicol Junior. Movicol is not appropriate for young children
- Nexium sachets – the tablets are covered but the sachets are not on the PBS

- Valaciclovir for cytomegalovirus – it is only covered for HIV patients, but not patients who are immunosuppressed and also require treatment
- Azithromycin for Cystic Fibrosis
- Ursodeoxycholic acid – only covered for primary biliary cirrhosis - but they do have other liver dysfunctions that require treatment with it
- Osmolax – not covered on the PBS
- Morphine mixture 1mg/mL – all other strengths are covered except this one, but it is usually the most appropriate for paediatric patients
- Filgrastim and pegfilgrastim for Wilms tumour – should be listed on the PBS for patients with Wilms tumour as these patients often receive highly immunosuppressive chemotherapy (and need to boost their white blood cells afterwards).

In some cases, sponsors choose not to have medicines assessed under the PBAC as it was noted that the listing of medicines is a costly and time-consuming process. Hospital stakeholders also noted that medicines approved by PBAC under specific clinical guidelines, are used in ways different to the registered use, such as different dose levels, alternate routes of administration as well as uses for patients or conditions outside the PBAC information guidelines. This creates a mismatch between PBS restrictions on clinical guidelines and prescribing in hospitals.

In addition, stakeholders noted that there are chemotherapy items where the active (pharmaceutical) agent in the preparation of chemotherapy may be reimbursed through the PBS, but not the cost of the infusion fluid, excipients and the administration aids. This adds greater complexity for hospitals and patients in fee arrangements and reimbursements given the use of PBS and non-PBS medicines. Hospitals are keen to seek further engagement to provide clinical input into PBS indications and to seek PBS reimbursement for infusion fluids, excipients and administration aids.

Insufficient notice of new PBS listings

States and territories and hospitals noted that in some cases, hospitals had limited notice before a drug was listed on the PBS, leaving limited time to put in place implementation arrangements. In addition, stakeholders noted that the listing of new expensive medications requires consideration of the administrative and financial burden on health care providers in all settings.

Stakeholders reported that sufficient advance notice and engagement with the hospital sector would enable:

- States and territories clinical and cost-effective assessments to be conducted for approval to list PBS medicines on state/territory and hospital formularies
- Establishment of procurement and supply arrangements for the newly listed medicine
- An assessment of impact on hospital budgets and local hospital arrangements for the provision of the medicine
- Consideration of changes on hospital administration and IT processes
- Clinical information and training for medical staff on new PBS listings.

3. Findings: Procurement and supply

As one participant noted "*States are concerned at not being consulted before medicines were listed on the PBS, but then states have to fund these medicines without a voice at the table*."

Prescribing limitations on treatment quantities and durations

Stakeholders reported that generally, PBS prescribing indications match standard treatment expectations. However, greater flexibility in prescribing and quantity is an issue for many hospital patients, particularly those with serious health conditions.

Other examples included:

- A patient may require antibiotics for seven days but the PBS quantity standard is five days. This then requires an authority approval to allow for seven days medicine to be dispensed. This approval may be difficult to obtain, particularly out-of-business hours. As such, doctors may prescribe outside of the PBS which unnecessarily disadvantages patients who pay the full price, or the hospital who will absorb the cost in their operational budget.
- The exact amount of medication required for an inpatient stay is often unclear at the time of treatment. The basic PBS operational rules are reported not to work in a hospital setting. For example:
  - If a medication changes, due to a blood test, the unused medicine goes to waste
  - It was suggested that the PBS claim be made upon discharge when the exact amount of medication is known.
- Patients with rare conditions often require non-PBS treatment as PBS listings for these rare diseases and their treatments are less frequently presented to PBAC and therefore less likely to be PBS listed. Treatment with non-PBS medication is then determined on a hospital-by-hospital basis. This reduces the ability of hospitals to provide relevant medicines on discharge.

For these reasons, all stakeholders suggested that:

- The Department introduce a more systematic way to consider the implications of new PBS listings for hospitals
- Greater engagement between the Department and the states and territories was needed, especially prior to the new high-cost PBS listings, to inform the process of implementation.

4. Findings: Prescribing arrangements

4.1. Introduction

Prescribing can be described as a four-stage process with each stage influencing the next (Coombes et al., 2011). The four stages involved are:

1. Information gathering including medication history, medicine taking behaviour and an accurate diagnosis
2. Clinical decision making to select the right medicine, form, route, dose, and duration of treatment
3. Decisions, as an instruction, for the supply and administration of medicine
4. Monitoring and reviewing the outcome of the prescribing decisions.

These four stages form the basis of the discussions for prescribing arrangements in hospitals.

In the community setting, prescribing predominantly involves a GP or authorised prescriber. A consultation is conducted with the patient and a PBS script is written which is presented by the patient to a community pharmacy.

In the hospital setting, prescribing is a more complex process:

- For inpatients, prescribing is done via hospital medication charts. Instructions are written on the NIMC, the new PBS HMC, or the hospital's electronic medicines management system. These are written orders rather than scripts and can be supplied from the imprest (ward stock) or via the hospital pharmacy, if not on the imprest.
- For patients being discharged, day-admitted patients and outpatients, patients will be provided with handwritten or electronic printed scripts. Hospital PBS scripts include:
  - s85 scripts – which can be dispensed at a community pharmacy
  - s100 private hospital scripts – which can be dispensed by the private hospital pharmacy or community pharmacy
  - s100 public hospital scripts – which can be dispensed by the public hospital pharmacy or community pharmacy. Note that s100 HSD non-CAR prescriptions can only be dispensed by s94 public hospital authorities.

Dispensing issues are considered further in *Chapter 5*.

Across the hospital, prescribing by clinicians can occur in a range of settings including in:

- Wards
- Day surgeries
- Emergency Departments
- Outpatient clinics. In relation to outpatients, clinicians in public hospitals may also conduct either public or private outpatient clinics in rooms in, or co-located, with hospital premises.

4. Findings: Prescribing arrangements

The extent to which the PBS is used will also depend on whether the hospital is public or private:

- In private hospitals, PBS scripts can be used for all types of patients in hospitals (inpatients, discharge patients, day-admitted patients, and outpatients)
- In public hospitals, the PBS in general does not reimburse hospitals for inpatients and the extent to which the PBS is used for other types of patients is determined by whether the state/territory has a PRA arrangement in place.

The process of prescribing however, will typically follow a similar pathway in both public and private hospitals. Clinicians may prescribe both non-PBS and PBS items on scripts and the scripts are reviewed by a clinical pharmacist. All hospital prescribers are required to follow the relevant PBS authority approvals processes. Both s85 and s100 medicines may be authority required and, depending on the type of authority, the process to receive and record the authority differs (see *Section 4.6*). In addition, prescribing processes will also differ depending on whether hospitals have in place paper based prescribing systems or electronic prescribing systems.

The following sections describe in further detail:

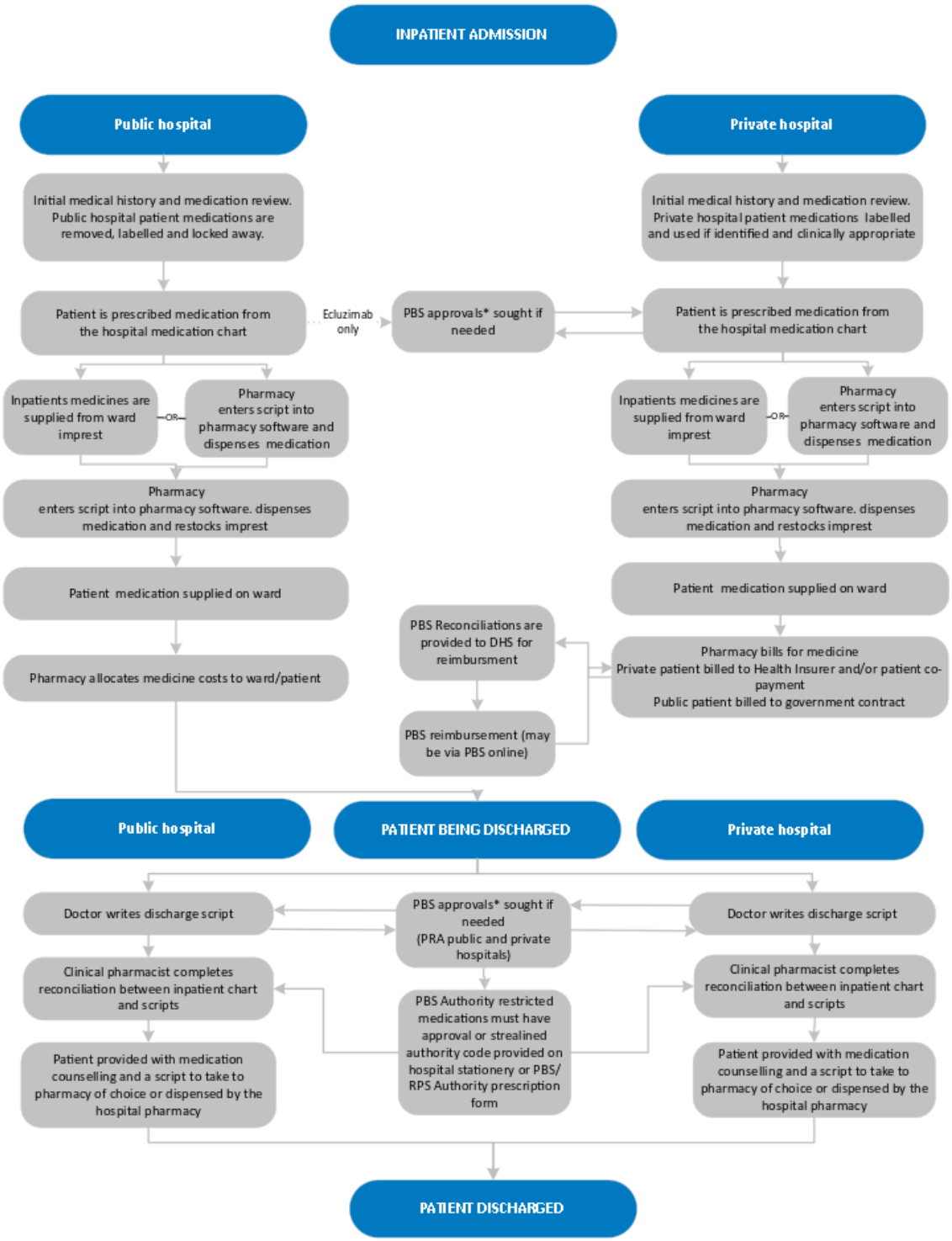
- Prescribing methods for:
  - Inpatients
  - Discharge patients
  - Day-admitted patients
  - Outpatients
- PBS authority approvals process
- Paper based and electronic prescribing.

4. Findings: Prescribing arrangements

4.2. Inpatients

Figure 4-1 provides an overview of the prescribing and dispensing process for inpatients through to discharge patients in both public and private hospitals.

Figure 4-1: Summary of PBS application for inpatients and discharge patients



4. Findings: Prescribing arrangements

Many hospitals employ clinical pharmacists on the wards to provide ward-based pharmacy services. These pharmacists are attached to units across the hospital and have a very active involvement in admissions and discharge, including providing support and advice to guide prescribers.

4.2.1. Initial patient history and medication review

When a patient is admitted, patient history is taken including the patient's use of medications. Patients may be asked to bring their medicines with them when they are admitted. The history is used to inform inpatient medication orders, to make treatment decisions and to identify adverse medication events.

Public and private hospitals deal with medicines brought in by patients for pre-existing conditions differently:

- In **public hospitals**, medications are locked away in a drawer beside the patient or in a cupboard elsewhere with the patient details, until the patient is discharged.
- In **private hospitals**, patients use their own medication supply, if available, and if the medication can be identified. In some private hospitals, all imprest medicines are non-PBS lines. However, some might stock PBS lines for use as starting doses. A PBS script would be produced soon after and dispensed to the patient for use.

4.2.2. Inpatient medication charts

Generally, during an inpatient stay, a prescriber provides written instructions and a third party (usually a nurse) would administer the medication to the inpatient. Written instructions are the preferred method of prescribing as this ensures medication safety. Instructions are written on either the NIMC, the new PBS HMC, or the hospital's electronic medicine management chart.

National Inpatient Medication Chart

Hospitals can use the NIMC for inpatients which exists in paper and electronic form.

The aims of these charts are to 'reduce the risk of prescribing, dispensing and administration error by health professionals through standardised presentation of information on the intended use of medicines for an individual patient, and through standardised presentation of medicines information in all high risk healthcare settings' (Australian Commission on Safety and Quality in Health Care 2017).

The NIMC authorises the third party to give the medication to the inpatient. A separate prescription is required for patients upon discharge (see *Section 4.3*).

Many hospitals have been asked to transition to the PBS HMC.

PBS Hospital Medication Chart

The PBS HMC is a new national standardised chart that was developed for use in inpatient and outpatient settings for both public and private hospitals. It allows for the prescribing, dispensing and claiming of PBS medicines directly from the chart and also accommodates for the provision of non-PBS

medicines (Australian Commission on Safety and Quality in Health Care 2017). Some hospitals reported transitioning from their electronic medicines management chart to the PBS HMC.

The claim for PBS medicines off the PBS HMC is completed through PBS online and does not require paperwork to be sent in. Pharmacies are able to enter prescription information into the prescription dispensing software which is sent to the DHS online claiming system. A message is returned in real time indicating whether the claim is payable. PBS online claiming has been praised by stakeholders in this Review for its ability to reject in real time.

4.3. Discharge patients

A clinical pharmacy team aims to be very involved in the discharge process to ensure there are no duplications of medicines or wastage.

Once a patient is ready for discharge, a junior doctor usually writes the discharge script for patients, however scripts can also be written by senior doctors and specialists. This usually involves transferring medicines from the inpatient chart into a hospital prescription form for discharge.

Any medications that are authority restricted must have approval or a streamlined authority code provided on either the hospital prescription stationery or on a separate PBS/RPS Authority Prescription form.

Hospital prescription stationery

Hospitals can use an **approved hospital PBS prescription** form to write prescriptions for PBS and non-PBS items. Computer-generated PBS prescription stationery is also available for hospitals. The PBS prescription forms may vary between state and territories; however, the PBS requirements remain the same. The hospital prescription stationery is not prefilled and thus prescribers must ensure that they have all their details accurately recorded, including:

- Patient details
- Medicine name and strength
- Route of administration
- Dose form
- Quantity
- Prescriber details including: name, prescriber number, contact details, signature
- Date.

Figure 4-2 provides an example of a hospital script.

Medicine reconciliation

On discharge, clinical pharmacists complete medication reconciliation between the NIMC/PBS charts, scripts at point of discharge and the patient's medicines for pre-existing conditions. This will involve counselling of patients on medicine usage.

4. Findings: Prescribing arrangements

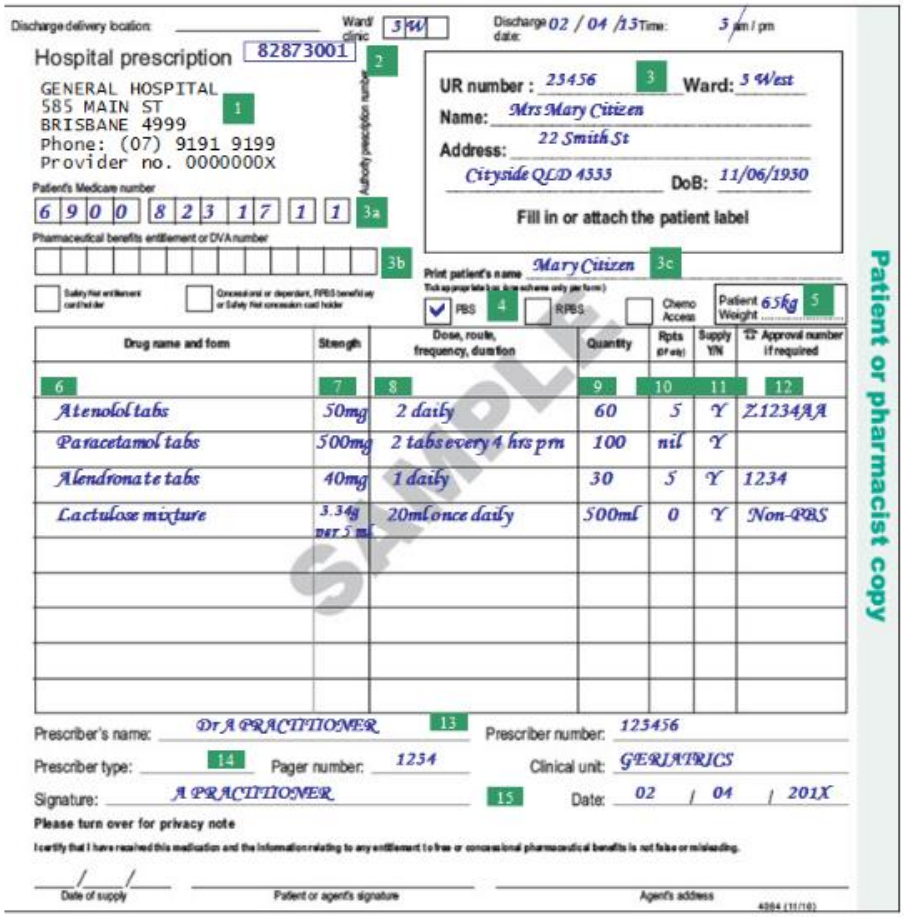
In public hospitals, where clinically appropriate, patient medicines brought in by patients will be returned to patients.

In private hospitals, the remaining supply of patient medicine brought in at admission will be returned to the patient.

Upon discharge, medicines that are not used during an inpatient stay undergo assessment by clinical staff who complete a safety check and reconcile the medications. The unused medicines may then subsequently be sent:

- Directly to the pharmacy with the discharge order where additional medications are added to make up the discharge quantity and given back to the patient
- Returned to the pharmacy and subsequently disposed.

Figure 4-2: Hospital prescription stationery



Source: Australian Government Department of Human Services (2017b)

4.4. Day-admitted patients

Figure 4-3 provides an overview of the prescribing and dispensing process for both surgical day procedures and chemotherapy day procedures.

Generally, prescribing for day-admitted patients utilises the hospital PBS script.

4. Findings: Prescribing arrangements

In relation to surgical patients, the clinician may prepare the discharge script in advance as part of the review process in preparation for the patient discharge after surgery.

In relation to chemotherapy infusions, the clinical preparation and prescription process is more complex. In the pre-treatment consultation, the clinician prepares the prescription, which is forwarded to the pharmacy for clinical review to ensure appropriateness and preparation for the day of the patients' treatment.

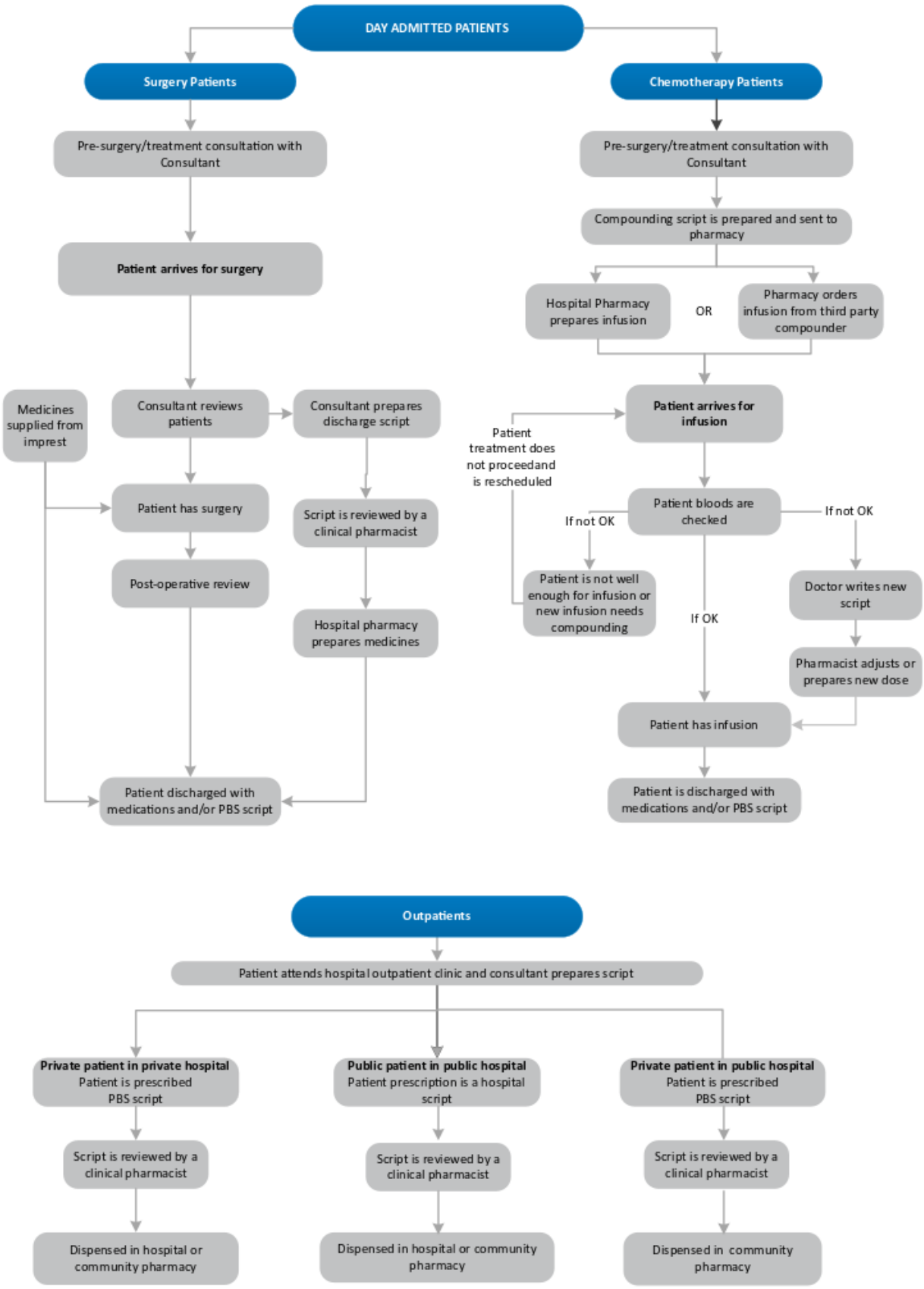
On the day of treatment, the patient has blood tests to determine the patient's readiness to proceed with treatment. If the blood results align with the patient's condition (as determined by the clinician), the patient receives the infusion and the appropriate medications and/or scripts are given to take home. If the patient cannot receive the treatment (for example, if they are not well enough) the appointment is rescheduled for a later date. Alternatively, a different dose may be required and depending on the compounding logistics involved, the dose may be adjusted on the day and be ready for the patient to be treated, or the patient may be rescheduled for a later date.

4.5. Outpatients

An outpatient sees a specialist who determines the most appropriate course of treatment. The consultant sees the patient in the outpatient clinic and may prepare either a PBS script or a hospital script, depending on the type of patient and hospital (see *Figure 4-3).* Note that in non-PRA states, patients may be seen as a privately-referred non-admitted patient in a public hospital setting.

4. Findings: Prescribing arrangements

Figure 4-3: Summary of PBS application for day-admitted patients and outpatients

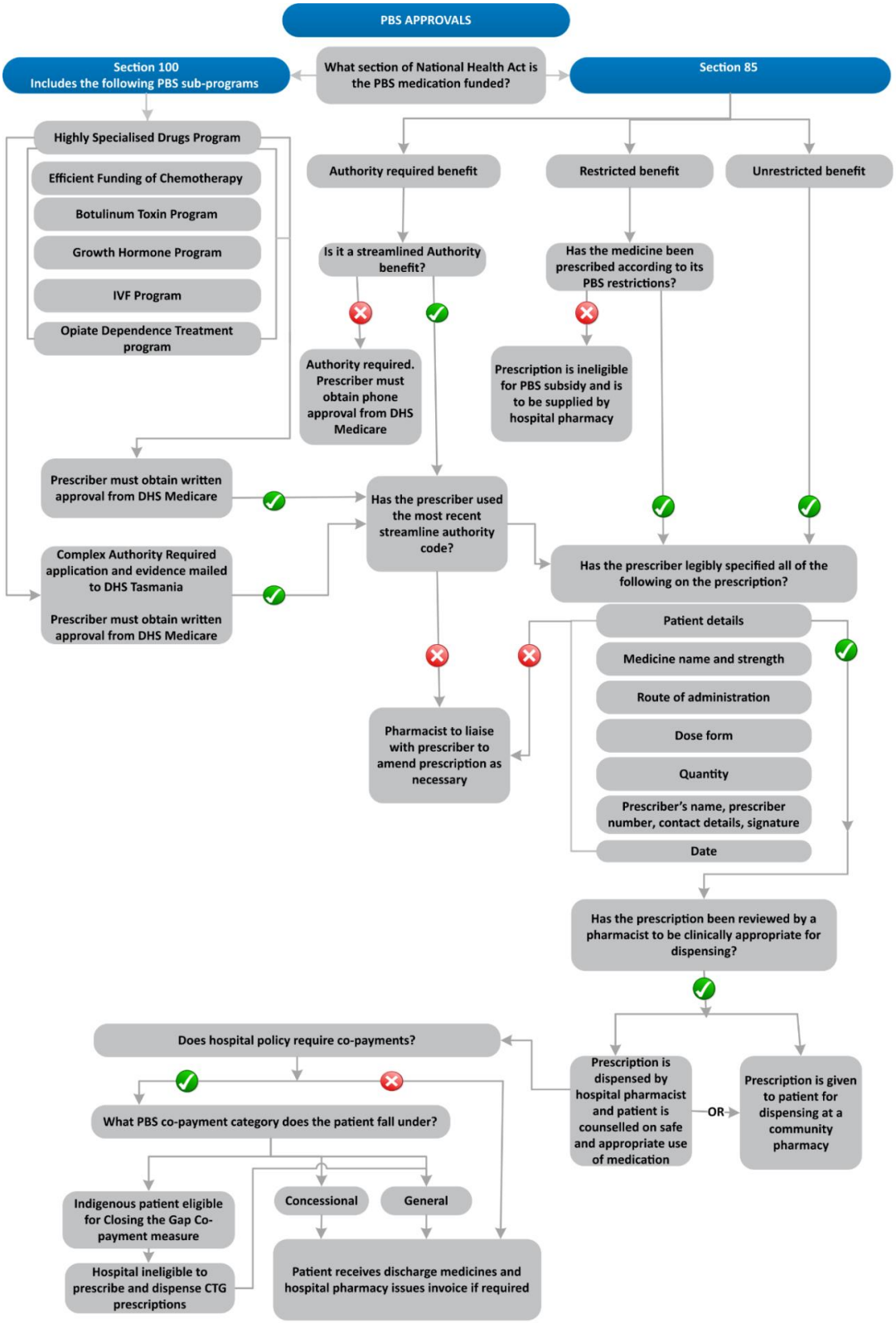


4. Findings: Prescribing arrangements

4.6. PBS authority approvals

Figure 4-4 summarises the PBS Authority process for s100 sub-program medicines and s85 medicines.

Figure 4-4: PBS approval processes



Adapted from SHPA 'Provision of medicines at point of discharge in public hospitals' (August 2017 SHPA submission to AHA)

4. Findings: Prescribing arrangements

Section 85

For s85 medicines, there are three streams of approvals:

- **Unrestricted benefits -** no restrictions on therapeutic use
- **Restricted benefits -** may only be prescribed for specific therapeutic uses
- **Authority required benefits -** these fall into two categories:
  - **Authority required benefits**: both PBS/RPBS benefits and require approval from the DHS, or the Department of Veterans' Affairs (DVA) through:
    - Posting an Authority Prescription form to DHS or DVA
    - Calling DHS or DVA telephone authority applications free call service
    - Using the DHS PBS authorities' website
  - **Authority required (streamlined) benefits:** exist only for PBS (not RPBS) and do not require prior approval by DHS, but require a valid streamlined authority code on the Authority Prescription form.

In 2014, the Department conducted a Post-Market Review of Authority Required PBS Listings to improve patient safety and care by reducing red tape and administrative burden for health professionals, resulting in the loosening of some restrictions.

Section 100

Some medicines may be categorised under more than one category, depending on the indication and/or the setting of the patient. s100 categories include:

- HSD Public hospital listings:
  - Streamlined Authority
  - CAR
- HSD Private hospital listings:
  - Streamlined Authority
  - CAR
- HSD Community Access listings:
  - Streamlined Authority
- EFC listed medicines:
  - Authority required
  - Authority required in writing
  - Streamlined Authority.

CAR listings require written application and approval from DHS. Authority Required listings require the prescriber to contact DHS for prior approval and can be achieved by phone, writing or online.

4. Findings: Prescribing arrangements

4.7. Prescribing stationery

4.7.1. Prescribing stationery

Pharmaceuticals can be prescribed using a variety of stationery depending on the pharmaceutical item, the prescribing practitioner, whether the pharmaceutical item requires supervision and whether the item is listed on the PBS. Descriptions of the prescribing stationery are detailed in the relevant sections; however, the range of prescribing stationery include:

- NIMC (*Section 4.2.2*)
- PBS Hospital Medication Chart (*Section 4.2.2*)
- PBS prescription form (*Section 4.7.2*)
  - A4 paper-size form approved for hospital-use
  - A5 paper-size form for use in the community setting
- Authority prescription form.

4.7.2. PBS prescription forms

There are five standard types of PBS prescription forms which can be used depending on the type of prescriber. These are most commonly used in the community setting, as opposed to the hospital setting. However, note that the Authority Prescription forms are used both in the community and private hospital setting. Public hospitals do not use Authority Prescription forms, as the three-part A4 prescription form *(Section 4.7.2)* can contain a mixture of Authority, non-Authority and non-PBS items.

PBS prescription forms are A5 paper-size and are provided for PBS prescribers free- of-charge.

Personalised forms and non-personalised (blank) forms are available for doctors, dentists, optometrists, midwives and nurse practitioners.

- **Personalised forms:** printed with the prescriber's name, qualifications, practice address/es, telephone number and prescriber number
- **Non-personalised (blank) forms:** distributed as an emergency supply when prescriber has run out of personalised forms.

The remaining three prescription forms can only be used by doctors, including:

- **Locum forms:** have the doctor's name, prescriber number, telephone number and a space to record the practice where the doctor is working
- **Computer PBS prescription forms:** these are either continuous or a single sheet and include the name, address, telephone number of the prescriber on the reverse side
- **PBS/RPBS Authority Prescription forms:** can be personalised, non-personalised or in locum format. There are three copies of the form: pharmacist/patient copy, Department copy and prescriber's copy (see below for more information).

4. Findings: Prescribing arrangements

In public hospitals, consultants may conduct both private clinics and public clinics and will need to select the correct stationery. It was noted that public hospitals and/or state health departments are required to pay for prescription forms and paper at a significant annual cost. There are concerns about the cost of hospital prescription stationery with a stakeholder suggesting the computer blanks are five times the cost of the stationery used previously in hospitals.

4.7.3. Electronic and paper-based prescribing

Across the country, hospitals are in various stages of transitioning from paper-based to electronic systems. Hospitals with paper-based prescribing systems consistently reported the administrative burden of paper-based scripts. Challenges included:

- Scripts written by junior doctors (interns, registers) may be incomplete or have missing information e.g. the quantities may be wrong, the drug may not be on the PBS, the indications may be wrong or missing prescriber numbers.
  - As hospital scripts are able to be dispensed in a community pharmacy, if a script is missing a prescriber number or has an ineligible doctor name, there are issues with following up the prescriber as there is no national database containing prescriber numbers and prescriber names
  - Moreover, with schedule 8 medicines, due to stricter regulations by state/territory legislation, pharmacists often need to confirm the order with the prescriber.
- Finding doctors within hospitals when there are problem issues with scripts could also be challenging, as doctors may be located in wards or clinics.

Hospital pharmacies which had introduced electronic prescribing systems are better able to manage the administrative complexity.

Stakeholders reported the move to electronic systems had improved the administration of prescriptions through electronic prescribing, where incorrect information would be identified immediately through the system or where specific authority approvals are required. There are a wide range of electronic systems used in public and private hospitals. The case studies below outline some examples.

4.8. Issues in prescribing arrangements

4.8.1. Unwieldy PBS authority processes (Issue 4)

PBS authority processes are difficult to navigate for prescribers due to the multiple listings of pharmaceutical items for different indications. It was reported that often there are difficulties in knowing which Streamlined Authority Code to use due to the frequent changes to these codes. The changes to these codes often occur without notification and render existing prescriptions obsolete and ineligible for subsidy. Pharmacists advised that they spend a substantial amount of time liaising with doctors about the new codes for prescriptions, which can delay medicine access for patients.

Stakeholders also raised the time delay for complex authority approvals required for specific HSDs due to their clinical use and other special features. These require the highest level of evidence and include

drugs used for the treatment of acute lymphoblastic leukaemia, cystic fibrosis, narcolepsy and rheumatoid arthritis.

Complex authority approval evidence is provided to DHS in Tasmania for review and approval. Stakeholders are concerned at the long turnaround timeframes (reportedly up to 6 weeks for approvals) for some CARS medicines, especially given that these could be used for patients requiring urgent treatment. One private hospital advised that they seek the patient's approval to cover the cost of these medicines should they not be approved by DHS, so that in urgent cases, the patient can proceed with treatment. This can be extremely expensive for patients if approval by DHS is not provided. Delays are particularly an issue for hospitals in remote areas including Western Australia and Northern Territory, however was raised by all state and territories across Australia. Prescribers suggested the introduction of electronic application processes to speed up authorisation processes.

4.8.2. Consistency of information technology infrastructure implementation (Issue 5)

An ongoing trial for electronic billing/ prescribing was established for a limited number of hospitals across the nation. However, there has been no apparent expansion which has created frustration in the industry. The benefits of electronic prescribing (as reported by stakeholders) include:

- Clear advantages around administrative efficiency
- Eliminating handwritten scripts, thereby improving accuracy and medication safety

As hospitals move towards implementing the PBS HMC, integration of electronic prescribing upon discharge was also viewed as essential. Stakeholders suggested that electronic medication charts would be beneficial for hospitals, but noted that this major piece of work for end-to-end digitisation requires a regulatory framework to enable change and requires input from both Australian Government and state/territory governments.

4. Findings: Prescribing arrangements

Case study: Information technology infrastructure

The Royal Children's Hospital in Victoria launched its electronic medical record in April 2016. This is a computerised version of the paper-based medical record and has the ability to adjust the amount of medication given to a patient depending on an estimated length of stay. The system prints onto a Medicare approved PBS script which includes a patient-identifying barcode. The hospital reports that the system has been working effectively and electronic prescribing has allowed for medicines to be ordered in advance. This allows pharmacists to see orders in advance and undertake the necessary checks.

In **South Australia**, an electronic patient administration system (EPAS) is used in hospitals and creates electronic health records for every patient. EPAS was implemented by Allscripts and SA is the only state that is using this Allscripts product. A handful of clinics in SA use a local version of the software, however state-wide adoption of Allscripts is anticipated over time.

HPS reported that their hospitals are working towards using a **Closed Loop Electronic Medication Management** (CLEMM) system. CLEMM was developed for use in the United States and allows for unit-dose medication management. All steps involved in the medication cycle are supported electronically from the ordering, verifying, preparing, and administering of medicines. CLEMM requires four components: an active medication order, an electronically-identified provider (nurse), a barcoded drug, and an electronically-identified patient (Clinical and Systems Transformation 2014).

Princess Alexandra Hospital has implemented the first pharmacy automation system in Australia. The pharmacy uses RoboPharma automated robots which selects medicines using barcode technology. RoboPharma allows for automated imprest picking for the wards, storage and dispensing of refrigerated drugs as well as providing modules for slower moving products. This dispensing system is reported to take ten seconds with the pharmacy robot, compared to twenty minutes by a pharmacist to select medications (RoboPharma 2012). This system is integrated with the iPharmacy as well as Charm Health (a specialist oncology clinical and administrative e-health system).

Joondalup Hospital uses an electronic NIMC on both the public and private wards throughout the hospital to increase medication safety. A feed comes through the pharmacy every fifteen minutes and identifies the location of a patient with information about the medications being used. Nursing staff may order medication on a requisition form and an invoice from the pharmacy is created and is charged to the hospital.

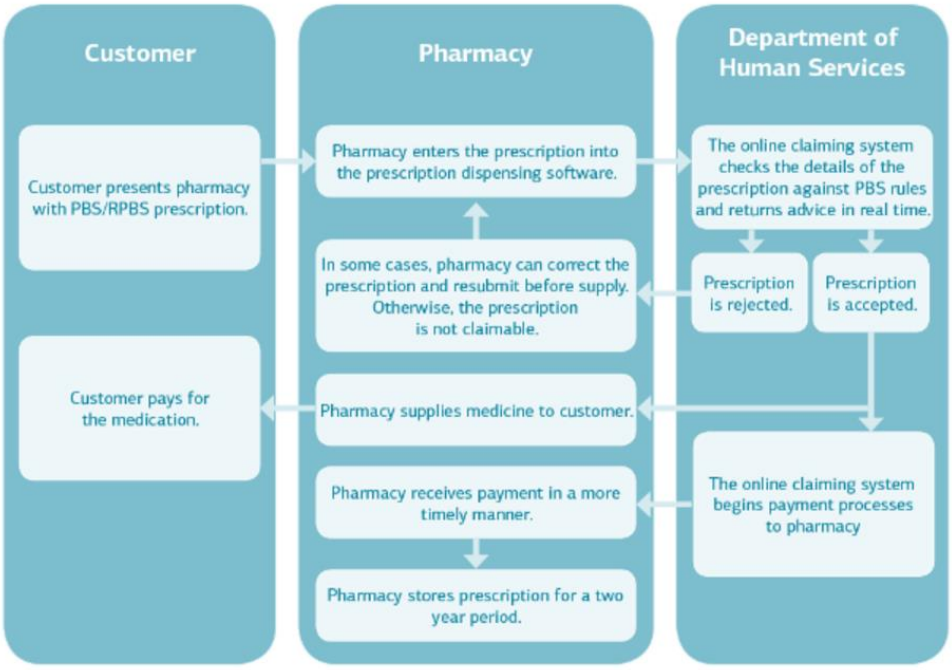
5. Findings: Dispensing and claiming

5.1. Introduction

Dispensing is the process whereby a pharmacist prepares and issues pharmaceutical items for a patient. Pharmaceutical items are then claimed under the PBS for the prescription product. The supply of pharmaceutical benefits is mainly through an approved pharmacist (who must comply with certain conditions) who is approved to dispense from a particular pharmacy. Other suppliers of pharmaceutical benefits include approved doctors who practise in isolated areas, Friendly Society pharmacies and approved hospitals.

Dispensing firstly requires a valid prescription from an approved prescriber to be presented to the pharmacy. The pharmacist determines the prescriber's intention and make full records of all aspects of dispensing. A pharmacist will review the medication history of the patient to ensure that the medicine is safe for use with consideration of all other non-prescription and complementary medicines used. The pharmaceutical item is selected and is clearly labelled with directions of use, including any cautionary or advisory labels. All dispensing procedures are checked again for accuracy and completeness. The patient is counselled and provided with all the information required (including consumer medication information leaflet) to safely and effectively use the medication (Australian Institute of Health and Welfare (AIHW) 2015). This process is summarised in *Figure 5-1.*

Figure 5-1: Online claiming process for PBS scripts



Source: Australian Government Department of Human Services (2017c)

The process for dispensing and claiming is generally uniform, however there are variations depending on the type of approval the pharmacy has, the type of patient and the type of pharmaceutical item. This chapter describes the range of settings where prescriptions are dispensed and discusses the issues related to dispensing and claiming.

5. Findings: Dispensing and claiming

5.2. Dispensing in hospital pharmacies

The pharmacy arrangements across Australia are dictated by the type of approval the pharmacy holds. There are differences in the supply of s85 PBS items under the s90 and s94 approvals:

- An **s90 approval** allows for the supply of PBS items to any Medicare card holder with a valid PBS prescription
- An **s94 approval** restricts the supply of PBS items to day-admitted, non-admitted and discharge patients of the hospital only and PBS scripts must originate from that hospital and be only written by hospital prescribers. However, in Queensland, the centralised PBS approval model allows the movement of scripts between public hospitals.

Public hospitals and private hospitals have different pharmacy arrangements that impact on PBS reimbursements:

- **Public hospitals** are serviced by s94 public hospital pharmacies, operated by the hospital authority. This is the most common arrangement in public hospitals. In limited circumstances, for example in hospitals that operate as a public-private partnership, or in rural or remote locations, public hospitals may also have pharmacy services provided under contract to an s90 community pharmacy.

  In some public hospitals, s90 pharmacies are situated within or adjacent to a hospital building, providing choice to patients to have hospital scripts that can also be filled in a community pharmacy.

- **Private hospitals** are serviced by s94 private hospital operated pharmacies under contract to an s90 community pharmacy. This is a more common arrangement in the private sector. They can also have an s94 private hospital operated pharmacy.

Different approval processes apply for s90 pharmacies and s94 pharmacies, with *Pharmacy Location Rules* applying to s90 community pharmacies. This affects the distribution of s90 and s94 pharmacies across community and hospital settings.

5.2.1. Imprest and pharmacy dispensing

Medication dispensing for **inpatients** differs across the public and private sector.

All medications provided to inpatients in public hospitals are provided from either the ward imprest or dispensed from the hospital pharmacy in a quantity that considers the patients' length of stay. Ward imprests contain commonly used medicines and medicines related to the ward specialty.

If a certain medication is not available, it would be dispensed from the pharmacy. In some cases, some hospital pharmacies dispense five days' worth of medicine at a time.

Hospitals may have printed a list or keep an electronic list as part of their system for each ward, that is printed out periodically throughout the day, so medicines can be supplied to the ward.

5. Findings: Dispensing and claiming

In public hospitals:

- In general, the medicines that patients bring with them are not used, as funding for medicines for inpatients should come from the state/territory budget. Some public hospitals will use the patient's own medication if it is not on their formulary. Pharmacists will identify and label these medications for use. This is to avoid patient confusion and concerns regarding allergies to coatings, binders, or fillings for brand substitutes
- Some hospitals, for example in SA, have automated dispensing cabinets which reduces the amount of wastage of medicines.

In private hospitals:

- Patient's medicines brought into hospital with them are used if available, and if the medication can be identified
- Otherwise, medications would be dispensed from the pharmacy and billed as a patient co-payment (from health insurance fund). A health fund allocates patients a certain amount to be used for medications per day.

5.2.2. Use of hospital or community pharmacies

There are many different factors that may influence whether a patient receives a medicine or has a PBS prescription filled in a hospital pharmacy or a community pharmacy. Factors that determine whether a hospital pharmacy will dispense a patient's medicine include whether:

- The hospital pharmacy is authorised to dispense PBS medicines and receive reimbursement for the patient
- The patient presents a script in a format that the hospital pharmacy is authorised to fill
- The prescribed medicine is on the hospital formulary
- The pharmacy stocks the medicines prescribed
- Medicines, or form, or brand are in stock, or a suitable alternative is available
- Clinical restrictions or PBS authorisations that mean that medicines must be delivered in a hospital environment, or are only available under specialist prescription through the hospital (s100 medicines)
- The hospital policy on filling scripts that could be completed in a community pharmacy
- Notwithstanding the above, the patient may choose to fill the script in a community or hospital pharmacy. This can be influenced by factors such as:
  - Whether the medicines are free to the patient or patient co-payments are charged
  - Hospital pharmacy waiting times or opening hours
  - Convenience for the patient
  - Whether the community pharmacy is more accessible for the patient, taking into consideration extra costs such as hospital parking and travel time.

Hospitals advise that pharmacists take into account the clinical interests of the patient when deciding whether to dispense a medicine. For example, hospitals may dispense a non-PBS medicine if the patient

is using this medicine for a pre-existing condition to avoid confusion for patients, or refer the patient to a community pharmacy to fill scripts not in the formulary or in stock.

5.2.3. Patient co-payments

Under the PBS, a patient pays a fixed co-payment (depending on concessional eligibility) meaning the cost of a prescribed PBS medicine is the same anywhere in Australia, with the balance reimbursed to the approved pharmacist by the PBS.

Patients who require a large number of PBS items are protected through the PBS safety net. Inpatients of private hospitals (particularly elderly patients) often do not know whether they have reached the safety net threshold. Hospitals reported that not having access to safety net information meant that, where patients had reached the safety net limit and are not aware that they had done so, hospitals are absorbing the cost of foregone PBS remuneration.

In other cases, public hospitals reported that they elected to cover the co-payment for specific groups of patients or diseases including:

- Mental health patients under involuntary treatment orders (as they have no choice as to whether they receive treatment)
- Tuberculosis treatment (covered on public health grounds to remove the barrier to treatment and reduce the passive spread to the wider population).

More commonly, waiving co-payments often required the approval of the hospital chief executive or delegate.

NSW s100 co-payments scheme

On 1 October 2015, NSW Health commenced a scheme, whereby patient co-payments are paid by the NSW Government for NSW residents who are patients of NSW public hospitals or community prescribers in NSW for specific medicines. These include:

- Injectable and infusible chemotherapy medicines
- HIV antiretroviral therapy, Hepatitis B medicines and clozapine (maintenance therapy only) available under s100 HSD community access arrangements.

In relation to chemotherapy infusions, this includes public non-admitted patients, outpatients or day patients, inpatients on discharge from public hospitals and privately referred, non-admitted patients of NSW public hospitals or by authorised community prescribers in NSW, regardless of whether they are dispensed in public hospital oncology services or community pharmacies in NSW. As NSW has not entered into a bilateral PRA, chemotherapy medicines are not available through the s100 EFC Program.

This includes eligible patients that choose to get their s100 HSDs dispensed in community pharmacies under community access arrangements.

Patients are required to provide consent to allow NSW Health to participate in the co-payment scheme. The NSW Ministry of Health reimburses Local Health Districts, Specialty Health Networks and pharmacies used by NSW public hospital oncology services from eligible patients, based on the

presentation of iPharmacy reports. Reimbursements for s100 HSDs dispensed from NSW community pharmacies are paid for by the NSW Government when a patient presents their consent form and prescription (including repeats) to a community pharmacy. The consent form is valid for 12 months and the reimbursement scheme is administered by the Pharmacy Guild of NSW.

Closing the Gap PBS Co-payment Measure

The Commonwealth established the CTG PBS Co-payment Measure to reduce the cost of PBS medicines for eligible Aboriginal and Torres Strait Islander people living with, or at risk of, chronic disease (see *Section 6.5.1*). Only prescribers affiliated with a general practice participating in the Practice Incentives Program Indigenous Health Incentive or an Indigenous Health Service in a rural or urban setting are able to annotate a script with "CTG". Hospital prescribers are not able to annotate a script with "CTG".

Hospitals repeatedly reported that hospital pharmacies would fill scripts for discharged patients who are registered for the CTG PBS Co-payment Measure and the hospital would elect to waive the additional co-payment cost in the interest of ensuring the patient goes home with the needed medicines. This was also often the case where CTG patients resided in rural or remote areas and a long distance from the hospital or community pharmacy. Some hospitals also spend significant amounts of administrative, patient and clinical time to get hospital scripts re-written by eligible GPs to allow patients to access CTG.

5.2.4. PBS dispensing and claiming technology

Approved pharmacists and approved hospital authorities are paid by the Australian Government for dispensing PBS items. Pharmacists claim these subsidies by lodging claims with DHS, which outline details of the PBS prescription dispensed.

There was universal support from stakeholders consulted that the online claiming process has made a major difference to efficiencies in the PBS claiming process. The ability to check the details of the prescription against PBS rules in real time was a key reason for this support. *Figure 5-1* depicts the flow of a PBS script through the pharmacy for dispensing and the online claiming process.

Many hospitals however, still use paper-based systems. Consultations revealed that where hospitals are implementing electronic medical records, hospitals are effectively running two systems to both manage electronic dispensing and satisfy PBS administration requirements. This can involve updating electronic health records, dispensing medicines and producing medicine labelling on different systems.

Reviews related to claiming

Since 2012, there have been ongoing trials of paperless claiming in hospitals with revocations and revisions including:

- *National Health Act 1953* - Special Arrangements under subparagraph 100(1) (b) (i) – Multiple Hospitals Paperless Claiming Trial (No. PB 16 of 2009)
- National Health (Multiple Hospitals Paperless Claiming Trial) Special Arrangement 2012
- National Health (Paperless Prescribing, Dispensing and Claiming Trial) Special Arrangement 2014
- National Health (Multiple Hospitals Paperless Claiming Trial) Special Arrangement 2015

- National Health (Multiple Hospitals Paperless Claiming Trial) Special Arrangement 2016.

Some hospital stakeholders expressed an interest in seeing these trials extended. In addition, the DHS has initiated a review of the PBS stationery.

Investment in electronic records in hospitals was recommended in the *2017 interim report of the Pharmacy Remuneration and Regulation Review,* and the interoperability of electronic health records and the PBS was identified as an issue:

> The lack of an interoperable electronic health record for patients also fragments care as prescribers in various settings, are often not aware of what the patient has been prescribed in other settings. From a hospital pharmacy perspective consideration of PBS claiming processes in the development of electronic health record infrastructure is highly recommended (SHPA).

5.3. Issues associated with pharmacy arrangements

5.3.1. Differential PBS reimbursement fees (Issue 6)

The funding received for similar services performed in public and private hospitals and the community differs. For example, community pharmacists receive a dispensing fee that is not provided to hospital pharmacists (see *Table 2-2).* Stakeholders perceived that the differentials in fees can result in a lack of fairness and equity and provides for potential gaming of the system. Fees did not reimburse "like work for like", or did not fully reimburse clinical work involved in the dispensing of medicines in hospitals.

Additionally, complex medicines are often dispensed in a hospital setting and require clinical services. Clinical services may include a review of the patient's status, their pathology results, treatment cycles, chemotherapy protocols (if appropriate), calculating dosages according to weight and height, education on how to best take the medicine and to monitor for side effects.

Stakeholders made a range of suggestions to improve fairness, equity and system efficiency and address the variation in PBS reimbursement fees that the Australian Government could consider. Hospitals contend that these clinical services are currently underfunded, which may impact on safety and quality. For example, warfarin (a widely used medicine) requires dose titration and therapeutic drug monitoring to ensure quality and safety of use.

As such, stakeholders made a range of suggestions that included:

- Greater alignment in mark up and dispensing fees
- Considering tiered fees that reflect the complexity of pharmacy services to ensure the sustainability of delivering cognitive medication review and appropriate access to medications.

Hospital wholesaler mark-up

Currently, public hospitals are remunerated for dispensing of s85 PBS items at the ex-manufacturer price, plus a wholesaler mark up of 11.1%, but no dispensing or other fees. At the time of establishing the wholesaler mark-up, the 11.1% was the community rate. For many low-cost medicines, this

percentage on-cost is small. However, this has caused concern for the Australian Government for high-cost medicines such as dispensing s85 scripts for Hepatitis C treatment.

Discussions with some PRA states and territories indicated a view that these jurisdictions would be willing to discuss this issue further with the Department. However, these states and territories also advised that in their view any negotiation on the wholesale mark-up depends on the revised arrangements being no worse than cost-neutral for public hospitals.

Chemotherapy Compounding fees

In relation to chemotherapy compounding fees, stakeholders raised a number of issues:

- Differentials in preparation fees for TGA licenced and non-TGA licenced compounders. Hospitals contended that the current compounding preparation fees are not reflective of the costs of compounding to hospitals and proposed removal of the differentiation between TGA licenced and non-TGA licenced compounders. Moreover, public hospitals are not able to be licensed by the TGA even if they would like to because of an exemption under the current legislation.
- States and territories advised that although hospitals meet TGA requirements, they are unable to obtain TGA licenses, which stipulate that the providers must have national coverage. Therefore, hospitals are ineligible for the TGA licensing compounding fee.
- There are some PBS medicines, other than chemotherapy, that also require manufacturing or compounding. For example, rituximab can be used as a cancer medication and for rheumatoid arthritis. When the indication is for cancer, it attracts a chemotherapy compounding payment under the EFC. The same compounding process occurs for rheumatoid arthritis however the process is not reimbursed. It was the hospitals' view that these costs should be recognised and funded accordingly.

s90 and s94 hospital pharmacies fees

Given the differentials between s90 and s94 pharmacy fees, stakeholders presented divergent views on whether there was a financial incentive for hospitals to operate with an s90 community pharmacy licence or an s94 hospital pharmacy licence.

On the one hand, the Pharmacy Guild was of the view that hospital pharmacies have a much-enhanced buying capacity, so are able to attract very good trading terms, which creates a competitive problem with the community pharmacies which cannot match hospital trading terms. Further, the Guild has the view that s94 pharmacies operate on a 11.1% wholesale mark-up whilst s90 pharmacies operate on a maximum of $69.94. The Guild states that this can create an incentive for hospitals to keep prescriptions, dispense repeats and to dispense high-cost drugs for maximum gain. In essence, it was much more profitable to dispense medicines under s94 and keep them within the hospital pharmacy.

On the other hand, private hospital stakeholders indicated that within the broader context of programs operated through the 6CPA, they would be more profitable if they were s90 pharmacies. There was some evidence that some private hospital providers are actively transforming their s94 authority to s90 approved pharmacies where the location rules enable them to do so. This would give them the

option to access the payments and fees that s90 pharmacies can access under the 6CPA such as Home Medicines Review fees.

Private hospital pharmacy mark-ups

Private hospital pharmacies are eligible to receive mark-ups and dispensing fees that public hospitals are not eligible for. It was reported from industry stakeholders that this incentivises private hospital providers to outsource their pharmacy services. This was of concern for some stakeholders, who stated that generally outsourced providers do not have access to inpatient records, thereby the appropriate clinical review would not be undertaken.

Dose administration aids

s94 hospital authorities are not recompensed for their time in packing dose administration aids (DAA). DAA are designed to support patients who have complex medicine needs to better manage their medication, with the objective of avoiding medication misadventure and improving medication compliance.

5.3.2. Script transferability and confusion about where scripts can be filled (Issue 7)

All types of public hospital pharmacies face issues where patients present with scripts that they cannot dispense, limiting dispensing only to hospital patients. This is particularly an issue for s94 approved hospital pharmacies which cannot dispense community scripts for PBS items or PBS scripts from another hospital, thereby limiting medicine access for patients. Patients find it hard to understand why scripts can and cannot be filled by hospital pharmacies.

Often, hospital pharmacies work in partnership with community pharmacies to service the local community. Many hospitals stated that encouraging patients to have their scripts dispensed in a community pharmacy was part of a strategic decision which reflected their clinical priorities. On the other hand, stakeholders such as the Pharmacy Guild cited a view that hospitals are incentivised to keep prescriptions, dispense repeats, and dispense high-cost drugs for maximum gain.

In general, hospitals stated they did not want to have the capacity to dispense community scripts. Some states, such as Victoria, have policies that mean they can only dispense to hospital patients. Other states identified some specific circumstances where there is the potential to dispense community scripts. These circumstances included:

- Rural and remote communities where there are no private pharmacies in the location
- Where local pharmacies did not stock high-cost drugs because of the financial risk to the pharmacy and these medicines are only available at the hospital
- Where residential aged care beds are co-located within a public hospital, however scripts written by the visiting GP are unable to be dispensed at the s94 hospital pharmacy. These prescriptions must be taken off-site to a community pharmacy, creating an unnecessary delay. This issue is being considered as part of the DHS PBS Stationery review.

5. Findings: Dispensing and claiming

Moreover, s100 HSD scripts that are written in an approved public hospital can only be filled by an approved s94 public hospital pharmacy and are **not transferrable** to s90 pharmacies or s94 private hospital pharmacy, whereas s100 HSD private hospital non-complex authority required scripts can be claimed by either a s94 private hospital pharmacy or a s90 community pharmacy. This was reported as confusing and frustrating for patients, as it inhibits patient-centred care, medicine access, and also ties patients to public hospitals (see *Table 5-1* for a summary of these restrictions).

Table 5-1: HSD dispensing and claiming eligibility

		Dispensing location		
		s94 public hospital	s94 private hospital	s90 community pharmacy
HSD Item prescription type	HSD public	✓	✗	✗
	HSD CAR public	✓	✗	✓
	HSD private	✗	✓	✓
	HSD CAR private	✗	✓	✓
	HSD community access arrangement	✓	✓	✓

Source: (Australian Government Department of Human Services 2017c)

Moreover, the **transferability** of s100 HSD public script and s100 HSD private scripts was identified to be an issue for remote communities where they have lots of travellers. These travellers, if they are organised, will contact a public hospital in advance. However, if the script is under a private hospital program the public hospitals cannot supply it. The current solution to this is to refer a patient to a doctor in the public hospital who has to rewrite the script, thereby creating a potential for medication error.

Stakeholders suggested that the Australian Government could consider streamlining approval arrangements to facilitate transferability of scripts and improve access for patients.

Different hospital models create issues for dispensing for both prescribers and for patients determining where they can get their scripts filled.

The DHS raised the following issues:

- **Public Private Partnership (PPP) hospitals** where state governments seek to combine private and public hospitals. This creates an issue where the hospital is declared as a private hospital under the *Private Health Insurance Act 2017* and the s94 approval is also private, however the

state government has outsourced the public component to the hospital. In relation to the PBS, this means that PBS claims and especially HSDs are potentially rejected through PBS online claiming.

This was brought to light in Western Australia, where the state government contracted the private hospital to manage public patients. The approval could only be for a private hospital. The private hospital had an s90 community pharmacy approved and the s94 private hospital approval was cancelled. The problem is that for public patients in this hospital, HSDs cannot be claimed as there is no approval in place. The prescribing doctor must use their own prescription pad and the medication is often supplied by a s90 community pharmacy.

- **Private hospitals outsourcing to a third party** – in some circumstances private hospitals are claiming for the PBS against the hospital approval number and the payment is going directly to the third party.

  In these circumstances it is not clear what the responsibility or role of the hospital authority who has the pharmacy approval is and whether this is considered a compliance issue.

- Public or private hospitals using/sharing their hospital approval number from more than one hospital location is another issue that may be considered a compliance issue.

It was suggested that the Department consider clarifying policies on these issues.

5.3.3. No direct access to required Medicare information (Issue 8)

Both public and private hospitals reported increased administrative time, complexity, and cost in accessing required patient information to prepare the PBS claim. This included:

- Information on the patient's PBS safety net limit
- Ability to check a patient's Medicare card number.

Lack of access to a patient's PBS safety net limit causes issues in determining the patient co-payments, and in turn, how to correctly bill the patient. Private hospitals tend to cover the co-payment for patients who do not know if they have reached their safety net. It was reported that the pharmacy will bill the hospital for the general co-payment amount ($38.80), however if the patient had reached the safety net, they should only be billing the concession co-payment contribution ($6.30). This costs private hospitals more than it should, because elderly sick patients are unable, and cannot be expected to keep track of their PBS safety net.

In a similar manner, patients being admitted to hospital are encouraged not to bring personal items, and therefore may not have Medicare cards with them when being discharged. Incorrect Medicare card information inhibited and delayed the claiming process.

It was suggested that these issues could be resolved through an automatic, electronic process. It was proposed that given PBS claiming is now completed online, information on the amount spent on medications should be linked to a patient's Medicare card to determine if a patient is eligible for concession.

6. Findings: PBS programs and operations

6.1. Introduction

Decisions affecting the operations of the PBS (including the number of medicines, the range of medicines, the number of brands on the PBS) reportedly put considerable pressure on hospitals. Changes to the PBS can be made more quickly in a community pharmacy setting, however in hospitals, new PBS listings often need to be put onto state and/or hospital formularies, meaning that the lead times are longer. Moreover, for any new drugs listed, hospitals need to consider if patients require initiation as inpatients.

The following section highlights the issues faced by stakeholders with PBS programs and the operations of the PBS. This includes consideration of the following:

- Issues faced by states/territories and private hospital operators in meeting business rules associated with the various PBS subprograms, including but not limited to the Highly Specialised Drugs Program and the Efficient Funding of Chemotherapy special arrangements
- Any reported access issues faced by particular patient populations (e.g. Aboriginal and/or Torres Strait Islander peoples or incarcerated persons) to PBS medicines through public hospital facilities.

Any issues raised that have been previously addressed are included for completeness but are summarised briefly.

6.2. Complexity of PBS arrangements

Throughout the consultations, the majority of issues raised about the s100 PBS programs related to the s100 HSD program. The following sections discuss issues related to the overall program with clear examples given of any issues related to relevant PBS subprograms. Note that NSW and ACT public hospitals dispense PBS medicines under the s100 HSD program but not under the other s100 programs.

Stakeholders are concerned about the overall complexity of arrangements related to the operation of the PBS. They noted that when an arrangement was not fit-for-purpose, in some cases the response has been the introduction of a more complicated rule. Stakeholders suggested that the simplification of arrangements would involve the re-design of some programs, which they would be willing to contribute to. Stakeholders are keen to see continued system efficiencies in the operation of the PBS by the Departments of Health and Human Services.

6.2.1. Dual listing medicines is unnecessarily complex (Issue 9.1)

Medicines that are listed under both s85 and s100 have the potential to be prescribed and claimed under either program. However, the listing depends upon the clinical purpose for which it is listed, as not all medicines are listed under s85/s100 for the same condition and where they are, the quantity and/or strength of the medicine can vary across listings.

In some instances, community pharmacies reported that claiming errors have occurred, as prescriptions are not checked to confirm whether the medicine should have been dispensed at the s85 or s100 remuneration rate.

Moreover, in some instances there are different authorised prescribers or prescribing requirements under s85 and s100, though the indications are identical. Whilst the indications may be identical, the form or dose may differ under the two listings. Stakeholders identified the following examples:

- Ciclosporin for the management of transplant rejection is a streamlined authority for s100 HSD but is unrestricted on s85
- Hepatitis C medicines can be prescribed under s85 by nurse practitioners, however nurse practitioners cannot prescribe under s100 HSD (Australian Government Department of Health 2017f).

Case study: Hepatitis C medication

The newer agents for chronic Hepatitis C (including ledipasvir + sofosbuvir) are PBS dual-listed on both s85 and s100 and are available for the treatment of adult patients.

For PBS purposes, the Hepatitis C suite of medicines can be prescribed by a medical practitioner experienced in the treatment of chronic Hepatitis C infection, or by a medical practitioner in consultation with a:

- Gastroenterologist
- Hepatologist
- Infectious disease physician experienced in the treatment of Hepatitis C infection (Australian Government Department of Health 2017f).

Nurse practitioners may prescribe Hepatitis C medicines under s85 listing but not under s100 listing.

Dual-listing issues

Even though these Hepatitis C medications are dual-listed, hospital-based prescribers reported a preference for patients to return to hospital for medication compliance monitoring and follow up, as patient compliance in this population is crucial for treatment success. Doctors reported that this, combined with the cost of these medicines, meant they prefer to prescribe under s100 rather than s85.

Some stakeholders suggested that s100 HSDs should cease as a separate category, as historically it required a specialist to prescribe the medications, but prescribing has been progressively expanded into a community setting. However, this would have a significant impact on PBS expenditure. In addition, should s100 HSDs be removed, the effect on prisoners would need to be considered as they cannot access s85 medicines.

Some stakeholders did not see the value of s100 classification. It was suggested that an alternative was to differentiate between medications based on whether a medicine is high-cost, high risk and/or requires specialist input to prescribe.

6. Findings: PBS programs and operations

6.2.2. Impact of revisions to PBS arrangements (Issue 9.2)

It was reported that changes in the implementation of changes to the PBS, lacked consultation with hospitals and could be detrimental. This was exemplified in the revisions to the HSD program in July 2015 which introduced clozapine maintenance therapy under the HSD Community Access program. The HSD Community Access program allows authorised community-based practitioners to prescribe medicines without being affiliated to a hospital. These arrangements include the prescription of:

- Clozapine for the maintenance treatment of schizophrenia
- HIV antiretrovirals
- Hepatitis B medicines.

There is a perception that the revision did not consider the clinical implications of shifting to a community access program which meant pathology and clinical review services are not adequately prepared for the new arrangements. The initiation of therapy for clozapine remains within the hospital setting.

Case study: Clozapine in the community

Due to its potential adverse effects including agranulocytosis, and fatal myocarditis and cardiomyopathies (Novartis 2017), clozapine has very strict prescribing, dispensing and patient monitoring requirements. This complication means that there is a relatively small network of general practitioners (especially in remote communities) who are able to provide complex medicines such as clozapine for maintenance therapy of schizophrenia, therefore clozapine is usually only supplied through hospital pharmacies.

An exception to this occurs in Victoria, where the NorthWestern Mental Health unit (part of Melbourne Health) monitors a cohort of approximately 800 clozapine patients, in partnership with the Royal Melbourne Hospital. A doctor in the community writes a Melbourne Health prescription for clozapine maintenance therapy. NorthWestern Mental Health unit has agreements with specific community pharmacies to dispense clozapine and the Victorian government covers the co-payment for these patients. The hospital pharmacy employs a person to collect the scripts that are dispensed through community pharmacies. The doctor will ask whether a patient has collected their drugs and the Royal Melbourne hospital can identify from which community pharmacy they collected their prescription.

6.3. Funding of chemotherapy

Under the 2011 Revised Arrangements, chemotherapy drugs used for the treatment of cancer that are through infusion or injection are covered through the EFC program. The EFC program replaced the Chemotherapy Pharmaceuticals Access Program with the intention to achieve greater efficiency in the use of injectable and infusible chemotherapy medicines.

NSW and ACT public hospitals are unable to claim for chemotherapy medicines under the s100 EFC as they have not entered into a bilateral PRA. However, in NSW and the ACT, chemotherapy patients are privately-referred, non-admitted patient and therefore are able to claim under s100 EFC. This category of patients is eligible to receive PBS prescriptions for medicines as these patients are not deemed to be

receiving public hospital services. These patients must obtain their PBS medications from an s90 community pharmacy rather than a s94 hospital pharmacy. NSW Health funds patient co-payments for injectable and infusible chemotherapy medicines by permitting patients to sign a patient consent form, which means that NSW Health pays the co-payment amount owed.

The vast majority of hospitals reported purchasing chemotherapy items from a third-party provider. Most source their compounded medicines from a TGA-licensed compounder (Slade Health, Baxter Healthcare and The Wesley Pharmacy) or from another non-TGA licenced compounder or community pharmacy. Where compounding is undertaken by a third party, prescribers cannot initiate chemotherapy for patients on weekends due to the medicine delivery cycle (particularly in remote areas). If a hospital has an aseptic unit and appropriate staff, compounding can occur on site, however this is not common for smaller hospital sites. Public hospitals are not eligible for the higher rate in the chemotherapy compounding payment scheme, as they are not TGA-approved (i.e. they are only eligible for $40 not $60 per infusion which is paid as part of the preparation fee).

Doctors can order chemotherapy in advance, however if there are last-minute dose changes they cannot claim the medication, resulting in wastage. For medicines with a short shelf life once compounded, i.e. within 24 hours, if patients do not present for treatment their chemotherapy dose is wasted.

6.3.1. Inpatient initiation for chemotherapy (and other high-cost drugs) (Issue 10.1)

Public hospitals reported that they are sometimes unable to fund treatment for expensive medicines without PBS support. This was often problematic for drugs that require hospitalisation as part of the treatment.

An example that was often cited was **blinatumomab** is listed for the treatment of acute lymphoblastic leukaemia and costs approximately $127,700 per course of treatment. The PBS listing notes that patients should be an inpatient for a minimum of nine days of the first cycle, and for at least two days for the second cycle. However, public hospitals are unable to initiate PBS subsidised treatment, as inpatients cannot access PBS medications.

A solution to this specific issue is to have a similar listing for high cost drugs that require inpatient admission. This has previously been done before for eculizumab (used for the treatment of atypical haemolytic uraemic syndrome) which is regarded as one of the most expensive medicines in the world and requires inpatient admission to appropriately monitor patients, however the Department notes this was an exceptional listing. In July 2016, a PBAC submission was made for potential public inpatient use of blinatumomab, however the PBAC reiterated that the PBS should not be subsidised for inpatient usage. Some states and territories viewed that this led to inequity in patient access, whilst a minority agreed with the PBAC decision.

6.3.2. Claiming of ancillary chemotherapy items (Issue 10.2)

Ancillary chemotherapy items are medicines that are used to manage the side effects of chemotherapy. They include items such as antiemetics, antinauseants, immunostimulants and detoxifying agents for antineoplastic treatment. Some ancillary chemotherapy items represent a significant expense to hospitals. Patients usually receive their treatments as part of a treatment regime. Same-day prescribing

is particularly prevalent in practices that use a computerised oncology management system. The management system stores details of chemotherapy regimes which may involve multiple days of treatment in each cycle (e.g. days 1, 8 and 15 in a 21 day cycle). The entire cycle will be prescribed on one occasion, and when day 8 and day 15 are dispensed) but can be claimed only for the day of prescribing as they are precluded from the same-day prescribing rules. This means that subsequent dispensing of these ancillary chemotherapy items from the first day of prescribing within a course of treatment is not funded under the PBS. Hospitals reported that some inexpensive ancillary chemotherapy items are dispensed as non-PBS items. However, there are other ancillary items that carry significant value.

The suggestion is for same day ordering of ancillary items which means that the date of administration, rather than the date of prescribing, should be what is entered in to the dispensing software. This would allow for claiming of second and subsequent doses of ancillary items in a course of chemotherapy treatment.

6.3.3. Sustainability of the EFC program in public hospitals (Issue 10.3)

There is evidence of a shift away from public hospital chemotherapy services, towards private hospital and day procedure centres administering chemotherapy. Approximately 60% of private hospital and day procedure centres administer chemotherapy compared to 40% in public hospitals (Australian Government Department of Health 2013).

The EFC program was considered by stakeholders in the public and private sectors as a valuable program to ensure equitable patient medication access across the public and private sectors. Furthermore, the introduction of vertically-integrated chemotherapy service delivery models adds to the discussion on the sustainability of the EFC program in the public sector. Notwithstanding the public hospital issue, private hospitals also reported that the long-term funding of chemotherapy medicines as important.

6.4. Other s100 programs

6.4.1. Botulinum Toxin Program

The Botulinum Toxin program provides PBS-subsidised botulinum toxin for eligible patients with conditions such as facial spasms, chronic migraine, urinary incontinence and symptoms associated with cerebral palsy. Botulinum Toxin can only be dispensed by s94 hospital pharmacies.

Whilst in general, most hospitals did not report issues with the Botulinum Toxin program, some issues included:

- Reports that the PBS reimbursement for botulinum toxin was less than what hospitals are able to purchase the product. It may be that private prices related to the cosmetic use of botulinum toxin are affecting the price.
- Tas and SA providing generous levels of access to botulinum toxin for patients who cease to be eligible under the PBS after the first four years of a patient's treatment.

6.4.2. Opiate Dependence Treatment Program

The ODTP assists people who have an opiate dependency to access medicines to help treat their opioid addictions. Through the program, the Australian Government pays the full cost of required medication by administering direct payments to the pharmaceutical manufacturers.

State and territory governments are responsible for the administration of the program, including the approval of participation for prescribers, dispensing outlets, and clients.

NSW public hospital outpatient services receive s100 PBS ODTP under a 'no charge' arrangement with the Australian Government.

This program was reported to occur largely in the community setting, whilst remote areas reported not having the capacity to deliver the program in smaller urban centres or remote health centres, as there are no community pharmacies to dispense the medications. There are reports of complexity surrounding how medications are reimbursed as community pharmacies and state-operated drug treatment clinics order directly from wholesalers, but do not pay for the medicines. The wholesaler provides the details to the respective pharmaceutical company, who in turn invoices the Department.

6.4.3. Growth Hormone Program and In Vitro Fertilisation program

There are no reported issues raised in the consultations for either of these programs.

6.5. Patient populations

6.5.1. Aboriginal and Torres Strait Islander population (Issue 11)

Aboriginal and Torres Strait Islander people can receive health care through Aboriginal Health Services and may be eligible to access more affordable medications through the CTG PBS co-payment measure or s100 RAAHS program.

Closing the Gap PBS co-payment measure

The Closing the Gap PBS Co-payment measure implemented on 1 July 2010, is one part of the Indigenous Chronic Disease Package. As part of policy efforts to improve the equity of medicine access, Aboriginal and Torres Strait Islander people are able to access PBS medicines with reduced co-payment amounts. To be eligible, patients must present with an existing chronic disease, or be at risk of a chronic disease, and need to be registered at either a general practice participating in the IHI under the PIP, or at an Indigenous Health Service in an urban or rural area. Eligible prescribers are members, employees or contractors of either of these settings.

Under the CTG PBS co-payment measure, eligible general patients who would normally pay the full PBS co-payment pay the concessional rate. Patients who would normally pay the concessional price receive their PBS medicines without having to pay the co-payment.

Hospital-based prescribers are unable to prescribe CTG prescriptions unless they are a specialist treating a patient that has been referred by a GP working out of a participating general practice (participating in

the PIP-IHI). The specialist must use their own prescriptions, not hospital prescription stationery. This means that patients are required to pay co-payments at discharge, thereby reducing access to medicines and contrary to the intent of the Indigenous Chronic Disease Package. Hospital pharmacists currently have to undertake 'workarounds' to facilitate access to PBS medicines for CTG patients. Moreover, some hospitals, reported honouring a CTG endorsement whereby the costs of medications for CTG patients is covered, thereby leading to a financial loss to the hospital.

All stakeholders consulted reported that hospital prescribers should be able to annotate a script as being "CTG" and that the program should be extended to all prescribers in all settings. The CTG eligibility status should also be registered through a patient's Medicare or Centrelink cards. Stakeholders reported that a patient-centred approach is required as this is a vulnerable group of patients who may have difficulty adhering to their medicine regime without assistance of the CTG measure (Australian Government Department of Health 2016b).

Remote Area Aboriginal Health Services Program

Under s100 of the Act, Aboriginal Health Services in remote locations (RAAHS) are approved to provide free PBS medicines[3] without a prescription to their patients. The RAAHS nominates an approved hospital pharmacy or community pharmacy to supply their PBS medicines. PBS medicines are generally provided on a bulk supply basis and the supplier claims reimbursement from DHS. Medicines are then supplied, without the need for a pharmacist to dispense, directly to Aboriginal and Torres Strait Islander patients by an eligible RAAHS employee at the time of consultation.

Stakeholders reported that issues arise when patients require hospitalisation, receive outpatient treatment, or visit locations which are away from their community. In such circumstances, clients are expected to pay the PBS patient co-payment for their medicine. This can be very confusing for RAAHS clients and may result in poor medication compliance when a patient cannot afford the co-payment amount.

Pharmacists in the Northern Territory

The Northern Territory has a large Aboriginal and Torres Strait Islander population and a large proportion of the population accesses medications through the Aboriginal Health Services. These services can own their own pharmacy, however the recruitment and retention of pharmacists (and other health professionals) is a challenge. It was raised that an investment in pharmacists is important as they can work directly with patients to assist them in maximising medication compliance. Moreover, it provides an opportunity for patients to discuss any side effects that are preventing them from continuing to take their medication with an appropriate professional.

6.5.2. Prisoner population (Issue 12)

Prisoners are generally the responsibility of states and territories; however, a provision has been made for prisoners to access s100 HSDs under the PBS. The prison population has higher rates of HIV,

[3] Emergency drug (doctor's bag) supplies, RPBS medicines, s100 HSDs, extemporaneously prepared items and schedule 8 medicines (as defined by the drugs and poisons legislation in the relevant jurisdiction) are generally not available under the arrangement.

Hepatitis B and Hepatitis C infection than the general population (Victoria State Government Department of Justice and Regulation 2017). Moreover, in the NT, WA and Queensland, a disproportionately large number of prisoners are of Aboriginal and Torres Strait Islander descent and this population have higher rates of multiple chronic conditions (Australian Institute of Health and Welfare 2011), which require ongoing management and medication. The provision of medical services and health care to prisoners is possible under state and territory enacted legislation that facilitates with the administration of corrective service facilities.

A number of care models provide treatment of prisoners, including:

- Being an outpatient of state public hospital clinics
- Being an inpatient of on-site corrective service health clinics
- Being supplied medicines via:
  - State/territory-operated services
  - Contracted private medicine supply services
- Being treated by visiting medical and/or allied health practitioners.

PBS claims for prisoners require valid Medicare numbers and are managed through formal agency arrangements between public hospitals and/or community pharmacies for their state/territory hospitals. Currently, prisoners' use of PBS medicines are not trackable in the PBS dataset and thus cannot be used to monitor usage for research nor policy purposes.

There are reports that private operators of prisons cannot claim s100. An example was given whereby a private hospital has to claim on behalf of the private operator and then be reimbursed later.

Another issue that was noted by stakeholders was the initial listing of the new treatments of Hepatitis C under s85 only. As prisoners only have access to s100 HSD medications, this created concern that the prison population would not have access to treatment. Stakeholders noted that the listing of new expensive medications requires consideration of the administrative and financial burden on health care providers in all settings.

6.5.3. Involuntary admitted mental health patients (Issue 13)

Each state and territory in Australia has a Mental Health Act that enables detainment of people with severe mental health conditions for care and treatment, without their consent. Stakeholders reported that considerable cost is associated with supplying medications for the treatment of these patients. Public hospitals reported that as these patients are classified as inpatients, they cannot claim under the PBS. This patient population was contrasted to prisoners who are able to access the s100 HSD program.

The view of one state was that the reimbursement of inpatient costs is a barrier to treatment for forensic mental health patients with hepatitis C and considered that selective use of Section 9A of the S100 HSD Special Arrangement would remove these distortions.

7. Pharmaceutical Reform Agreements

7.1. Analysis of PRAs

The bilateral PRAs were introduced as a variation to the AHCA between the Australian Government and states and territories. The objective is to reform pharmaceutical services available to patients of public hospitals and to improve the continuum of care for patients leaving hospital. All states and territories, with the exception of NSW and ACT, signed PRAs.

In particular, the reforms:

- Provided access to the PBS for non-admitted patients and admitted patients upon discharge from public hospitals. This allowed hospital doctors to prescribe via the PBS and hospital pharmacies are authorised to claim PBS supplied medications
- Enabled the supply of s100 chemotherapy medications to day admitted and non-admitted public hospital patients
- Ensured that hospitals adopt the Australian Pharmaceutical Advisory Council guidelines on the continuum of pharmaceutical care between hospitals and the community, enabling hospitals to prescribe up to 28 days of medications under the PBS for the discharged patient and to ensure the quality use of medicine and clinical pharmacy activities
- Allowed the Australian Government and PRA states and territories to share the risk of high growth in hospital prescribed PBS medications, including s100 chemotherapy medications supplied to non-admitted patients and discharged patients.

The key benefits arising from the PRAs are perceived to be:

- Equity of access for patients
- An improved continuum of care for patients and patient-centred care
- Improved quality use of medicines
- Increased clinical pharmacy resources, systems, and processes to ensure that medicines used in hospital are done so in a cost-effective, safe and equitable manner; and in line with APAC guiding principles (*Section 7.1.3*)
- Fewer doctor Medicare-billed consultations post-discharge to obtain medications
- Hospital access to the PBS, employment of clinical pharmacists and the provision of clinical pharmacy services.

PRAs were progressively signed with states and territories between 2002 and 2010. Variations exist in the agreements across states and territories, as identified in *Table 7-1*. Amendments were made to the Victorian and South Australian agreements to bring these agreements in line with more recent PRAs. Over time, Agreements were changed to clarify that hospitals can both prescribe and dispense PBS medicines to public hospital patients. Stakeholders noted that initially the introduction of the PRA required IT administration and upgrades, but now these have been incorporated in hospital systems.

7. Pharmaceutical Reform Agreements

Table 7-1: Differences between bilateral PRAs conditions

State/ territory	Year signed (amended)	Patient groups	Prescribing practitioner	Reporting	Medications on discharge policy
Vic	2001 (2003)	Day-admitted Non-admitted Discharge	Medical Dental	Monthly utilisation data submission	28 days or prescribed course of medicines
Qld	2002	Day-admitted Non-admitted Discharge	Medical Dental *Nurse practitioner	Monthly utilisation data submission	28 days or prescribed course of medicines or PBS quantities
WA	2002	Day-admitted Non-admitted Discharge	Medical Dental	Monthly utilisation data submission	28 days or prescribed course of medicines
NT	2007	Day-admitted Non-admitted	Medical Dental	• Monthly utilisation data submission • A list of quantities of hospital authority PBS medicines • A fully electronic authority approval mechanism • A fully integrated electronic prescribing and dispensing system (paperless) within the life of this Agreement	7 days for urban settings or 2 weeks for more remote locations; or prescribed course of medicines
SA	2008	Day-admitted Non-admitted Discharge	Medical Dental Optometrist	Monthly utilisation data submission	28 days or prescribed course of medicines
Tas	2010	Day-admitted Non-admitted Discharge	Medical Authorised midwife Nurse practitioner Optometrist	Monthly utilisation data submission	28 days or prescribed course of medicines

*Queensland policy also permits nurse practitioners to prescribe.

7. Pharmaceutical Reform Agreements

7.1.1. Community dispensing of hospital scripts

There appears to be some confusion regarding the appropriateness or otherwise of public hospitals that are s94 Approved Hospital Authorities providing PBS prescriptions to patients to be dispensed by a community pharmacy (i.e. not by the hospital).

A small number of stakeholders are under the impression that PRAs enabled s94 public hospitals to prescribe under the PBS only where those medicines are also to be dispensed by the public hospital. This understanding however, does not appear to be accurate based upon wording in the PRA which indicates that:

The Commonwealth and <jurisdiction> agree that pharmaceutical benefits prescribed in accordance with Clause 8 of this Schedule may be supplied by an approved pharmacist, an approved medical practitioner or an approved hospital authority.

This apparent misconception may arise, in part, due to the definition for '*Pharmaceutical Reform Arrangements'* included in the National Health Reform Agreement which is as follows:

> Means arrangements which provide for public hospitals that are Approved Hospital Authorities under Section 94 of the National Health Act 1953 to supply pharmaceuticals funded by the PBS specific categories of patients including:
>
> – Admitted patients on separation;
> – Non-admitted patients; and
> – Same day admitted patients for a range of drugs made available by specific delivery arrangements under Section 100 of the National Health Act 1953.

The above definition, does not fully describe the purpose and intent of the PRAs and may provide an incorrect impression that approved hospital authorities cannot provide PBS prescriptions where the medicine is not to be supplied by the hospital authority.

Notwithstanding the above, it appears to be relatively common practice for PBS prescriptions provided by public hospitals to be taken to a community pharmacy to be dispensed; reasons included:

- Long waiting times in hospital pharmacies to have prescriptions dispensed
- Dispensing of scripts when hospital pharmacies are closed, for example from emergency afterhours or on weekends
- Convenience for patients.

Interestingly, the Pharmacy Guild expressed concern that in some cases public hospitals are encouraging patients to have prescription repeats dispensed in the hospital, rather than in the community. Consultation with public hospitals indicated a clear preference for prescriptions to be dispensed in the community where feasible/possible. Public hospitals did however indicate that repeats are sometimes dispensed by the hospital where this was more convenient for the patient, where specialist monitoring was required or where it was a Section 100 EFC medicine with a public hospital authority. Additionally, some states and territories noted that the PRA and associated PBS dispensing revenue are of vital importance to implementing the APAC guiding principles and any move towards greater community dispensing would impact upon this.

7. Pharmaceutical Reform Agreements

7.1.2. Continuum of medication for patients

For those states and territories which have signed PRAs for discharge patients, hospitals are prescribing medications for up to 28 days or a prescribed course of medicines.

However, in non-PRA states and in the Northern Territory[4], in general, patients are being discharged with smaller supplies of medication. For example, in Northern Territory urban areas, public hospitals provide medications for seven days or a full course or longer if required (for example, if patients need to stay in town for ongoing treatment before going home to their remote community).

NSW Health policy in relation to take home medicine is that they should not exceed seven days without prior authority, irrespective of whether they are prescribed to inpatients or same-day patients and regardless of whether they are public or private patients.

7.1.3. APAC guidelines

APAC guidelines detail the requirements of the PRAs (specifically principles 1, 2, 4, 5, 6 and 7 of the national guidelines) to achieve the continuum of quality use of medicines between hospital and community (Australian Pharmaceutical Advisory Council 2005) (see *Table 7-2*).

In relation to the key guiding principles, feedback suggests that public hospital systems have well developed:

- Medication management policies and systems
- Clinical dispensing practices that involve the employment of clinical and non-clinical staff to provide pharmacy services and advice to medical staff, including junior doctors, on wards and in pharmacies and to be involved in
  - Clinical review
  - Medicine preparation and labelling
  - Patient counselling, including providing consumer medicines information

In relation to meeting the APAC guidelines, three issues are particularly identified:

- Concern about the impact of medicine shortages on patients and, in particular, changes to medications that could impact the safe and effective use of medicines
- Lack of access to reimbursed formal medicine reviews which are available in community pharmacies. Pharmacists considered that medicine reviews are highly valuable for high-risk patients exiting acute care. SHPA noted that the evidence base showing improvements in patient outcomes after pharmacist-led medication review justifies the expansion of clinical services for high-risk patients.
- A number of stakeholders proposed that this should include the introduction of a hospital referral pathway for home medicine reviews. SHPA cited a study showing this could lead to a

[4] NT's PRA does authorise PBS prescribing by approved hospital authorities for discharge patients however the NT has chosen not to utilise this.

25 per cent reduction in hospital readmissions for patients aged 51-65 years (Australian Pharmaceutical Advisory Council 2005).

Table 7-2: APAC guiding principles

Guiding principles	Objective
1. Leadership for medication management	Health service managers should provide leadership to ensure that the systems exist and resources are provided to enable medication management across the continuum of care.
2. Responsibility for Medication management	Health service managers and health care professionals have a responsibility to participate in all aspects of medication management in partnership with consumers and/or their carers.
4. Accurate Medication History	An accurate and complete medication history should be obtained and documented at the time of presentation or admission, or as early as possible in the episode of care.
5. Assessment of current medication management	From the early stages and throughout each episode of care, current medicines and other therapies should be assessed to ensure the quality use of medicines, which means selecting management options wisely, choosing suitable medicines if a medicine is considered necessary, and using medicines safely and effectively.
6. Medication action plan	A Medication Action Plan should: • be developed with the consumer and relevant health care professionals as early as possible in the episode of care • form an integral part of care planning for the consumer • be reviewed during the episode of care and before transfer.
7. Supply of medicines information to consumers	Before consumers transfer to another health care provider, they and/or their carers will receive sufficient information, in a form they can use and understand, to enable them to safely and effectively use all medicines in accordance with the agreed Medication Action Plan.

7.2. Consultation responses

All PRA states and territories are strong supporters of the PRA and its continuation. A summary of responses from SHPA members summed up the value of the PRAs:

> "The Agreement allows access to the Pharmaceutical Benefits Schedule (PBS) to enable public hospitals to provide medicines to patients being discharged from hospital or attending as outpatients or for receiving chemotherapy as a day stay patient. Our members advocated for access to PBS medicines in public hospitals and supported implementation of reform agreements. These agreements have enabled hospitals to provide patients with an adequate supply of medicine on discharge, putting an end to unnecessary and costly medical appointments simply to obtain a prescription and stopping years of inefficient cost-shifting between public hospitals and the Commonwealth, particularly for those in need of PBS listed oncology drugs".

Public hospital pharmacists consulted in PRA states reiterated the value the PRA has added in relation to improving patient quality use of medicines. The PRA has enabled the employment of clinical pharmacists to improve patient care and transition from hospitals. All states and territories have

embedded the PBS into their operations and have evolved their governance and information management systems since the introduction of the PBS.

However, two jurisdictions (NSW and ACT) have not agreed to sign the PRA. Some stakeholders noted that this may have resulted in inadequate care for patients who require s100 medicines living in non-adopter states of PRAs. For example, in a written response, SHPA indicates that:

> "As a consequence of the uneven adoption of the PBS medicines in hospital program patients in non-PBS states and territories often experience inadequate care, especially for complex and unusual conditions. Two examples of these conditions and problematic responses are discussed below:
>
> The supply of botulinum toxin for paediatric patients in New South Wales is challenging, as paediatric public hospitals are unable to dispense medicines under the botulinum toxin program. SHPA is aware of arrangements where one hospital issues prescriptions, which are then sent to a private hospital pharmacy in another territory to dispense and supply botulinum toxin. The private hospital pharmacy then sends the vials of botulinum toxin back to the relevant public hospitals, who then reimburse the private hospital pharmacy for the PBS co-payments where appropriate. This scenario is problematic, and risks sub-optimal care. The public hospital pharmacies have no recording of dispensing botulinum toxin, as it has been outsourced, similarly, the private hospital pharmacy has dispensing records for patients who have never stepped foot inside the hospital, and for whom they have no role in treatment.
>
> Restrictive PBS listings also cause issues with the management of severe inflammatory bowel diseases such as ulcerative colitis and Crohn's disease. Monoclonal antibodies such as infliximab and adalimumab are routinely used to treat these conditions, with patients in NSW public hospitals able to access infliximab as there is a S100 HSD public hospital listing for it which permits its use in this setting. However, if patient's response to infliximab changes over time and no longer achieves clinical objectives, a switch to adalimumab may be warranted. Adalimumab unfortunately does not have a S100 HSD public hospital listing for the treatment of severe inflammatory bowel disease, only a Section 85 General Schedule listing. As such, if a NSW hospital prescriber wishes to prescribe adalimumab for severe inflammatory bowel disease, this prescription is unable to be dispensed in the hospital setting, and the hospital and patient and their carers must arrange for these medicines to be dispensed in the community. This causes logistical issues for patients, especially rural and regional patients, who then obtain the medicines from a community pharmacy, and bring them back to the public hospital for administration. An additional layer of complication is the need for adalimumab to be kept refrigerated during transit to ensure safe and appropriate administration.

One state proposed a policy position that there be a High Cost Drugs Program for inpatients and a 'rolling up' or diminishing of the s100 HSD which is an outpatient program only.

7. Pharmaceutical Reform Agreements

7.3. Future risk sharing arrangements

All PRA contracts include complex formulae to calculate the risk sharing ceiling. The purpose of the ceiling was to set a level of expenditure, which if reached, would activate risk sharing arrangements, resulting in shared cost between the states/territories and the Department.

The implementation of the risk sharing ceiling was phased in over time, with the Australian Government setting the level of the ceiling. Victoria, which was the first state to sign the PRA, advised that for the first 15 years, the risk sharing ceiling was never reached, with the highest ever level at 75%. However, with the addition of Herceptin and the Hepatitis C medications, the risk ceiling was exceeded by 300%.

As a result, Hepatitis C medications were excluded from risk sharing ceiling calculations. All states and territories have questioned the value of including risk sharing ceilings in future PRAs. All PRA states and territories noted that Australian Government reporting on risk sharing levels are considerably delayed and are received well after hospital budgets were in place, making it difficult for hospitals to adjust their budgets if required. The consensus by all consulted was that the risk sharing ceiling is outdated and no longer serves an effective purpose in the current environment. The impact of high cost medicines on the risk sharing arrangements under the PRA was considered by some as a priority issue to be addressed.

7.4. Governance arrangements

Consultations with states and territories indicated that in the past there had been a range of Commonwealth/state forums in relation to pharmaceuticals and the PBS. These included:

- Highly Specialised Drugs committee
- Paediatric Medicines Advisory Group advising the TGA on paediatric medicine.

The HSD committee was established to advise the PBAC on the suitability of medicines listing on the HSD program. The Department advises that the committee was disbanded on the basis that PBAC conducted a more thorough assessment.

There is currently no forum(s) where appropriate Commonwealth and state personnel can meet to discuss PBS–related issues. Stakeholders considered that such forums help to prevent issues arising associated with new PBS listings, changes to business rules or other PBS-related reforms.

All stakeholders considered that a forum which involved health department representatives and chief pharmacists would be beneficial, given the increasing use of the PBS in the hospital setting. States and territories are keen to engage with the Department prior to the implementation of PBS listings, where these listings have a direct impact on hospitals.

CATAG was concerned that PBAC does not explicitly consider hospital budgets when listing new treatments that require hospital admission or hospital treatment of side-effects. CATAG noted that earlier and ongoing engagement with CATAG is likely to ensure a more seamless and less costly implementation of PBS decisions.

7. Pharmaceutical Reform Agreements

Currently the only way hospital pharmacy representatives can provide input into the PBAC review process is through the public consultation process, which was deemed to be unsuitable for hospital purposes. A more formal mechanism was requested by states and territories that recognised the experience and expertise of drug and therapeutic committees across the country. Improved dialogue was also seen to have the potential to alleviate implementation issues such as those seen with the PBS listing of hepatitis C medicines and clozapine.

Public hospital stakeholders noted that the dual funding of medicines by the Commonwealth and state/territory governments creates duplication in systems. It was suggested that a single funder model could reduce this duplication. Stakeholders acknowledged that this is part of a larger reform discussion and an alternative would be to provide the opportunity to utilise PBS inside hospitals (without the duplication of payments) thereby leading to greater patient safety and financial improvements.

Appendix A State and territory procurement models

A.1 Queensland public hospitals

Pharmaceutical Reform Agreement

Queensland Health was an early signatory to the PRA, signing in 2002. Queensland provides general (s85) PBS medicines for non-inpatients, (i.e. outpatients, patients on discharge) and for day-admitted chemotherapy patients. The key s100 PBS programs accessed in Queensland are Highly Specialised Drugs and Efficient Funding of Chemotherapy. To a lesser extent, other programs such as the botulinum toxin program and opiate dependence treatment program are also utilised in the state.

Formulary and listing medicines

Queensland has a state-wide formulary known as the List of Approved Medicines (LAM) for use in all Queensland public hospitals and institutions, including for outpatients. The LAM was established before the PRA and contains more molecules than on the PBS. Restrictions are placed on the listing of therapeutically equivalent agents, for instance there are only four ACE inhibitors on the LAM and only three statin drugs to treat hypercholesterolemia. For generic medicines, brands are not specified on the LAM and, therefore, prescribers are encouraged to write prescriptions using the generic name of the medicine, rather than the trade name.

Before a drug is listed on the LAM, it is assessed for its safety, quality, efficacy, and cost effectiveness by Queensland Health Medicines Advisory Committee (QHMAC), a committee of Queensland Health. Only clinicians, not sponsors, can submit items for consideration to QHMAC. QHMAC may approve a submission, reject it or defer it until more information is obtained. When approving a submission, QHMAC may place restrictions on the use of a medicine (e.g. for use in intensive care and coronary care units only).

Queensland Health operates a centralised model for the procurement, warehousing, and distribution of medicines via its Central Pharmacy. Central Pharmacy operates within HSQ, which is a department of Queensland Health, and provides its service to public hospitals across the state. HSQ also has a Strategic Procurement and Supply unit, which is responsible for working with QHMAC and Central Pharmacy to initiate the procurement and price negotiation process with sponsors. This centralised model contributes towards maintaining a robust medicines supply chain in Queensland Health, by creating efficiency and equity of access to medicines across Queensland Health, improving the ability to manage the impact of medicine shortages, and enabling a coordinated response to medicine recalls and safety alerts.

Queensland Health believes that QHMAC decision making could be improved if access to the HTAC data and cost-benefit analyses for drugs was provided by the Commonwealth. It is noted that access is allowed to public documents, but most relevant information is redacted, and so their usefulness is limited.

Appendix A. State and territory procurement models

With the general exception of s100 HSDs, PBS listed items are not automatically added to the LAM until a LAM application is considered and approved by QHMAC. Conversely, not all medicines on the LAM are listed on the PBS. If an inpatient commences a new medicine which is on the LAM but not on the PBS, arrangements post-discharge need to be made, which may involve the patient purchasing the medicine privately, or receiving ongoing prescriptions (at PBS co-payment rates) from public hospitals.

Procurement model

HSQ procures a wide range of hospital services such as medicines management, health equipment, pathology, radiology, linen and laundry, and payroll services. As the state-wide medication wholesaler, stock is warehoused by Central Pharmacy until ordered by a hospital. Queensland is the only state that purchases and warehouses medicines for its public hospitals. This is seen by Queensland Health to be advantageous to managing supply and distribution of medicines, including managing medicine shortages across hospitals and in providing cost-savings through large-scale tenders or Deeds of Arrangements with suppliers. This approach is also beneficial for prescribers and patients as there is assurance that whichever public hospital in Queensland they attend, access to a formulary medicine is guaranteed.

Price negotiation

Queensland Health has previously conducted tenders for the supply of pharmaceuticals and now has Standing Offer Arrangements with suppliers. Each Standing Offer Arrangement requests a particular brand and strengths from a sponsor. Contract periods for Standing Offers operate under a four year Header Agreement arrangement. From time to time, tenders for HSDs are also issued.

Purchasing and distribution

Public hospitals in Queensland order medicines via the iPharmacy catalogue. The Central Pharmacy also has a role in rationing the distribution of medicines to hospital pharmacies across the state, if a medicine is in short supply. The hospital purchases medicines directly from wholesalers or manufacturers in circumstances where the Central Pharmacy cannot fill the order, or where there is bilateral agreement that there is no benefit in double handling items such as bulk IV fluids.

Only limited stocks of some very expensive medicines (such as those to treat Hepatitis C) are held by the Central Pharmacy in an effort to contain costs. This means that at times of high demand, the lead time may be longer for these medicines than desired by pharmacy departments.

SAS medicines (for instance, older agents to treat parasitic worms) can be attained from overseas sources, however, from a hospital pharmacy perspective, the process is difficult. An authority form from the TGA must be completed to attain permission to import the drug in addition to other administrative tasks. Hospitals report that it is simpler and easier to use the Central Pharmacy to procure such medicines.

Non-LAM items are usually sourced by Central Pharmacy, but occasionally by individual hospital pharmacies. Ideally these agents are attained from a single wholesaler and a limited number of brands are sourced in order to manage stock levels and reduce confusion amongst patients and hospital staff. However not all brands are interchangeable; there may be different excipients (coating, fillers, binders)

which bring about variable therapeutic responses. This constraint, however, is not limited to non-LAM items.

There are costs associated with using the Central Pharmacy. Ordering this way, however, provides access to the tendered price and there is also transparency, for example, around the handling fee charged by Central Pharmacy.

Appendix A. State and territory procurement models

A.2 Victorian public hospitals

Pharmaceutical Reform Agreement

The Victorian government was the first jurisdiction to sign the PRA in September 2001. A further exchange of letters occurred in 2011 allowing for the Efficient Funding of Chemotherapy measure to supersede the s100 Chemotherapy Pharmaceuticals Access Program. In Victorian public hospitals the PBS is used to supply medicines to outpatients, inpatients including day-patients, emergency patients on discharge and for day-admitted chemotherapy patients.

Procurement model

HPV was established in 2001 to improve the collective purchasing power of Victorian public health services and hospitals. HPV, under the Health Act coordinates procurement across 48 contract categories including medicines, consumables, and medical transport. This state-wide approach is thought to help simplify and streamline the procurement process for hospitals, and bring about cost savings.

Formulary and listing medicines

The PBS is used as a basis for procurement, like a pseudo state formulary, however every hospital adopts its own method to determine which drugs are procured and from where. There is no official state formulary, decisions are devolved to health services, in particular, the hospital Drug and Therapeutic Committee. In the past, manufacturers would approach the hospital for formulary listing, now companies are usually advised by HPV and hospital pharmacies to apply to the PBAC in the first instance. HPV and hospitals don't perform any clinical or cost effectiveness studies. The PBAC review alone is considered adequate.

Hospitals in Victoria, such as Royal Melbourne Hospital, have a therapeutic equivalent program for common drug classes such as ACE inhibitors, PPIs, and statins. Also, generally only one brand is used in the hospital. For non-PBS items which are not on a hospital formulary, clinicians present case reports which the Drug Therapeutic Committee evaluates on a case by case basis. Sometimes agents are added to the formulary because of so many individual requests, such as rituximab.

Price negotiation

HPV adopts a procurement approach which aims to deliver the best value for Victoria. This may be regional sourcing or local sourcing. HPV, along with other jurisdictions, is exempt from ACCC competition regulations, and so collective tenders can be run. Individual health services are prohibited from conducting collective tenders. Contracts are confidential and so HPV is unable to check the agreements between suppliers and other states. The price HPV is able to secure is almost always better than what individual hospitals are capable of achieving. Prices are thought to be on par with those enjoyed by large retail pharmacy chains such as Chemist Warehouse.

HPV's main pharmaceutical tender is a two-year contract. Supplementary sourcing activity is run in between this period, for instance, for drugs that are near patent expiry or new agents. About 95% of medicines are solely sourced. The list of pharmaceuticals under the HPV state-wide contract is driven by

directors of pharmacy who provide HPV with guidance around clinical acceptance, risk for diversion (for s8 medicines), and the need to stock multiple brands to meet clinical needs. Quarterly meetings are held and all directors of pharmacy are invited to attend and provide input.

HPV contract holders are obliged to provide an alternative clinically acceptable substitute in the event their agent is unavailable. The sourcing of chemotherapy is not currently within HPV contract scope; however, HPV can attain individual chemotherapy drugs for local hospital compounding.

Purchasing and distribution

In Victoria, the Victorian Product Catalogue System, which is based on the National Product Catalogue, is available to all Victorian health services with unrestricted access to HPV contracts. HPV is moving toward a common catalogue of product and pricing information for the health sector.

Individual health services coordinate the ordering and storage of medicines. The majority of medicines used in Victorian hospitals are procured via HPV. For agents not able to be procured by HPV individual patient approval may be required by the hospital pharmacy, before sourcing independently of HPV. In essence, HPV typically manages tenders where there is competition in the market through generics and biosimilar products. Instances where there are no direct competitive options are typically managed by health services.

For drugs not secured through HPV, a single supplier arrangement is sought by health services. The contract can be for three years. The alternate supplier often tries to help the hospital source drugs as best they can. This means hospitals may not have trouble accessing drugs, aside from agents which are in short supply globally. Hospitals typically do not import their own drugs from overseas as it is an administrative burden and a very protracted process.

Appendix A. State and territory procurement models

A.3 New South Wales public hospitals

Pharmaceutical Reform Agreement

NSW is not party to the PRA and therefore the PBS is not used in NSW public hospitals except for medicines that fall under the s100 HSD program, where the patient meets the necessary eligibility requirements of the program. Individual public hospital pharmacy departments make PBS claims for s100 HSD medicines that are dispensed to eligible patients.

Privately-referred, non-admitted patients are the only other category of patients in NSW public hospitals that are eligible to receive PBS prescriptions, as these patients are not deemed to be receiving public hospital services. These patients must obtain their PBS medications from an s90 approved community pharmacy, rather than from a public hospital pharmacy.

Formulary and listing medicines

All NSW public hospitals have a hospital formulary which is overseen by a local Drug and Therapeutics Committee (DTC). Formularies are fairly consistent throughout the state, even though there is no state-wide formulary. Prescribers working within public hospitals in NSW may only prescribe medicines included in the relevant hospital formulary.

The listing of medicines on a hospital formulary is overseen by the DTC. The evaluation of applications for formulary listing includes a review of the clinical effectiveness, cost effectiveness, expected benefit to patient care, safety requirements and staff competencies to prescribe, dispense or administer the medicine.

The DTC must have a process in place for non-hospital formulary medicines (such as those prescribed in the community and continued in hospital) with regard to the approval for use, supply during hospitalisation and discharge, monitoring and reporting of use to the DTC. The use of a medicine by an individual patient outside the hospital formulary regulations must be applied for by a clinician.

Procurement model

HealthShare NSW coordinates health procurement activities for the state. This includes the procurement of most medicines plus other necessary clinical equipment, uniforms and hospital supplies. Both PBS and non-PBS medicines are procured for NSW public hospitals under state-wide contracts administered by HealthShare NSW in an effort to facilitate competitive pricing for high volume items used in all public hospitals.

Price negotiation

HealthShare NSW conducts open tenders leading to standing offers for the supply of drugs and pharmaceutical products. The most recent HealthShare NSW tender for pharmaceuticals occurred in 2015. HealthShare NSW has standing offer agreements with 45 pharmaceutical manufacturers and distributors on a three-year standing offer duration.

Appendix A. State and territory procurement models

Purchasing and distribution

Public hospitals access most medicines through the HealthShare NSW tender process. NSW also provides access to HealthShare NSW contract prices for ACT hospitals and approved not-for-profit private hospitals in NSW.

This procurement process applies to all medicines, irrespective of whether they are PBS or non-PBS medicines. In the event the required item is unavailable as a HealthShare NSW contract item, Local Health Districts and/or individual hospital pharmacy departments are responsible for sourcing it in accordance with supply contracts arranged by the NSW State Contracts Control Board. However, where a required medication is not available as a contract item, it may be purchased from a non-contract supplier.

Larger public hospitals generally have basic compounding facilities and outsource more complex chemotherapeutic agents to TGA licensed compounders or unaccredited community pharmacies that meet other practice standards.

Stock management in NSW varies on a hospital-by-hospital basis and is the responsibility of the hospital's Director of Pharmacy. There is some variation between metropolitan and regional NSW stock management practices.

Appendix A. State and territory procurement models

A.4 South Australian public hospitals

Pharmaceutical Reform Agreement

South Australia was a relatively late signatory to the PRA, signing in August 2008. Under the PRA, PBS reimbursement is claimed for medicines supplied to eligible outpatients, patients on discharge and day-admitted patients. SA hospitals partake in the PBS subprograms.

Under the PRA, public hospitals can claim reimbursement for PBS medicines for eligible patients and must ensure the quality use of PBS medicines by implementing the APAC guiding principles. The PBS subsidy covers only the actual drugs, not the services involved in delivering the APAC guidelines (e.g. via clinical pharmacy services). In this sense, the PRA has not been updated to reflect changes in the hospital pharmacy practice. SA hospitals, as with all signatories to the reforms, receive no dispensing or service fees for PBS medicine supply and are subject to different criteria to that applied in the private hospital system.

The PRA has not been updated to account for PBS listing of high-cost drugs and risk sharing arrangements. Further, states and territories have no direct input into PBAC decision-making, in this regard. The lack of input being an issue not only in relation to risk sharing, but when PBS listing has implications for hospital care including requirement for commencement in the inpatient setting and in management of significant side effects of PBS drugs requiring hospital admission and monitoring.

Formulary and listing medicines

The South Australian Medicines Formulary[5] is a list of medicines and the criteria for which they are approved for initiation within public hospitals and health services. The first compilation of the formulary has been completed in 2017 and is overseen by the South Australian Formulary Committee, an expert standing committee of the South Australian Medicines Advisory Committee (SAMAC). The South Australian Medicines Evaluation Panel, also a standing committee of SAMAC, was established in 2011 to ensure that all public hospitals provide a consistent approach to the management of High-cost Medicines.

To initiate treatment with a non-formulary drug in a public hospital, a prescriber is required to complete an Individual Patient Use request form and submit for approval to the Drug and Therapeutic Committee at the treating hospital. Items will be reviewed for safety, efficacy, clinical need and cost effectiveness to determine if they should be listed on the Formulary. There is also a *Streamlined Formulary (and rarely, Non-Formulary), approval Request* process for a small number of medicines which are restricted for use in certain patients or circumstances. A request form must be completed by the prescriber and presented to the pharmacy prior to the initial supply of medicine. Brands may be substituted within hospitals according to the state pharmaceutical contract but not pharmaceutical items. Patients who are admitted to hospital on a particular medicine are continued on the same medicine, therapeutic substitution is not implemented in SA Public Hospitals.

5 http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/south+australian+medicines+formulary

Appendix A. State and territory procurement models

PBS listed items are not automatically added to the formulary. This approach has been adopted in an effort to optimise the quality use of medicines, improve access to medicines and improve the cost effectiveness of medication usage in the state. The formulary is developed based on assessment of safety, efficacy, and cost effectiveness. The state procurement process is utilised in tandem with the state formulary processes.

In some cases, hospital clinicians at the forefront of clinical practice seek to commence prescribing new agents 18-24 months before PBAC review /approval and therefore there can be a significant time lag which is a cost burden to the state. In many cases, it is anticipated the drug costs paid by hospitals are higher than the pricing arrangements eventually negotiated within the PBS. Many medicines prescribed for hospital patients are not covered by the PBS for example, in rare conditions or low numbers of patients resulting in lack of adequately powered trials, off label indications (e.g. in paediatrics), hospital only conditions. For outpatients roughly 60% of medications dispensed are PBS listed compared with 40% non-PBS.

Procurement model

SA adopts a state-wide approach to the procurement of pharmaceuticals and other materials for public sector use. SA operates a public tender process for Pharmaceutical products and large volume fluids, with the current 6-year tender period due to conclude in 2018. Approximately 60-70% of all medicines used in public hospitals are attained via a state contract. Most s100 high-cost medicines are not on contract.

Price negotiation

Negotiation on price is between the Department and the manufacturer of a given medicine. Wholesalers then supply at that price (with mark-up). Contracts are secured with no option for second negotiation. Typically, one brand of medicine is specified in the contract.

Purchasing and distribution

Each public hospital pharmacy directly purchases from the wholesaler. With the introduction of price disclosure, the price of PBS listed medicines has dropped. It has been observed that manufacturers appear to be increasing the cost of non-PBS drugs to compensate for the drop of PBS-listed prices.

Appendix A. State and territory procurement models

A.5 Western Australian public hospitals

Pharmaceutical Reform Agreement

Western Australia is party to the PRA, signing the agreement in 2002. PBS medicines are supplied to eligible outpatients, patients on discharge and day-admitted patients.

Formulary and listing medicines

The Western Australia Drug Evaluation Panel has recently developed the Statewide Medicines Formulary (SMF) framework. The Panel considers clinical efficacy, cost-effectiveness, evidence of need, patient safety and equity aspects of medication use. The Panel works closely with hospital Drugs and Therapeutics Committees, lead clinicians, expert advisors, and Chief Pharmacists in the review process.

The Formulary items are listed on an external site called Formulary One together with prescribing tips, PBS listing information and consumer medicine information.

Not all PBS items are on the Formulary, for example, not all ACE inhibitors are listed. The Formulary specifies the drug, form and strength. Hospitals may use medicines with more restricted indications than those listed on the PBS. For instance, antimicrobials have additional in-house restrictions to reduce inappropriate use which may give rise to antibiotic resistance.

There is a streamlined process for PBS listed medicines going on the formulary. A full cost effectiveness review is not undertaken, however costs in a hospital setting are considered. It was viewed that the number and range of items and brands on the PBS, does put pressure on hospitals to list medications. The rules and administration of PBS sub-programs are seen to be particularly complex.

Procurement model

The WA Department of Health Procurement Directorate is responsible for the procurement of medicines for public hospitals. Western Australia Health conducts tenders for pharmaceutical products which offer a three-year contract with the option of two 12-month extensions. Tenders are set with ceiling price, which is in some cases, equivalent to PBS maximum claim price. The tenders are categorised into sole supply pharmaceuticals (Group A) and competitive products (Group B). Western Australia Department of Health also conducts tenders for pharmacy service provision to remote areas.

Price negotiation

State contracts are held with three major wholesalers, a distribution chain, compounders, and manufacturers. Prices for this common use arrangement are fixed so buyers can pick and buy the specified products from the contractors or their nominated distributers, where the total value of the line item purchased is less than $250,000.

There are three major wholesalers in Western Australia. Manufacturers will sell at different prices depending on s85 or s100 eligibility. This gives rise to three types of prices: contract prices used in hospitals, s100 prices and s85 prices. Pricing can be different, given that s100 items have no wholesale mark-up. Where medicines are dual-listed on s85 and s100, some suppliers will not provide the

medicine at the s100 price. Given that there are items that could be dispensed from s85 and s100 listings, Western Australia Health are of the view that the administrative burden would be reduced if s100 was removed and there was just one system.

Private contracts (such as the Ramsay contract) can achieve lower prices than the state contract as these groups have significant purchasing power. Some companies will not sell to private operators due to concerns of unfair advantage.

Purchasing and distribution

Individual hospitals purchase their own medicines, drawing from the agreed contract price. Orders are placed directly with contractors or their nominated distributers. Delivery is usually through a distributor (Symbion or Clifford Hallam Healthcare). Individual hospitals decide which brand to order based on price, convenience and whether the wholesaler or manufacturer have stock.

Given the remoteness and sparse population density, Western Australia is also affected by significant supply shortages. WA Health advise that during a shortage it can be expensive and resource intensive to source essential drugs from all over the world, just to meet their standard supply requirements. Where the normal supply chain does not work, hospitals are required to look elsewhere.

Appendix A. State and territory procurement models

A.6 Tasmanian public hospitals

Pharmaceutical Reform Agreement

Tasmania signed up to the PRA in 2010 and the agreement was implemented in 2011. It was viewed as being of significant benefit to the local health system and patients. In particular, beneficial to inpatients on discharge as an appropriate amount of medicine could be supplied. The revenue derived from the PBS is enabling the employment of extra clinical pharmacists. This additional expertise has enabled more prescription medication errors to be detected and resolved.

Tasmania participates in the PBS subprograms except for the IVF program which is not provided in any public hospital. The Opiate Dependence Treatment Program is also not operating much in Tasmanian public hospitals.

PBS prescriptions are used upon discharge, for day patients and outpatients. Public hospital pharmacies do not dispense non-hospital prescriptions.

Formulary and listing medicines

A fairly robust and well managed state-wide formulary, known as the Tasmanian Medicines Formulary, has been in place since 2001. It includes PBS items plus any other drugs deemed necessary for Tasmanian patients. The PBS was used as the basis for the formulary, even prior to signing the PRA. Biosimilar agents are however carefully considered before formulary listing. The non-PBS items are predominantly dispensed to outpatients, in particular, oncology patients.

The Tasmanian Medicines Formulary is included as part of Health Care Software (HCS) management system available to Tasmanian public hospitals. HCS documents medication history and reconciliation, inpatient medication chart, discharge prescription, discharge summary and outpatient prescriptions and aligns with PBS. This electronic approach is being developed incrementally towards paperless, closed loop medication management. The management of the formulary is supported by the Statewide Therapeutic Drug Committee.

Procurement model

A state-wide tendering model is adopted in Tasmania across three contracts: (1) pharmaceuticals, (2) compounding and (3) fluids and other long-term items. Symbion and CH2 warehouses operate in Tasmania, with CH2 having about 80% of business by volume.

Price negotiation

A two-year contract is negotiated in accordance with Treasury policies. There are 40 contractors in the arrangement. Contracts are based on generic medicines except for biosimilar agents. Some direct purchasing also occurs between pharmaceutical companies and health services. For example, CSL supplies vaccines directly to hospitals, as do suppliers of Special Access Scheme drugs. Australian importers may also be used to procure medicines from overseas. Shortages are increasingly common and damaging, having escalated significantly over the past two years.

Appendix A. State and territory procurement models

With low volume drugs, the price listed in the state contract is greater than the reimbursed price which means the hospital is paying to dispense the medicine to patient. However, the majority of drugs are reimbursed in full.

Purchasing and distribution

Each of the three large public hospitals largely operates independently in the ordering and storage of medicines, however do share the cost of medicines where necessary. Smaller hospitals may get some basic medicines (such as paracetamol) from the larger facilities. Hospitals hold only a small supply of medicines and wholesalers will buy back excess stock.

Appendix A. State and territory procurement models

A.7 Northern Territory public hospitals

Pharmaceutical Reform Agreement

The Northern Territory signed the agreement with the Commonwealth in early 2007. The Territory is not using PBS for inpatient discharge or day admitted patients owing to the requirement for a patient co-payment. Many patients are eligible for the Closing the Gap and RAAHS programs, and therefore are otherwise able to receive medicine without payment, but cannot access these programs upon discharge, or through outpatients or emergency departments from a hospital. A minimum of seven days' supply (funded by the Northern Territory government) is issued for urban patients and a longer course for individuals returning to a remote area.

For outpatients, doctors write PBS scripts which non-Closing the Gap patients can take to community pharmacy. Closing the Gap patients come to hospital pharmacy and will not pay a co-payment.

There is no involvement in the PBS IVF subprogram in the Northern Territory. Participation in the opiate dependence program is limited as there is a high doctor turnover, and pharmacists cannot meet ongoing training needs, especially in remote areas. There is also a lack of community pharmacy facilities in remote areas and thus an inability to provide continuous supply of medication.

Formulary and listing medicines

The Northern Territory Hospital Formulary is a list of medicines approved by the Northern Territory Drugs and Therapeutics Committee for use in regional hospitals. There is a territory formulary and a standard drugs list for remote health services. Doctors are encouraged to prescribe according to the list.

Procurement model

There is a three-year Northern Territory purchasing contract for Pharmaceuticals products, intravenous fluids and compounding services in place with multiple contractors (both wholesalers and manufacturers) for the procurement of pharmaceuticals. This is an open tender for supply to Alice Springs, Darwin, Katherine, Nhulunbuy, and Tennant Creek hospitals. Chemotherapy is also part of the tender and all compounding is done externally.

Price negotiation

Hospitals buy directly from suppliers from the Territory contracts.

Purchasing and distribution

Around 30% of the Northern Territory population live outside the large towns, in areas without hospitals or community pharmacies. Community pharmacies only exist in Tennant Creek, Alice Springs, Darwin, Katherine, Gove, and Nhulunbuy. Regional hospital pharmacies are in Alice Springs, Gove, Katherine, and Darwin.

Hospital pharmacies provide a range of medicines and services to RAAHS clients. Medicines supplied predominantly include those that fall outside the scope of the s100 supply arrangement, and are

therefore not provided by the s100 contracted pharmacies. These include non-PBS and s8 medicines. Medicine is supplied as bulk pharmaceuticals or via an individual patient prescription.

Most remote health services are considered RAAHS and therefore are able to access Commonwealth funded medicines, except those in s8. These services have a formal contract agreement with a private community pharmacy which provides medicines ordered by the health service through prescription or bulk supply. The RAAHS keep a stock of PBS and non-PBS medicines and dispense as needed.

Medicine takes longer to arrive in the Northern Territory compared with other jurisdictions. Also, the distribution and supply of medicines across the territory, including remote communities, is costly and the hospitals absorb this cost. There are no wholesalers based in the Northern Territory that supply to Northern Territory hospitals, and medicines come from major centres, particularly Adelaide, via road freight. Deliveries can take up to a week to arrive. Urgent orders can arrive by plane however there are associated freight costs. There are no deliveries on the weekend or Monday which limits the ability of patients to commence treatment.

Compounded products are purchased from an external supplier. In Alice Springs is comes from Baxter. Sourcing product externally means there is a reduced flexibility in terms of dose changes and treatment delay which leads to wastage. Also, given the short expiry once prepared (24 hours) there is no leeway if a patient does not arrive or if freight transport is delayed.

There are cold chain issues with medicine supply in the Northern Territory due to extremes in temperature. Upon arrival in the Northern Territory, a medicine's stipulated temperature storage requirements may not be met and hospital staff become unsure if the medicine is acceptable to use if not monitored correctly. This has been an issue with chemotherapy supply from the current supplier.

Appendix A. State and territory procurement models

A.8 Australian Capital Territory public hospitals

Pharmaceutical Reform Agreement

Like NSW, ACT is not part of the PRA. In ACT public hospitals, the PBS is only applied in the context of s100 HSD medicines where the patient meets the required program eligibility requirements. In all other cases outpatients, day-admitted patients and discharged patients receive three business days supply of medication, or longer if a course of antibiotic treatment has been prescribed.

Formulary and listing medicines

The territory has no state formulary and so decisions around pharmaceutical use are made at an individual hospital level. The Medicine Advisory Committee advised ACT health on clinical matters involving the regulation of controlled medicines prescribing in the ACT, under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

Procurement model

There are two large public hospitals in the ACT: Canberra Hospital and Calvary Hospital. These public hospitals can access the NSW state contracts for pharmaceuticals. There are minimal local contracting arrangements in place. The lack of local contracts may mean access to some antibiotics and life-saving drugs can be compromised. Contractors have a financial incentive to fulfil their contract obligations with NSW hospitals in the first instance, and so supply to the ACT is deprioritised.

Price negotiation

Given the ACT can access NSW state contract prices, price negotiation takes place between territory health facilities and suppliers.

Purchasing and distribution

Usually only one brand of each medicine is provided under contract. Hospitals can purchase other brands or switch to another agent if desired.

Appendix B Summary of stakeholders

Table Appendix B-1: Summary of stakeholder interviews

Public hospital	Private hospital	Industry	State/territory
• Qld Princess Alexandra Hospital • Vic Royal Melb Hospital • Tas Royal Hobart Hospital • SA Flinders Medical Centre • WA Joondalup • NT Alice Springs • Vic Royal Children's Hospital	• Icon Cancer Care • HealthScope/HPS • Sydney Adventist • Catholic Health Australia	• Australian Private Hospital Association • Pharmacy Guild • Society of Hospital Pharmacists • CATAG	• Qld • WA • Vic/HPV • SA • NSW • NT • ACT • Tas

Note: Ramsay Health Care and Pharmaceutical Society of Australia were approached but consultations were unable to be scheduled.

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