



Australian Government
Department of Health and Aged Care

Pharmaceutical Reform Agreement Review Report



Contents

Introduction.....	2
Review of PRAs.....	2
Aim.....	2
In Scope of the Review.....	2
Out of Scope of the Review.....	2
Key areas this review examined.....	3
Recommendations out of the <i>PBS Pharmaceuticals in Hospitals Review</i>	3
Stakeholder consultation.....	4
Pharmaceutical Reform Agreements.....	5
Background and History.....	5
Legislative and regulatory framework.....	6
PRAs and NHRA.....	6
PRA Objectives.....	7
Governance.....	7
PBS expenditure in hospitals.....	8
Evaluation and Consultation.....	10
PRA Principles.....	10
Consultation Summary.....	11
Removing Barriers to Access.....	11
Quality Use of Medicines.....	13
Building and maintaining a quality hospital pharmacy program.....	14
Transparency and accountability.....	17
Department response and Recommendations.....	18
Recommendation Summary.....	18
Recommendations.....	19
Quality Use of Medicines.....	21
Building and maintaining a quality hospital pharmacy program.....	22
Transparency and accountability.....	25

The purpose of this document is to provide recommendations to Government in relation to the Pharmaceutical Reform Agreement Review

Introduction

The Department of Health and Aged Care (the Department) has conducted a review of Pharmaceutical Reform Agreements (PRAs), to support the development of new arrangements or variations to existing arrangements to meet the contemporary objectives for access to Pharmaceutical Benefits Scheme (PBS) medicines in the public hospital setting.

Much of the healthcare and PBS landscape has changed since the first PRA was signed in 2001. There is increasing use of complex and highly specialised medicines and health technologies, along with significant increases in PBS expenditure. New and updated policies, standards and agreements across the healthcare sector are also now in place. The Department has consulted widely with a diverse range of stakeholders to understand the benefits and drawbacks of the current PRAs.

This report explores and recommends several elements to align with the contemporary use of the PBS in public hospitals and to promote timely, safe and cost-effective access to PBS medicines and improve patient outcomes. The report has been prepared during a time when several other reviews within the medicine space are being conducted. Consideration of the reviews ongoing during the writing of this report, the National Medicines Policy (NMP) and the Efficient Funding of Chemotherapy, has been included in this report to ensure any findings in these reviews pertaining to PRAs were incorporated in future agreements.

Review of PRAs

Aim

The aim of this review is to provide an opportunity to examine how existing PRAs are currently being utilised, what changes could be made to improve PRAs to increase their utility and to better align PRAs with the aims of the National Health Reform Agreement (NHRA) and NMP.

In Scope of the Review

All aspects pertaining to how PRAs were initially designed and updated, as well as how the agreements are currently being used, were considered within the scope of the review. Consideration of new additions to PRAs were also in scope.

Out of Scope of the Review

Items relating to the purpose and functionality of the PBS were considered to be outside the scope of the review.

Key areas this review examined

The success of the current PRAs by evaluating their objectives against outcomes to date, including:

- Leadership, responsibility and accountability for medication management;
 - Governance
 - Objectives
- Evidence of streamlined and consistent application of arrangements;
 - Transparency and Accountability
 - Risk share arrangements
- Outcomes or evidence of improvements in medication access when transitioning between hospital and community settings.
 - Flexibility
 - Barriers to incorporate new programs
- The alignment of the PRAs with current policies and legislation, and whether any future arrangements as an outcome of the Review should have a broader focus, providing clearer understanding as to the interaction between Australian Government funding for state and territory governments under the National Health Reform Agreement (NHRA) and under the PBS or other programs.
- Recommendations from the Australian Healthcare Associates (AHA) report *PBS Pharmaceuticals in Hospitals Review*¹.
- The patient journey into and out of the public health setting, ensuring consistency with the principles of the quality use of medicines.
- The interaction and alignment of the PRAs with the NHRA².

Recommendations out of the *PBS Pharmaceuticals in Hospitals Review*

The AHA *PBS Pharmaceuticals in Hospitals Review* of 2017 (the Review) found that 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 a PRA. The Review recommended that NSW and ACT enter into a PRA with the Commonwealth.

The Review found strong support from stakeholders to improve access to PBS medicines for Aboriginal and Torres Strait Islander people. The Review recommended the Commonwealth consider extending the Closing the Gap (CTG) PBS Co-Payment Program to allow hospitals to prescribe under the program to discharged patients and outpatients.

The Review noted that states and territories felt that the PRAs were outdated, and that it was timely to review and update them. 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

¹ PBS Pharmaceuticals in Hospitals Review, available at: www.pbs.gov.au/info/reviews/pbs-pharmaceuticals-in-hospitals-review

² Addendum to National Health Reform Agreement 2020-2025, available at: federalfinancialrelations.gov.au/sites/federalfinancialrelations.gov.au/files/2021-07/NHRA_2020-25_Addendum_consolidated.pdf

state/territory and the Australian Government would be activated) was questioned, particularly in light of the exclusion of Hepatitis C medications from the calculations. Jurisdictions also noted that Departmental reporting on risk sharing levels was delayed and received after hospital budgets were finalised, which made it difficult to adjust budgets if required.

The Review noted that all stakeholders considered that a forum which involved Departmental representatives and Chief Pharmacists would be beneficial, given the increasing use of the PBS in the hospital setting. States and territories were 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 funded model could reduce duplication. Stakeholders acknowledged that this would be part of a larger reform discussion.

Stakeholder consultation

In January 2022, the PRA Review 2021-22 Consultation Paper was circulated to selected stakeholders. Stakeholders were also invited to attend one of four virtual workshops conducted in February 2022.

The stakeholder groups were:

- Non-Government Organisations (Consumer Health Forum, National Aboriginal Community Controlled Health Organisations (NACCHO), Pain Australia and Rare Voices)
- The Society of Hospital Pharmacists of Australia
- Pharmaceutical Society of Australia
- All state and territory health departments.

All stakeholder groups were also invited to provide written submissions to the consultation paper. Written submissions were received from:

- Pain Australia
- Pharmaceutical Society of Australia
- NACCHO
- Northern Territory Health
- Queensland Health
- Department of Health Victoria
- NSW Ministry of Health
- Tasmanian Department of Health
- The Society of Hospital Pharmacists of Australia (SHPA)

After the first round of consultations and written submissions, a draft consultation report was developed and circulated to all participants. Stakeholders were offered the chance to provide further feedback via individual meetings or critique of the consultation report. Four stakeholders took up the opportunity to provide further input: Queensland Health, Tasmanian Department of Health, Northern Territory Health and SHPA.

Pharmaceutical Reform Agreements

PRAs are bilateral agreements between the Commonwealth and jurisdictions that allow access at public hospitals to PBS medicines for non-admitted patients, admitted patients on discharge and day-admitted patients.

The PRAs support the NMP principle of timely and affordable access to medicines, by ensuring that patients can access medicines when they need them. For example, a patient discharging from a participating PRA hospital can be dispensed a full PBS quantity (generally 28 days) of their medication and be charged the usual PBS co-payment. In contrast, a patient discharging from a non-PRA hospital will usually be dispensed a small quantity (3-5 days' supply) of their medication and subsequently need to arrange an appointment with their general practitioner (GP) shortly after discharge to attain a prescription for further supply. PRAs support patients during the critical transition of care from hospital to the community.

PRAs are in place with Victoria, South Australia, Northern Territory, Western Australia, Queensland, and Tasmania. There is no PRA in place for the Australian Capital Territory and New South Wales.

Background and History

In Australian public and private hospitals, PBS medicines are supplied either by a hospital pharmacy (authorised under Section 94 of the *National Health Act 1953* (the Act)) or a community pharmacy (authorised under Section 90 of the Act). Public hospital pharmacies can only be approved to supply PBS medicines if the jurisdiction is signatory to a PRA.

In 1998, as a component of the negotiation of the Australian Health Care Agreements (AHCAs), the Commonwealth, states and territories discussed issues concerning access and equity in the arrangements governing the supply of pharmaceuticals in public hospitals. The National Health Reform Agreement (NHRA) (2011), which succeeded the AHCAs and the interim National Healthcare Agreement, which succeeded the AHCAs, specifies that it is the states and territories which must provide and fund pharmaceuticals for public non-admitted patients in public hospitals (except where PRAs are in place).

Before the availability of PRAs the differing arrangements under which pharmaceuticals were subsidised created inequities. Funding by the Commonwealth through the PBS for community based patients and provided by the states and territories for public hospital based patients for the supply and payment for a range of medicines available in each sector led to differing access based on location. These arrangements did not deliver consistent patient based outcomes as desired by both the Commonwealth and stakeholders.

In August 1999, the Department wrote to state and territory health departments offering to provide access to the PBS for medicines supplied to admitted public hospital patients upon discharge and as out-patients. This resulted in Victoria (2001), South Australia, Northern Territory, Western Australia, Queensland, and Tasmania (2010) each signing a bilateral PRA with the Commonwealth. There is no PRA in place for the ACT and NSW.

In return, participating jurisdictions were required to implement best practice guidelines for the continuum of pharmaceutical care between hospital and the community.

The essential elements for a hospital to be included under a PRA for participating jurisdictions are:

- access to the PBS to be provided to all non-admitted patients and admitted patients on discharge from public hospitals;
- access to chemotherapy drugs for day-admitted and non-admitted chemotherapy patients;

- hospital to ensure patients receive appropriate quantities of medications when discharged from hospital, up to one month's supply of medication;
- hospital generated PBS prescriptions may be dispensed by the hospital pharmacy or presented at a community pharmacy;
- hospitals are to adopt the Australian Pharmaceutical Advisory Council (APAC) Guidelines on the continuum of pharmaceutical care between hospitals and the community;
- PBS joint safety net arrangements will remain; and
- the usual PBS requirements apply, i.e. authorities, patient co-payments, brand price premium and therapeutic group premium policies.

Legislative and regulatory framework

The Act and any instruments under the Act as well as the *National Health (Pharmaceutical Benefits) Regulations 2017* provide the legislative framework under which the PBS operates. The PRAs specify that any pharmaceutical benefits including any chemotherapy drug must be prescribed and supplied in accordance with this legislation.

In 2011, the PRAs were each varied to include revised arrangements for access to chemotherapy medicines under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, enacted under Section 100 of the Act. Further to this, once a jurisdiction has entered a PRA, their approved Hospital Authorities under s94 of the Act are subject to a number of terms and conditions.

Hospital Authorities must apply to become a PBS approved supplier ([Department of Health | Hospital Authorities](#)). For public hospitals, which PBS medicines or programs the approval covers depends on whether the hospital is in a PRA jurisdiction or not.

PRAs and NHRA

Currently, the PRAs are identified as exceptions through the National Health Reform Agreement 2020-25 (NHRA), Schedule A, A10, A25 to A28 and agreed at Section G5 (Pharmaceutical Reform Arrangements).

PRAs are defined in the NHRA as:

“... 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 for 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.”

It should be noted that access to PBS medicines included in the Section 100 Highly Specialised Drugs (S100 HSD) program sit outside the current PRA arrangements. The public hospital S100 HSD program was specifically designed to provide access to day-admitted patients, non-admitted patients and patients on discharge and is enacted through separate legislation, the *National Health (Highly specialised drugs program) Special Arrangement 2010*, not through PRAs.

A subset of the long-term reform goals of the NHRA are to:

- deliver safe, high-quality care in the right place at the right time
- prioritise prevention, and help people manage their health across their lifetime
- drive best-practice and performance using data and research
- improve efficiency and ensure financial sustainability.

There is strong alignment in goals and objectives between the NHRA and PRAs, particularly for goals and objectives which focus on reliable and convenient access to medicines for patients, to facilitate the continuum of care and quality use of medicines.

Both the NHRA and PRAs aim to address financial efficiency and sustainability, by balancing state and territory access to Commonwealth funding or Commonwealth funded programs, such as the PBS, with measures to ensure financial risk is shared across parties.

PRA Objectives

PRAs are intended to enhance patient access to PBS medicines through the public hospital system. Objectives that are critical to the success of PRAs are:

- **Equity of access** – that all eligible patients are able to access PBS medicines through public hospitals
- **Continuum of care for patients** – patients receive adequate medicine to support them in the community
- **Quality use of medicines** – that public hospitals continue to improve on QUM measures

By highlighting their importance, the Commonwealth calls on all partners to proactively develop and promote these objectives.

Governance

While the PRAs are designed to enable the supply of PBS medicines to public hospital patients in certain circumstances, other agreements also govern service delivery and financial responsibility within the public hospital system and form a shared governance system between the Commonwealth 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 (in conjunction with the Commonwealth through the NHRA);
- Funding of pharmaceuticals for admitted patients (in conjunction with the Commonwealth through the NHRA), subject to reform agreements with the Australian Government; and
- 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. The Department is responsible for:

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

The payment of benefits under the PBS is the responsibility of Services Australia.

No single PRA partner can be completely responsible for achieving the PRAs' objectives. All partners need to work together, by acknowledging and respecting the contributions of others to achieve each agreements' objectives. There are no formal governance arrangements in the current PRAs.

PBS expenditure in hospitals³

In 2020-21, public hospitals participating in a PRA accounted for 21% of annual PBS expenditure (Figure 1). PBS expenditure in public hospitals includes a significant proportion of two programs – s100 Highly Specialised Drugs program (HSD) and s100 Efficient Funding of Chemotherapy program (EFC). In the same year, HSD accounted for 50% of PBS expenditure, while EFC accounted for 35% of PBS expenditure in participating PRA public hospitals (Figure 2).⁴ Access to the S100 HSD program is not dependant on the jurisdiction being a signatory to a PRA. This decreases the overall impact of PBS expenditure accessed through PRAs, however expenditure on general schedule and other S100 programs by PRA hospitals is still a significant proportion of overall PBS expenditure and therefore of the overall Health budget.

³ Data referenced in this section is based on PBS online claims data. It includes data for prescriptions dispensed by public hospitals in states and territories participating in the PRA. One public hospital (Albury) in NSW participating in the PRA has been counted in the Victorian totals. Data excludes medicines prescribed in public hospitals and dispensed in community pharmacies. Total PBS expenditure figures includes payments processed through the PBS Online system but excludes scripts dispensed by Remote Area Aboriginal Health Services, Opiate Dependence Treatment Program, and Continuing Medication Program as they were subject to manual processing. The data also excludes bulk manual adjustment for nusinersen. Figures are subject to change due to late claims and adjustments by pharmacies.

⁴ Source: PBS online claims data (extracted 22 October 2021)

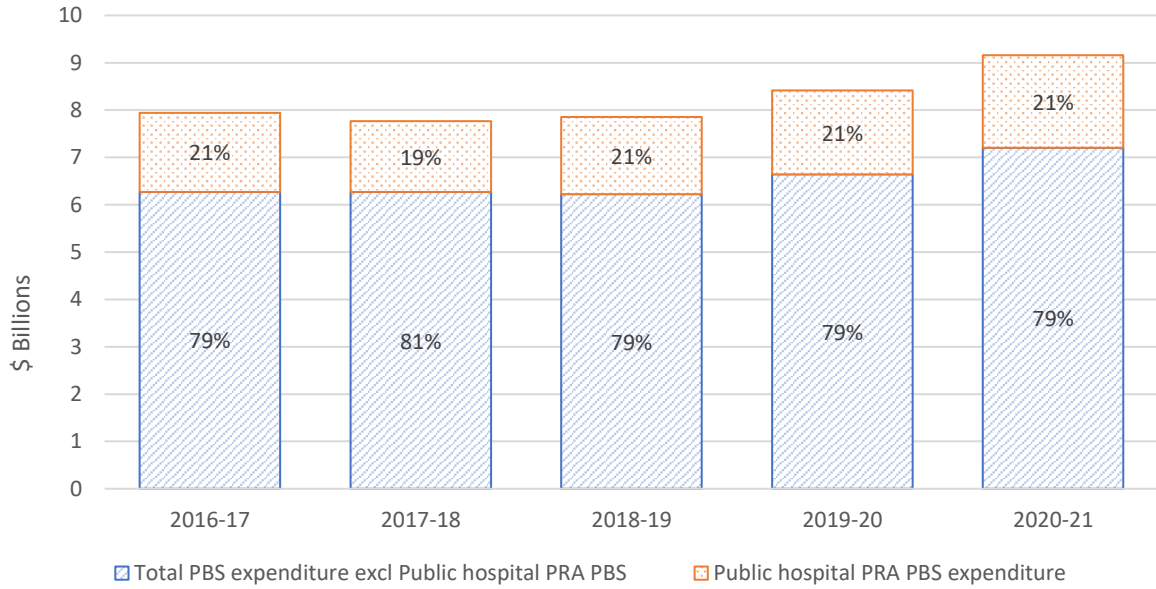


Figure 1. Annual PBS expenditure in public hospitals (inclusive of S100 HSD) as expressed against total PBS expenditure

All PRA jurisdictions - PBS expenditure in public hospitals

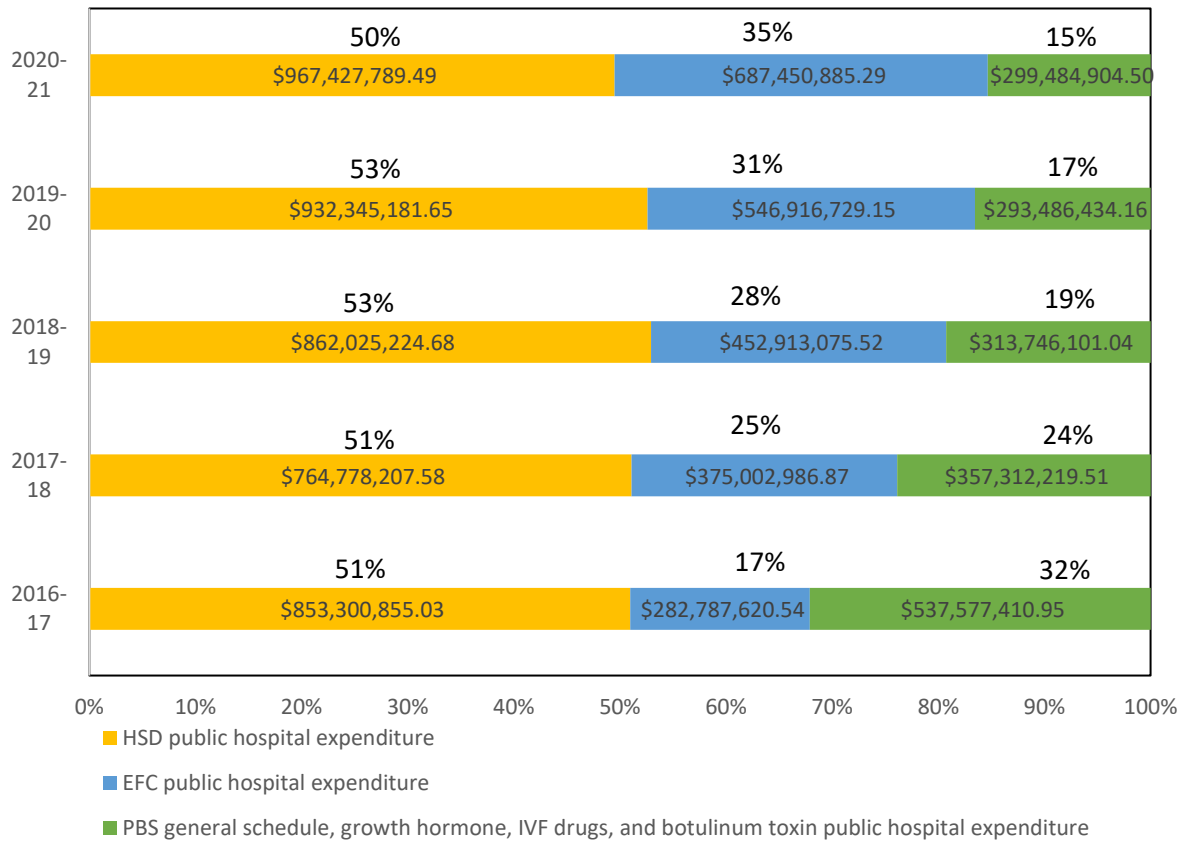


Figure 2. Breakdown of total PBS expenditure in public hospitals by program.

Evaluation and Consultation

This is the first systematic review of PRAs to be undertaken by the Department. Currently no PRA with any jurisdiction contains a mechanism to trigger a review process or any regular evaluation process. While some of the PRAs are over 20 years old, they have never been formally reviewed. Some updates to the structure and wording of PRAs have been enacted through exchanges of letters, however these were only to address specific aspects such as removing Hepatitis C medicines from the calculation of any Risk Sharing Arrangement processes and changing details for access to the chemotherapy program.

PRA Principles

These principles have been derived to enable the PRAs to deliver successful outcomes for the Commonwealth, jurisdictions and patients. The Department proposes the following principles encapsulate the overarching goals of PRAs:

- **Equity** – same-day, outpatient and discharged patients receive safe, high-quality, and affordable access to PBS medicines in the public hospital setting.
- **Person-centred** – PBS access in public hospitals is considered from the needs of the person receiving care.
- **Partnership based** – active, respectful, and collaborative partnerships, that harness stakeholders' skills, experience and knowledge, increased health literacy are established, and maintained.
- **Accountability and transparency** - all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of PRA objectives.
- **PRA Stewardship** – all stakeholders have a shared responsibility, limited by individual roles and responsibilities, to ensure that PRA objectives are met in an equitable, efficient and sustainable manner, as stewards of the health system, as it relates to the supply of PBS medicines.

There was considerable discussion among stakeholders about the content and applicability of these principles. An area of serious contention was around the final principle of stewardship. This was especially raised by end user representatives where they indicated that there was a perception that patients are expected to contribute to the management of their care often with no control over the programs and services available and with limited medical knowledge. Stewardship in the context of PRAs is limited to the signatory stakeholders of the agreements with the Commonwealth responsible for the stewardship of the PBS as a whole and the jurisdictions responsible for service delivery within the public hospital domain.

Consultation Summary

It has been widely acknowledged by multiple stakeholders that PRAs have supported participating jurisdictions to provide continuity of care for PBS medicines at discharge and for day-admitted and non-admitted patients. The ability to access up to one month's supply of PBS medicines was noted to be of particular benefit to those who live in rural or regional Australia where access to community pharmacies and GPs is generally more difficult than in metropolitan settings. Stakeholders noted the age of the agreements and that a review of the PRAs was welcomed to bring them in-line with current practices in hospitals.

As indicated above, all jurisdictions, including those without a PRA, along with organisations representing pharmacists and end users of PBS services through public hospitals were involved in the consultation stage of this review.

- Issues raised are summarised below. The four key themes of the recommendations are: Removing Barriers to Access;
- Quality Use of Medicines;
- Building and maintaining a quality hospital pharmacy program; and
- PRAs need to be more transparent and accountable.

Removing Barriers to Access

Bilateral agreements

Currently, each PRA is an individual bilateral agreement between the Commonwealth and a particular state or territory government. This has led to each agreement containing slightly different wording and details. There is a "no disadvantage" clause in each agreement to the extent that if the Commonwealth enters into an agreement with another jurisdiction that is comparatively more advantageous for that jurisdiction then the Commonwealth will make efforts to negotiate to adjust the existing PRA to a similar advantage for the other jurisdictions. Each PRA is considered to be an in-confidence document between the signatories and as such is not publicly available. This is not best practice from a governance perspective.

PBS Closing the Gap Co-Payment Program

The CTG PBS Co-payment Program (CTGCP) was established in July 2010 to improve access to affordable PBS medicines for Aboriginal and Torres Strait Islander people living with, or at risk of, chronic disease, and who in their doctor's opinion would experience setbacks in the prevention or ongoing management of chronic disease if they did not take the prescribed medicine and would be unlikely to adhere to their medicines regimen without assistance through the program. When obtaining PBS General Schedule medicines, eligible general patients who would normally pay the full PBS co-payment pay the concessional rate and those eligible patients who would normally pay the concessional rate receive their PBS medicines without being required to pay a PBS co-payment.

Currently CTG prescriptions can only be dispensed at community pharmacies or Section 94 Approved Private Hospital pharmacies. Under recent changes to CTGCP included in the Seventh Community Pharmacy Agreement (7CPA) eligible public hospital prescribers can now issue prescriptions under this program, however public hospital pharmacies are ineligible to dispense these prescriptions under the program. Eligible prescriptions issued by PBS prescribers within public hospitals are able to be dispensed by a community pharmacy or Section 94 Approved Private Hospital pharmacy.

NACCHO has received significant feedback from across their national network of the poor outcomes associated with the current arrangements. The ineligibility of public hospitals to

access this program has anecdotally resulted in eligible patients being discharged from hospital without receiving the maximum quantity of PBS medicines (i.e. up to one month's supply) due to the hospital pharmacy needing to account for the co-payment amount for each prescription.

There was wide support from all stakeholders for CTGCP to be expanded to public hospital pharmacies through the PRA process.

NSW and ACT PRAs

NSW and ACT are not signatories to a PRA. There was unanimous agreement by consumer and professional representative organisations that the Commonwealth should seek to enter into agreements with these two jurisdictions to ensure fair and equitable access for all Australians. Entering into a PRA with NSW and the ACT will ensure that all eligible patients in Australia receive equal access to PBS medicines upon discharge from public hospitals and to section 100 programs (including the Efficient Funding of Chemotherapy Program, Growth Hormone Program, In vitro Fertilisation (IVF) Program and the Botulinum Toxin Program) regardless of the jurisdiction they are in.

The ACT has approached the Commonwealth in the last two years to enter into a PRA, coinciding with their digital health strategy, while NSW has made early contact also.

Delayed/restricted access to high cost drugs

Stakeholders raised the issue of barriers in accessing high-cost drugs for inpatients. Hospitals are reportedly reluctant or unable to fund these high cost medicines and reportedly may delay treatment until the patient has been discharged, where possible.

This was particularly noted in the example of Hepatitis C treatments (costing approximately \$12,500 per prescription) for involuntarily admitted mental health inpatients. The inability to access PBS subsidised medicines was seen as an impediment to starting, or continuing treatment, of Hepatitis C for public hospital inpatients.

It was also raised that multiple drugs included on the PBS require at least the initial dose of the drug to be administered in a hospital setting to qualify for later PBS subsidy, e.g. blinatumomab. This was raised in the 2017 *PBS Pharmaceuticals in Hospitals Review*, however inpatient subsidy remains the remit of the jurisdictions. This was indicated as a drain on hospital budgets that should be the responsibility of the Commonwealth to fund.

Access to PBS medicines for inpatients in the public hospital sits outside the scope of the PRAs. As clearly outlined in the NHRA, the states have an obligation to provide clinically necessary services to public patients, including the provision of any associated pharmaceuticals, with the Commonwealth then making a funding contribution through the mechanisms of the NHRA.

Geographic / time of service constraints

External stakeholders provided feedback that access to PBS subsidised medicines on discharge is reportedly somewhat dependant on the location and, to a lesser extent, the time of service. Anecdotally, variances in access were found to be dependent on jurisdiction, hospital, ward, patient risk factors, day (weekday or weekend) and time of day of discharge with large variations in service delivery especially after hours. These variations are of concern as they go against the principles of the PRAs to deliver fair and equitable access to PBS medicines.

Indigenous Dose Administration Aids program

The Indigenous Dose Administration Aids (IDAA) program is a Community Pharmacy Program funded under the 7CPA. Dose Administration Aids (DAAs) are provided with the aim of assisting people with the management and timing of their medicines. A DAA is a well-sealed,

tamper-evident device that allows individual medicine doses to be organised according to the prescribed dose schedule.

Some stakeholders made representations during the review about barriers to accessing the IDAA program, and that there should be allowance for public hospital pharmacies to provide IDAAs particularly in rural and remote areas where patients may need immediate changes to the DAA but experience delays in accessing their community pharmacy to make these changes.

The rules of the IDAA program stipulate that participating pharmacies are restricted to section 90 pharmacies, i.e. community pharmacies. As such, public hospital pharmacies are excluded from participating in the program. Also, the patient's usual community pharmacy that provides their IDAA will hold the prescriptions for the supply of medicines and any outstanding medicines already dispensed for scripts but not yet supplied in a DAA.

Quality Use of Medicines

Inclusion of QUM issues in PRAs

Current PRAs contain clauses that ensure eligible patients are supplied with a clinically appropriate quantity of pharmaceutical benefits and/or chemotherapy pharmaceuticals, irrespective of whether those pharmaceutical benefits and/or chemotherapy pharmaceuticals are supplied in accordance with the Agreement. Also, generalised clauses ensure the continuum of pharmaceutical care between the hospital and the community, including obtaining medication history, evaluation of current medication, and development and coordination of a medication discharge plan for each patient. However, while these were best practice at the time of entering the agreements the references have remained static for the duration of the agreement.

Stakeholders reported that medication management in hospitals has improved significantly over the last 20 years and that the tools and resources provided by the Australian Commission for Safety and Quality in Healthcare (ACSQHC) should be referenced in PRAs. Stakeholders considered that there is no need to make specific references to quality use of medicines criteria or goals, as ACSQHC standards and guidelines provide this detail and advised that public hospitals are well across this detail.

There remains a need to continue to include adoption and implementation of the *Guiding principles to achieve continuity in medication management*⁵ or its replacement guidelines in future PRAs. PRAs have strengthened the commitment of jurisdictions to adopt best practice medicine management. This has widely been acknowledged as a major success of the PRAs, therefore this should continue to be encouraged by inclusion in new PRAs and expansion to those jurisdictions without a PRA in place.

The ACSQHC administers the *National Indicators for Quality Use of Medicines (QUM) in Australian Hospitals 2014* which support measurement of safety and quality use of medicines for quality improvement purposes, and to help health services to drive changes in healthcare practice⁶. This program also includes a number of indicator measures that could be used to quantify potential key performance measures (KPM) (discussed below), including percentage of patients whose current medicines are documented and reconciled at admission, percentage of patients whose discharge summaries contain a current, accurate and comprehensive list of

⁵ *Guiding principles to achieve continuity in medication management*, available at: www.health.gov.au/sites/default/files/documents/2022/04/guiding-principles-to-achieve-continuity-in-medication-management_0.pdf

⁶ *National Indicators for Quality Use of Medicines (QUM) in Australian Hospitals 2014*, available at: www.safetyandquality.gov.au/our-work/medication-safety/quality-use-medicines#national-indicators-for-quality-use-of-medicines-in-australian-hospitals

medicines and percentage of patients who receive a current, accurate and comprehensive medication list at the time of hospital discharge.

Building and maintaining a quality hospital pharmacy program

Prescribers

Current PRAs vary in the wording around eligible prescribers; while some PRAs contain definitions that allow all eligible prescribers to issue PBS prescriptions for dispensing, some PRAs still refer to medical practitioners which is seen as limiting prescribing to doctors. Stakeholders indicated that PBS prescribing should be by individual practitioners' scope of practice under the broader PBS, including nurse practitioners where applicable in a jurisdiction.

It was never the intention of the PRAs to restrict the scope of prescribers eligible to prescribe outside of the restrictions already in the PBS; this has occurred as new prescribers were permitted under jurisdictional and Commonwealth legislation since the inception of the PRAs.

New Hospital programs

Since the inception of PRAs, new models of care have been established, in particular since the onset of the COVID-19 pandemic in 2020. PRAs currently restrict prescribing and dispensing to patients on discharge, day-admitted patients and non-admitted patients.

An admitted patient is defined as a patient who undergoes a hospital's admission process to receive treatment and/or care. This treatment and/or care is provided over a period of time, and can occur in hospital and/or in the person's home (for hospital-in-the-home patients). Inpatients are currently outside the scope of access to PBS medicines under the PRAs as these are the responsibility of the jurisdictions to provide and are funded through the NHRA. The NHRA provides for the delivery and funding of public hospital services delivered through emergency departments, hospitals and community health settings.

Non-admitted care includes all hospital services and care provided to a patient who is not formally admitted at the time when the care is provided (e.g. in an outpatient clinic).

Out-patients are covered for access to PBS medicines by PRAs while all in-patients including day-admitted patients are not, except for access to S100 EFC medicines.

Jurisdictions strongly argued for the inclusion of new models of care in the public hospital setting to be included in PRAs. It was proposed that the expansion of eligible patients to include those covered in public hospital programs such as Hospital in the Home be considered as part of updated PRAs, as they argued these are "community based programs" to avoid or reduce hospitalisation timeframes. While on the surface these programs meet the intention of the PBS to subsidise the cost of listed medicines to people in the community setting, it is noted that many of these models of care require patients to be classified as admitted hospital patients. This complicates the funding model in regard to PRAs as funding for these patients is already embedded in the NHRA.

High cost treatments

Multiple stakeholders indicated that the cost of treating in-patients with individually tailored therapies and medicines was a significant and increasing component of some tertiary hospital budgets. Jurisdictions noted that the majority of these treatments are currently funded by mutual agreement between jurisdictions and the Commonwealth through the NHRA. There was discussion that this current situation was not sustainable and that the Commonwealth should contribute more to the funding of these treatments.

Harmonisation / Activity based funding

Stakeholders have indicated a desire to harmonise the fee and mark-up structure between public hospitals, private hospitals and community pharmacies. However the fees to community pharmacies are designed to ensure the viability of community pharmacies in accessible retail settings. As such it would not be appropriate to pass this fee onto public hospital pharmacies where the Commonwealth is not responsible for ensuring the viability of the pharmacy as this remains the remit of jurisdictions.

There is a marked difference in the Commonwealth remuneration structure for public hospitals and private hospital/community pharmacies. As outlined in Tables 1-3, all pharmacies upon dispensing a PBS script are eligible to claim the Wholesale Mark-up of up to a maximum of \$54.14 (as at 1 January 2022) for medicines over \$720. However, while private hospitals can claim dispensing fees and dangerous drug fees and community pharmacies can claim dispensing fees and Administration, Handling and Infrastructure (AHI) fees, public hospitals currently cannot claim these fees – however, the NHRA does allow public hospitals to charge patients a fee for pharmaceuticals at a level consistent with PBS statutory co-payments. The aim of the AHI fees is to ensure the viability of community pharmacies in accessible retail settings to continue to dispense PBS medicines. AHI fees were introduced in 2015 to delink pharmacy remuneration from the price of PBS subsidised medicines through the introduction of a predominantly fixed fee, to replace the previous six tier retail mark-up fee.

Table 1. Wholesale mark-ups (for all pharmacy types)

Level	AEMP	mark-up
1	AEMP up to \$5.50	\$0.41
2	AEMP \$5.50 - \$720.00	7.52%
3	AEMP > \$720.00	\$54.14

AEMP: approved ex-manufacturer price

Table 2. AHI Fee (for s90 Community Pharmacies only)

Tier	PTP	AHI Fee
1	PTP < \$100	\$4.32
2	PTP \$100 - \$2000	\$4.32 + 5% of the amount which the PTP for max qty exceeds \$100
3	PTP > \$2000	\$99.32

Not applicable for private and public hospital pharmacies

AHI: administrative, handling and infrastructure

PTP: price to pharmacy, i.e. AEMP plus wholesaler markup

Table 3. Other Fees

Fee	Community Pharmacy (s90)	Private Hospital (s94)	Public Hospital (s94)
Dangerous Drug Fee	\$4.84	\$4.84	not applicable
Ready Prepared Dispensing Fee (RPDF)	\$7.82	\$7.82	not applicable
Extemporaneous Prepared Dispensing Fee (EPDF)	\$9.86	\$9.86	not applicable
PBS Safety Net Recording fee (RPDF)	\$1.31	\$1.31	\$1.31
PBS Safety Net Recording fee (EPDF)	\$1.68	\$1.68	\$1.68
PBS Safety Net Card Issue fee	\$10.34	\$10.34	\$10.34

It was raised by some stakeholders that high cost and highly specialised medicines generally necessitate a high level of clinical services (e.g. patient review, interpretation of pathology results, managing treatment cycles, etc.) and as such, they are often dispensed in a hospital setting with minimal remuneration for these clinical services. This was raised as an equity issue between community pharmacy and public hospital pharmacy that could be addressed by increasing remuneration to public hospital pharmacies for these embedded services. It is unclear if these concerns have been raised with the Independent Health and Aged Care Pricing Authority and their annual National Hospital Cost Data Collection process, which seeks to capture the actual costs of delivery for the provision of public hospital services.

Programs / Policies

Currently no PRA has reference to specific programs outside of the inclusion of the PBS and Section 100 Chemotherapy programs. During stakeholder consultation there was discussion around whether it would be appropriate to include specific Commonwealth programs or policies in PRAs, such as the biosimilar uptake initiative. However, there is a need to be cautious about including specific programs within the PRAs as they can age badly. The PRAs intention was to enable access to PBS medicines through public hospitals for all eligible patients in a safe and equitable manner. While the introduction of PRAs into the majority of jurisdictions has facilitated greater uptake of QUM measures, the jurisdiction's inclusion of a reference to ACSQHC *National Safety and Quality Health Service Standards* in PRAs would continue to promote this initiative. Inclusion of specific programs could be negotiated with stakeholders as part of a governance program as discussed below.

Risk-share arrangements

It was noted by several jurisdictions that while there may have been a perceived requirement for a risk sharing arrangement during the initial phase of the introduction of PRAs this has since passed its usefulness. The only time in which the individual jurisdiction ceilings were

breached was with the introduction of the high-cost hepatitis C medicines. These medicines were eventually removed from the calculation of each jurisdiction. The lack of any other breaches in the ceilings was raised as justification for removing the need for a risk sharing agreement in any future PRA. It was also noted that if the intention of the PRAs was to maximise access to PBS medicines for non-admitted public hospital patients then the need for a risk sharing arrangement was no longer required.

Digital health / ePrescribing

It was noted that jurisdictions are moving to a digital health model in public hospital, with digital health and medicine charts, with ePrescribing a key component of this model. This is driven in part by the ease of claiming PBS subsidies through Services Australia with ePrescribing in addition to other advantages for both the hospital and the patient. ePrescribing will most likely lessen instances of incorrect dispensing at the pharmacy level for both the hospital and hospital issued prescriptions dispensed in a community pharmacy.

Transparency and accountability

Ongoing consultation

It was noted that there is no requirement under a current PRA to consult with the jurisdictions on aspects pertaining to PRAs. This has led to PRAs forming a virtual snapshot in time from when they were entered into, with some of these agreements now over 20 years old. It was suggested by multiple stakeholders that a forum which involved Departmental, jurisdictional health representatives and Chief Pharmacists would be beneficial for the maintenance of PRAs. Indicative support has also been received from multiple stakeholders to enact 5 year agreements with states and territories. This PRA would include a regular forum to discuss current PRAs and any changes that should be included either as addendums to the current agreement or for future agreements.

PBS updates

Jurisdictions expressed a desire to engage with the Department prior to the implementation of PBS listings, where these listings have a direct impact on hospitals. It was noted that jurisdictions are usually restricted to an annual budget negotiated based on the current environment and that the listing of new high cost drugs, especially those that require initiation as an in-patient, have a negative impact on hospital budgets. The Department is aware that while there is a process for new drugs, provided to inpatients to qualify for ongoing PBS access, to be added to the funding model for each jurisdiction, through IHACPA, it was indicated during the consultation phase that this mechanism is slow and can take up to 2 to 3 years for it to be flowed into hospital budgets.

Department response and Recommendations

Recommendation Summary

Multilateral agreement

- Include the PRAs as a schedule to the NHRA.
- If PRA functions are not included in the NHRA, negotiate a multilateral agreement with all jurisdictions to replace individual bilateral agreements;
- Include a pharmacist professional organisation in the negotiation of future PRAs, but not as a signatory.
- Publish agreements to improve transparency.
- Develop an appropriate governance structure, including a regular discussion forum.
- Include an agreed evaluation mechanism.
- Continue to include quality use of medicine specific issues.
- Enable all eligible prescribers to be able to prescribe PBS medicines through PRAs.
- Include clauses to reduce variances in access to medicines.

Extend the CTG PBS Co-Payment Program

- Expand the Closing the Gap PBS Co-Payment Program (CTGCP) to include public hospitals.

Interim PRA with NSW and ACT

- If PRA functions are not included in the NHRA, consider entering into negotiations with the ACT and NSW governments for interim PRAs, pending agreement to a multilateral agreement.

Recommendations

PRA / NHRA relationship

Strong consideration should be given to incorporating the PRA functions into the NHRA through negotiations for the period 2025 - 2030. The shared health funding responsibilities between Australian governments can only benefit from greater policy coherence and a holistic approach to public hospital funding.

The NHRA already takes into consideration many aspects of hospital medication dispensing. The inclusion of the PRA in the NHRA means that all costs associated with medicines delivery in public hospitals would then be included as part of the NHRA negotiations. This approach could also allow for the possibility of access to PBS medicines for all or a select sub-set of in-patients as well as for outpatients and upon discharge, due to the all-encompassing funding nature of a combined PRA / NHRA negotiation.

By combining the PRA with the NHRA the final agreement would cover all treatment modalities for public hospitals in a single agreement and be subject to increased input from the Independent Health and Aged Care Pricing Authority (IHACPA). This would also align with the inclusion of highly specialised therapies in the NHRA. The IHACPA currently receives a detailed breakdown of the actual costs experienced by public hospitals in the delivery of hospital services including the costs involved in dispensing medicines.

Finally, there would be benefits from reducing the cost of maintaining a number of different bilateral or multilateral agreements to achieve the same outcome and ensuring a holistic approach to governance for all funding of medicines in public hospitals.

Multilateral agreement

If the above recommendation to include PRAs in the NHRA is not supported it is then recommended that the Commonwealth seeks to engage with jurisdictions to move to a single multilateral agreement between the Commonwealth and all jurisdictions. During the negotiation phase it may be beneficial to include a professional pharmacist representative organisation, for instance SHPA, to provide technical input and subject matter expertise, however, signatories to the agreement should be restricted to the Commonwealth and jurisdictions. The agreement should not contain any information in it that could be considered to be commercial in confidence. This agreement would contain appropriate governance arrangements, outlined below, to ensure that it maintains its relevance to real world hospital practice and should be published, similar to the NHRA, for improved transparency.

PBS Closing the Gap Co-Payment Program

It is recommended that CTGCP is amended to permit dispensing of CTG prescriptions in public hospitals. This could be achieved by either:

- costing the implementation for each jurisdiction and a commensurate decrease in Commonwealth funding through the NHRA agreements for each jurisdiction; or
- seeking new Commonwealth funding to enable public hospitals to recover the cost of providing PBS medicines through CTGCP.

This recommendation supports the Government's commitment to work in partnership with Aboriginal and Torres Strait Islander peoples to improve health outcomes through:

- working towards the Priority Reform commitments under the National Agreement on Closing the Gap;
- supporting the delivery of culturally appropriate, high-quality essential health services; and

- implementing targeted efforts to improve health outcomes, including through smoking cessation and chronic disease management programs.

In consultation with the Efficient Funding of Chemotherapy (EFC) Review Team they have indicated that they intend to recommend “*Expand the availability of the Closing the Gap arrangements to all eligible Indigenous peoples accessing cancer medicines listed in Schedule 1 or Schedule 2 of the EFC, irrespective of the setting from which those medicines are prescribed.*”

Extending CTGCP to allow public hospitals to dispense prescriptions will also support the Government’s commitment to fixing the cost of living pressures for eligible people.

NSW and ACT PRAs

If the first recommendation for the inclusion of PRA functions into the NHRA is not supported then consideration should be given to entering into interim PRAs with NSW and the ACT, until future decisions on PRAs are made. This recommendation will ensure that all eligible patients in Australia receive equal access to PBS medicines upon discharge from public hospitals and to section 100 programs (including the Efficient Funding of Chemotherapy Program, Growth Hormone Program, In vitro Fertilisation (IVF) Program and the Botulinum Toxin Program) regardless of the jurisdiction they are in.

There will be a budget impact on entering into new PRAs with NSW and the ACT, as expenditure on the PBS for general schedule and chemotherapy will most likely increase with more patients eligible for subsidy. However, no formal costing calculation has been conducted at this time to quantify the magnitude of any budgetary impact.

Inpatient access to PBS medicines

Access to PBS medicines for inpatients in the public hospital sits outside the scope of the PRAs. As clearly outlined in the NHRA, the provision of inpatient medicines remains the remit of the jurisdictions for which there are established funding arrangements through the NHRA. It is recommended that no change be made to PRAs to allow for inpatient access to PBS medicines.

The inclusion of inpatients, including programs like hospital in the home, under a PRA would be a significant policy shift and would require a significant adjustment to funding for both the PBS and the NHRA. This could be facilitated by combining the role and function of PRAs into future NHRA negotiations, as recommended above. An increase in funding of the PBS to accommodate inpatient access to PBS medicines would be required as currently these medicines are supplied and funded by the jurisdictions outside of the PBS. Approximately half of the increase in PBS medicines could be saved from the NHRA, where currently the Commonwealth provides 45 per cent of growth in the price and volume of public hospital services including inpatient medication, the other 55 per cent of the cost would need to be sourced from outside of the current Health Budget. It is not recommended that any inpatient access to PBS medicines be included in future PRAs without consideration of the funding issues above.

There is an increasing trend in new treatments to be tailored to individual patients. Examples of these treatments are CAR T-cell therapy where the patient’s own T-cells are collected from the patient, activated against specific antigens (currently blood borne cancers) to form chimeric antigen receptors, or CARs, and expanded in a laboratory and then re-introduced to the patient. These treatments are currently funded through provisions in the NHRA with the Commonwealth and jurisdictions jointly responsible for funding. While the number of these tailored medicines/treatments is expected to rise in the near future, their inclusion in any future PRA is not recommended, as they are highly specialised treatments that at the moment require hospitalisation to administer. The Department is currently investigating the future

direction of the Commonwealth funding of these treatments, through the HTA Review Panel, which falls outside the scope of this report.

Geographic / time of service constraints

Issues regarding equity of access is a major concern to the Commonwealth and exacerbated through factors that can be managed through judicious use of existing resources. However, they are outside the remit of the Commonwealth.

Jurisdictions are responsible for which hospitals, if any, are approved to participate in the PRA and for the day to day management of the pharmacies within each hospital, which is the driving force of this issue. Future PRAs may consider including a clause that reduces variances in access to medicines due to individual differences in approved hospitals.

Indigenous Dose Administration Aids program

The aim of the PRA is to allow access to PBS medicines, not to provide funding for quality use of medicines programs. As outlined previously, jurisdictions are responsible for the management and delivery of public hospital services. Therefore, the IDAA program is not amenable to inclusion in future PRAs. No recommendation is made in regard to changes in the IDAA program as this is considered out of scope of the PRA Review.

Recommendations: Removing Barriers to Access

1. Include the PRAs in the NHRA.
2. If PRA functions are not included in the NHRA:
 - a) negotiate a multilateral agreement with all jurisdictions to replace individual bilateral agreements;
 - b) consider entering into interim PRAs with the ACT and NSW, pending agreement to a multilateral agreement.
3. Include a pharmacist professional organisation in the negotiation of future PRAs, but not as a signatory.
4. Publish agreements to improve transparency.
5. Amend the CTG Co-Payment Program to permit dispensing of CTG prescriptions in public hospital pharmacies.
6. Include clauses that reduces variances in access to medicines.

Quality Use of Medicines

Inclusion of QUM issues in PRAs

As indicated in the stakeholder summary the uptake of QUM principles by jurisdictions has been an important and tangible benefit of the implementation of PRAs. Building on this the Department recommends that reference to ACSQHC *National Safety and Quality Health Service Standards*⁷ or its successors should be included in the PRAs as it would be advantageous to continue to advance this initiative. This includes a need for communication to patients to be clear, accessible, and easy for patients to understand.

Recommendations: Quality Use of Medicines

7. Include reference to ACSQHC *National Safety and Quality Health Service Standards*.

⁷ National Safety and Quality Health Service Standards, available at: www.safetyandquality.gov.au/standards/nsqhs-standards

Building and maintaining a quality hospital pharmacy program

Prescribers

It is recommended to enable all PBS approved prescribers to prescribe eligible prescriptions via PRAs, i.e. doctors, dentists, optometrists, midwives, and nurse practitioners subject to individual jurisdiction regulation. Words to the effect of allowing all approved PBS prescribers, without quantifying which prescribers, to prescribe to all eligible patients would allow for any future changes in PBS prescribers to be incorporated in the PRA without the need to amend the PRA.

Harmonisation / Activity based funding

The request to harmonise the fees and marks between community pharmacies and hospital pharmacies has several considerations that impact the validity of this request. The fees to community pharmacies are designed to ensure the viability of community pharmacies in accessible retail settings. It is one of the mechanisms by which the Commonwealth ensures that a pillar of the National Medicines Policy, ensuring Australians have equal and affordable access to medicines, is maintained. As such it would not be appropriate to pass the Administration, Handling and Infrastructure (AHI) fees onto public hospital pharmacies where the Commonwealth is not responsible for ensuring the viability of the pharmacy as this remains the remit of jurisdictions. It should be noted that the NHRA does allow public hospitals to charge patients a fee for pharmaceuticals at a level consistent with PBS statutory co-payments.

It should be noted that consideration of all the costs involved in dispensing these medicines is currently factored into hospital funding, in that the Independent Health and Aged Care Pricing Authority (IHACPA) collects information for the National Hospital Cost Data Collection (NHCDC), which provides a detailed breakdown of the actual costs experienced by public hospitals in the delivery of hospital services⁸. One of the categories of cost that is collected in the NHCDC is the pharmacy sub-costs related to the costs of delivering public hospital services, which is defined as:

Pharmacy costs are goods and services used in the provision of a pharmaceutical service and consumables or the actual cost as billed by a provider. They include the purchase, production, distribution, supply and storage of drug products and clinical pharmacy services of both Pharmaceutical Benefits Scheme (PBS) reimbursed pharmaceuticals and PBS non-reimbursed pharmaceuticals. This includes the cost of pharmacy staff.

This sub-cost is then further divided into direct pharmaceutical costs (which are mostly the cost of the medicines) and overheads pharmaceutical costs (which are mostly the cost of staff and storage). The NHRA operates in such a way as the total cost of actually delivering public hospital services gets factored into the setting of the National Efficient Price to be paid for the future delivery of public hospital services. Therefore the actual costs of operating a public hospital pharmacy will be picked up and incorporated into the Commonwealth's future contributions to the states and territories under the pricing mechanisms of the NHRA. As such, changes to fee structures sit outside the scope of this review. Any activity based funding for clinical services provided by hospital pharmacies is outside the remit of this review and should be addressed through NHRA processes.

⁸ The 2019-20 results of the NHCDC are available at: <https://www.ihacpa.gov.au/resources/national-hospital-cost-data-collection-nhcdc-public-hospitals-round-24-financial-year-2019-20>

Risk-share arrangements

During the initial negotiations of PRAs there was a perceived risk of a considerable growth in the overall cost of the PBS due to prescribing and dispensing PBS medicines through public hospitals. Current PRAs include risk sharing arrangements (RSA), whereby the Commonwealth and PRA states and territories share the risk of high growth in hospital prescribed PBS medications, including s100 chemotherapy medications supplied to non-admitted patients and discharged patients.

The RSAs contained a ceiling which was to set a level of expenditure, which if reached, would activate risk sharing arrangements, resulting in shared cost between the state/territory and the Commonwealth. These ceilings were indexed on an annual basis based on the performance of the jurisdiction in the previous year. The indexation of the PBS expenditure is linked to the overall growth of the PBS excluding the S100 program drugs. Cost saving measures implemented to the PBS over the years have slowed the growth of overall PBS expenditure (particularly when the average cost of S100 medicines generally higher than the general schedule medicines).

The current RSAs have never been enacted. In 2016, there was a high risk the caps would be breached by jurisdictions due to the listing of the Hepatitis C medicines on the PBS, as these cost over \$20,000 per treatment when first listed, with expenditure in the first 6 months of listing exceeding \$2 Billion dollars. The proportion of hospital prescribing and dispensing is not available but inclusion of these costs in the RSA cap calculations would have greatly exceeded the caps and was not the intention of the Commonwealth. These medicines were removed from the expenditure calculations for the RSA.

The major contributor to increases seen in payments made to public hospitals has been through a steep increase in S100 EFC claims from 2016-17 onwards, as seen in Figure 2. As such the RSA component of the current PRA is redundant as it is not managing any real risk to the Commonwealth Budget and it is recommended that it should not be part of any new PRA negotiations.

Digital health / ePrescribing

Jurisdictions should be encouraged to continue moving towards a digital health model in all public hospitals. The shift to a digital health model should be holistic in nature to harness the unique situation where multiple disciplines of medical professionals are able to work collaboratively within a hospital setting. This would include medical interns, residents, registrars and consultants along with nurses and clinical pharmacists working collaboratively to chart and review individual records to ensure accuracy and to lessen the chances of mis-prescribing of medicines. The move to a digital based health record and charting model within the hospital system should also include a switch to ePrescribing as a key component of this model. ePrescribing as an output of the collaborative charting process above will most likely lessen instances of incorrect dispensing at the pharmacy level for both the hospital and hospital issued prescriptions dispensed in a community pharmacy. The uptake of this initiative should be encouraged in each jurisdiction and it is recommended that this be included in future PRAs as commitment by jurisdictions as current best practice and include capacity for this to be replaced by newer more rigorous models during the life of the PRA.

Recommendations: Building and maintaining a quality hospital pharmacy program

8. Allow all eligible prescribers under PRAs.
9. Include reference to a move to digital health records and ePrescribing

Transparency and accountability

Ongoing consultation

Indicative support has been received from multiple stakeholders to enact 5 year agreements with states and territories, in line with the multilateral agreement recommendation above. This PRA would include a regular forum to discuss current PRAs and any changes that should be included either as addendums to the current agreement or for future agreements.

Inclusion of programs or policies in PRAs may be possible if there is a 5 year review/expiry on any new PRA. This would apply to programs such as the biosimilar uptake driver initiative, as well as any other proposed new programs, as the review/replacement clauses would allow for the removal or replacement of specific programs on a regular basis.

Governance issues

As indicated above it is recommended that the current arrangements be replaced by a multilateral agreement with a defined end or review date. There should also be a requirement for regular formal consultation on aspects of the agreement with all signatories to keep the agreement as up to date as possible. These meetings would also be an ideal forum in which to discuss and agree to any new Key Performance Measures (KPM) that would indicate the value of the agreement to all stakeholders. There should be relevant dispute resolution clauses included in the agreement, similar to other Commonwealth agreements, which the current agreements do not contain. This would allow an avenue for dispute resolution for any aggrieved party within the construct of the agreement.

KPM / evaluation

There is no measurement of outcomes under the current PRAs to indicate that the PRAs are meeting their intended purpose. It is proposed that any new PRA entered into should include KPMs to allow for the evaluation of the agreement. As outlined above in the QUM section the *National Indicators for Quality Use of Medicines (QUM) in Australian Hospitals 2014* contains several indicators that could be used to formulate KPMs; these were taken into consideration in the possible measures below. For future PRA negotiations possible KPMs may include:

- The number of patients discharged with at least one PBS quantity of medication;
- Less than 30 percent of patients require a GP appointment within the first five days post discharge or a breakdown of the time to first visit to a GP;
- Time from discharge to provision of medicine discharge summary to primary care provider (including aged care);
- Demographic breakdown of patients accessing the PBS upon discharge/outpatient treatment;
- Analysis of ACSQHC related Patient-reported outcome measures (PROMs) or Patient reported experience measures (PREMs) to evaluate patients' experiences as a measure of the success of PRA to deliver meaningful results to patients.

It is recommended that KPMs are negotiated with signatories and included in the PRA document before finalisation.

PBS updates

Jurisdictions expressed a desire to engage with the Department prior to the implementation of PBS listings, where these listings have a direct impact on hospitals. It was noted that jurisdictions are usually restricted to an annual budget negotiated based on the current environment and that the listing of new high cost drugs, especially those that require initiation

as an in-patient, have a negative impact on hospital budgets. The Department is aware that while there is a process for new drugs provided to inpatients to qualify for ongoing PBS access to be added to the funding model for each jurisdiction and that this can take some time to be reflected in hospital budgets.

Discussion of the PBS listings with the Department is outside the remit of this review. However, the PBS listing process, and any implications on hospitals, is a commercially sensitive process between the Commonwealth and individual medicine sponsors, usually commercial pharmaceutical companies, that cannot be shared during negotiations with outside bodies. States and territories receive the same notification as other dispensers of PBS medicines for new and revised listings.

There is currently no way for the Department to provide further clarity of when new or expanded listings will be available on the PBS. It is recommended that this current process be maintained and not included specifically in any future PRAs.

It is open to the jurisdictions to request from the Department a forum with relevant areas of the Department involved in the listing of a medicine on the PBS, to discuss possible future listings as an aid to forecasting future budget constraints. However, it is a decision of Government on whether to list a medicine for subsidy on the PBS.

Recommendations: Transparency and accountability

10. Include regular consultation and governance clauses.
11. Negotiate and include an agreed evaluation mechanism.