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**title** The impact of Australian hospital medicines funding on achieving the objectives of the National Medicines Policy

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## Key messages

- Like many aspects of the healthcare system, medicines funding in Australian hospitals is complex, with multiple sources of funding. This depends on many factors, including: what the medicine is, and what it is used for; whether the patient is a public or private patient; and where the patient is being treated.
- There have been a number of partial reforms over time that have contributed to fragmentation of funding.
- Funding fragmentation may compromise the cost-effectiveness and value of the medicines use within the health system as a whole. It also inhibits achievement of the objectives of the National Medicines Policy though not being patient-centered.
- Medicines funding reform has the potential to improve quality of care for patients, improve effectiveness of medicines use, reduce government expenditure, and enable more timely and equitable access to cost-effective and safe medicines.

## Executive summary

In Australia, the National Medicines Policy (NMP) provides a framework for the way we use medicines across our health services with an aim to deliver medicines and related services while achieving optimal health outcomes and value. The policy identifies key objectives to achieve its aim: the quality use of medicines; access to cost-effective medicines; medicines meeting standards of safety and quality; and a viable medicines industry. The amount we spend on medicines is increasing, growing each year at around 4-5% [1]. These rising costs come at the same time as increased demand for services, resulting in considerable pressure to cut costs, with an associated risk of compromised care.

The funding of medicines in Australia is complex, with many factors contributing to who funds what medicines and when they are funded. Further, medicines funding, particularly in hospitals, has become increasingly fragmented over time. These reforms have included:

- The establishment of an activity-based funding model and the associated funding of medicines for hospital patients through this model.
- Extension of the Pharmaceutical Benefits Scheme allowing federal funding for all private hospital patients, but only non-admitted patients in public hospitals.

While past reforms have been aimed at aligning hospital medicines and related service delivery to the objectives of the NMP, their limited scope has contributed to issues such as:

- Failure to promote quality use of medicines where funding arrangements do not promote optimal and consistent medicines choices in hospitals.
- Limiting equitable and timely access to medicines, due to the inconsistent effects of various hospital, patient and medicines factors that in turn determine applicability of complex and overlapping funding arrangements.
- Failure to consistently and equally encourage the use of cost-effective medicines, and incorporate cost-effective and evidence-based medicines management interventions into routine clinical practice.
- Limiting development of a viable and prosperous medicines industry, supporting access to safe medicines.
- Fostering inefficiencies through fragmentation, work duplication and cost shifting.

These issues are caused by a fragmented system with complicated state and federal government and private contributions that may not optimally align government spending on medicines with policy. Although medicines funding reform has been proposed over time by numerous experts and discussed in the literature, reforms have been limited by historically difficult funding negotiations between the federal and state and territory governments, and the numerous stakeholders involved. While there is not enough evidence to propose a preferred solution for reform, moving towards a less complex model that is integrated and patient-centric may help achieve government intentions at both federal and state and territory levels as well as meeting objectives of the NMP.

## Introduction

In Australia, the National Medicines Policy (NMP) provides a framework for the way we access and use medicines across our health services [2]. This policy identifies a number of objectives that underpin many aspects of medicines management. Broadly speaking, the aim of the NMP is to deliver medication and related services while achieving optimal health outcomes and value for money. At the foundation of the NMP are the following specific objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

These objectives provide guidance to services that deliver medicines and related services to Australians. They apply to medicines management across all sectors, all services and by all funders. The attempt to meet the NMP objectives by delivering medicines and related services comes at a cost, with medicines making up 15% of total health spending in 2013 [3]. However, this figure only includes prescription and over-the counter medicines, and excludes medicines consumed in hospitals and other health care settings. Public hospital expenditure makes up 31% of overall health spending [4], yet the extent to which medicines contribute to hospital expenditure overall is not well understood.

Similar to all health care, the amount we spend on medicines is increasing, growing each year at around 4-5% [1]. The rate of growth is slowing, except for medicines that are high-cost which are showing rapid rates of growth, resulting in greater pressure on medicines expenditure as more high-cost medicines become available [1]. It is important and increasingly relevant that medicines are used judiciously, safely and sustainably.

There is considerable pressure, however, to find savings in public hospitals across Australia. The Australian Medical Association has warned that the current funding of hospitals and pressure to reduce costs may compromise patient care by encouraging underfinanced hospitals to find efficiencies [5]. The Australian Government Productivity Commission has also acknowledged that the current model of public hospital funding may encourage the lowering of quality of care in order to reduce costs [6].

## The funding of medicines in the Australian healthcare system

The funding of medicines in Australia is complex with many factors contributing to who funds what medicines. Some of the contributing factors to the source of medicines funding include where the patient is located at the time a medicine is needed, what the medicine is for, and the setting the medicine is intended to be used in.

The medicines funding responsibilities of the federal and state and territory governments were outlined in the 2011 National Health Reform Agreement [7], the 2012 National Healthcare Agreement and individual Public Hospital Pharmaceutical Reform agreements between the Australian

Government and some states and territories. In addition to this, relevant legislation and agreements also govern the roles and funding responsibilities of some non-governmental parties, including individual consumers and private insurance organisations.

### ***Funding of medicines used in the community***

The Australian Government is responsible for funding access to medicines. This is achieved through the regulation of medicines available for supply in Australia (e.g. by the Therapeutic Goods Administration) and providing affordable access through the Pharmaceutical Benefits Scheme (PBS). The PBS schedule lists all of the medicines available to be dispensed at a Government-subsidised price, who can prescribe them, any constraints on prescribing and dispensing, and patient co-payments that apply. Most of the medicines listed on the schedule are dispensed by pharmacists and used by patients in the community setting.

Since its introduction, the PBS has evolved over time to provide controls over volumes and expenditure in this uncapped scheme, but also to improve access such as with the introduction of the highly specialised drugs program. This program subsidises specialised medicines used for chronic conditions that require medical supervision through specialised medical services, where usual supply through community pharmacies may be unsuitable, and instead may be obtained through a hospital pharmacy. In addition to this, other specialised medicines and medicines not listed on the PBS may be accessed and funded by hospital pharmacies for ongoing use in the community.

### ***Funding of medicines used in hospitals***

State and territory governments are responsible for funding medicines for admitted public patients at public hospitals. In the case of private patients at public hospitals, medicines are usually funded in-part by the state and federal governments and in-part by private insurance companies. However medicines used in public hospitals are not funded directly. Rather, public hospitals are funded based on their activity, or in other words, funding is provided to hospitals in a way that reflects the work they do, where practicable. In this way, the cost of medicines for admitted patients is included in the determined price for treating patients with the associated reason for admission and resultant care. This is paid for in part by the federal government and part by the state and territory governments [8]. For non-admitted patients in public hospitals, the state or territory governments generally fund medicines. In the case of states and territories with Pharmaceutical Reform agreements in place there may also be funding by the federal governments for medicines listed on the PBS.

Public hospitals will then control the medicines used in their institution, typically through a Drug and Therapeutics Committee (DTC) or equivalent overseeing the governance of the medicines management system. Formulary management is usually the role of the committee, with reference to decisions made by state-wide or other site-based formulary committees taken into account, along with compelling local circumstances or where important new information becomes available. Individual patient approvals, endorsed by DTCs, can also be made to address circumstances where the patient requires high cost medicines not on the formulary or for off-label use based on critical evaluation of the literature. Medicines received by public patients as part of their admitted care in public hospitals are provided free of charge and without any co-payment. Medicines in public hospitals may also be funded by pharmaceutical companies to facilitate deferred cost, cost-free or subsidised

access to medicines. Guiding principles exist for the governance of such medicines access programs in Australian hospitals.

Private hospitals can supply medicines under the PBS to patients receiving treatment in or at the hospital. These are funded by the federal government and the standard patient co-payments apply, which are typically paid by private health insurance, if covered, while an inpatient. Medicines not listed on the PBS Schedule and that are supplied to inpatients may or may not be covered by private health insurance, depending on a patient's insurer and level of cover, and are usually governed by hospital or group based DTCs or local administrators. Out of pocket costs may therefore apply to the patient.

### ***Alternative funding arrangements and schemes***

There are a number of alternative funding arrangements for specific groups of patients or types of medicines that are funded by the federal government and sit alongside the other arrangements such as the PBS. The scope and form of these varies - each scheme has eligibility criteria, which establishes the medicines that are funded through the scheme, for which patients they are funded, and in what context. However, the intention of each arrangement is generally to better support medicines access for specific complex or priority medicines. Several programs for the funding of specialised medicines requiring additional regulation exist and include the Highly Specialised Drugs (HSD) program, the Efficient Funding of Chemotherapy (EFC) program, and programs designed to fund botulinum Toxin, human growth hormone, IVF Program, and pharmacotherapy for the treatment of opioid dependence [9]. Additionally, the federal government also directly funds other high cost medicines through the Orphan Drugs Program, the Life Saving Drugs Program and the Herceptin Program [10]. These programs fund medicines that may not have demonstrated cost-effectiveness due to limited data or their intended use being for only a small number of patients [11].

Several schemes exist to support medicines access for Aboriginal and Torres Strait Islander people. The Closing the Gap (CTG) PBS Co-payment Measure was introduced in 2010. It is a federal government supported scheme that was established to reduce the cost of PBS medicines, allowing these patients to access PBS medicines at a reduced co-payment or nil cost [12]. Prescribers must be registered with CTG, with hospitals unable to participate in the scheme. Once endorsed, prescriptions may be dispensed at pharmacies within the community, with the relevant patient co-payment reductions effected. In addition to this, legislation also allows for some PBS listed medicines to be supplied to remote Aboriginal Health Services with reduced prescription requirements and no cost. The intention of these arrangements is to improve access to medicines for these patients by reducing cost and administrative restrictions in an attempt to reduce the health gap between Aboriginal and Torres Strait Islander people and non-Indigenous people in Australia [12]

### ***Hospital medicines funding reform***

One of the first major reforms to medicines funding was the extension of the PBS for use for private patients admitted to private hospitals, as well as for private non-admitted patients. Private hospitals therefore became eligible to access federal funding of medicines through the PBS; similar to how the PBS operates in community pharmacies. This extension was not made available to private patients who were admitted into public hospitals however. For these patients, as with other public hospital

admitted patients, medicines are funded by the state governments, with no funding contribution by the PBS.

In the early 2000s, Public Hospital Pharmaceutical Reforms were introduced which allowed the limited extension of the PBS into public hospitals. These reforms were initiated by the Council of Australian Governments to promote quality use of medicines and restore equity in medicines access [13]. The funding of medicines through the PBS was only extended to non-admitted patients, however, with medicines for admitted patients still being funded by the state governments. The reforms enable public hospitals to access medicines funded by the federal government under the PBS for non-admitted patients or patients upon discharge from hospital, as well as the EFC medicines for day-admitted or non-admitted chemotherapy patients. Any medicines funded through the PBS by non-admitted patients or patients upon discharge may attract a patient co-payment. Importantly, these reforms have only been partially implemented with the ACT and NSW choosing not to participate. [14].

At this time, there was also concern regarding the growing burden of high-cost and complex medicines on hospitals. As a result of this, the PBS was expanded with the addition of section 100 to the National Health Act 1953. This outlined an additional list of medicines also funded by the federal government, which was referred to as the HSD program – a scheme funding highly specialised medicines that required additional expertise and specialist care for safe management. Section 100 medicines were differentiated from medicines listed in section 85, or everyday medicines that were available from community pharmacies. For this reason, HSD medicines were originally only accessible for all private patients and all public non-admitted patients (participation in Public Hospital Pharmaceutical Reforms was not a requirement for hospitals to access HSD funded medicines). In 2015, this expanded to allow access to medicines funded by the HSD program for the broader community through community pharmacies. Now medicines formerly only listed in either section 85 or section 100 lists may be in both, creating administrative challenges.

In 2014, legislation relating to the operation of hospital specific PBS items changed to allow the PBS to be used for selected medicines for admitted public hospital patients [15]. This was following recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), the committee tasked with evaluating the cost-effectiveness of medicines, and with extensive consultation around the reimbursement of the life-saving but expensive medicine, eculizumab, a medicine that stops blood clots forming that can damage the kidneys and other organs. This legislative change, and the allowance of PBS funding of a medicine for admitted public patients in a public hospital was the first of its kind. Since then, the PBAC has received a submission for blinatumomab, a medicine used to treat leukemia, which also asked for listing on the PBS that includes reimbursement for the medicine when given to public hospital admitted patients. Although this medicine has now been accepted for inclusion on the PBS, unlike in the case of eculizumab, the applied restrictions state that PBS funding is not provided when the medicine is used for admitted patients in public hospitals.

## The interrelationship between fragmented sources of funding

This overview of hospital medicines funding highlights the complexity of the current funding model. It is a model that funds medicines differently based on number of patient specific and medicines specific factors, which includes:

- Admitted status: Is the patient an admitted or non-admitted patient?
- Setting status: Is the patient a public or private patient?
- Insurance status: Does the patient have private insurance?
- Patient status: Is the patient an Aboriginal or Torres Strait Islander People, concessional, non-citizen etc?
- Medicine status: Is the medicine on the PBS or the list of another funded program, or part of a medicines industry access program?

However, the factors that determine eligibility for funding arrangements are not necessarily mutually exclusive, nor are they necessarily fixed with individual clinicians and patients often accessing medicines funded through numerous arrangements within and between episodes of care, making it difficult to determine which arrangements may be applicable at any time. This close relationship between funding arrangements has meant that changes to individual schemes in the past have resulted in much broader and unanticipated implications for funding [16].

Whilst the intentions of past reforms may have been to improve the medicines funding model, changes over time have made the system increasingly complex to the point of it being described as fragmented [17]. Fragmentation in healthcare refers to uncoordinated and poorly integrated services, systems or programs which can result in inefficiency, ineffectiveness and inequality [18]. The current funding model has been described as so complicated it is too difficult for patients to navigate [19]. Consider the implications of when an individual patient's eligibility to access a particular funding arrangement might suddenly change, for example when a patient is discharged from hospital back to their home, or when multiple types of medicines are required that meet different funding arrangement criteria. In addition to being confusing for patients, poorly integrated funding arrangements have the potential to result in inefficiencies such as cost-shifting incentives [9, 19, 20].

Whilst healthcare is complex and variable by nature, any *unnecessary* variability and complexity resulting from the medicines funding model undermines our ability to meet the objectives of the NMP.

## The impact and consequences of current funding arrangements

### *Partial implementation of Public Hospital Pharmaceutical Reforms*

As mentioned, the intention of the Public Hospital Pharmaceutical Reforms were to promote quality use of medicines, reduce cost shifting incentives and improve equity in medicines access [13, 21]. Concern was growing that hospitals were limiting the provision of medicines to patients on discharge in order to limit expenditure, a practice that was considered to be compromising the quality of care [21]. The result was the supply of only 5-7 days of medication at a cost to the state government, with patients needing to visit a GP to obtain a prescription within this time period to ensure continuity in

medicines supply. The expansion of the PBS for public hospital discharged patients facilitates the supply of medicines usually in quantities of a month, at a cost to the federal government, thereby supporting continuity of care between acute and primary care and reducing inequity between public and private hospitals [14].

Whilst the rationale behind this reform is reasonable and aligns with the NMP, partial implementation has limited effectiveness and resulted in *more* inequity. Although evidence suggests the effects of the reforms have been positive where implemented, the ACT and NSW have not participated due to unknown financial risk to the state/territory governments, despite early recommendations for continued implementation [13]. The result of partial implementation is inequity in medicines access for public hospital patients at discharge between states, and the limited ability to support quality use of medicines and continuity of care.

### ***Hospital formularies and the effect on hospital medicines use***

While there is some uniformity in the medicines used across Australia as a result of the national PBS list, this does not translate into hospitals. The use of medicines within hospitals is restricted by its own medicines formulary, with the management of a formulary and the list of medicines it contains varying due to capped hospital budgets and variation in capability and capacity of decision makers [22]. Hospitals have no requirement to match their formularies to the PBS formulary and although there are some limited financial incentives to encourage this, there are also some discouraging it. The result is a potentially different list of medicines that may be used from one hospital to the next, with differences particularly likely between public and private hospitals. This creates an environment of inequity, with the location and type of hospital influencing patient access to medicines, with particular concerns of inequity for access to high cost medicines [23]. Additionally, capped hospital budgets and an uncapped PBS budget further drive inequity between hospitals and patient classification types [9], where access to the PBS for admitted patients allows private hospitals to provide medicines without the restrictions of cost. In public hospitals, the provision of expensive medicines may have additional restrictions or not be approved for use in admitted patients. Timeliness of medicines access may also be affected with formulary restrictions sometimes requiring approvals to be granted prior to accessing and funding medicines.

More broadly speaking, medicines formularies are developed to meet the needs of the patients being treated in that setting. The PBS is a formulary intended for use in the community and as such the list of medicines on it reflects that. Conditions managed in an acute setting may require very different medicines to those required in primary care – recognising the need for a different range of medicines for acute conditions, surgeries, and specialised care, medicines kept in a hospital pharmacy cannot and will not be the same as those in a community pharmacy. It is important to note that while a medicine is cost-effective for the health system overall, it may not be cost-effective for the state government or hospital to fund. Hospitals may choose to use medicines that may be cheaper in the short-term, without consideration of optimal ongoing management in primary care, reflecting the lack of integration in funding arrangements. The nature of regulatory approval processes and PBS listing provides little incentive and support for medicines to be listed on the PBS if they are primarily used within hospitals, and even if they were to be listed, the lack of access for public hospital admitted patients would limit the effect of this to private hospitals [24, 25].

### ***Drugs and therapeutics committees and medicines expenditure governance***

Australia utilises comprehensive evaluation processes to inform medicines reimbursement and funding decisions. Broadly speaking, this assessment takes into consideration medicines effectiveness and the associated costs. Individual hospitals are currently required to manage formularies that include many PBS and non-PBS medicines, due to the wide variety of medicines use in hospital and the reduced likelihood for hospital-specific medicines to be listed on the PBS [24, 25]. Through dedicated resourcing and the sourcing of expert representation on the PBAC, medicines listed on the PBS undergo rigorous assessment to determine value to the overall health system. This expertise includes a variety of clinicians, epidemiologists, public health professionals, consumer representatives and health economists. Whilst cost-effectiveness assessments are essential to support sustainability, some concerns have been raised as to the applicability of cost-effectiveness evaluations across community and hospital populations [26].

Regardless of data applicability issues, assessment processes are at least consistently applied to all medicines that go through the PBAC and PBS listing process. However, assessment processes for any other medicines required for use in hospitals are fragmented across levels of government with duplicated and often ad hoc processes operating at both state and hospital levels [6]. This fragmentation results in inefficiency as assessments of the same medicines can be duplicated in several jurisdictions at additional cost, and widespread access to new, more clinically effective and cost-effective interventions can be slowed down [27]. Individual public and private hospitals, or even state health departments, may have limited capacity or capability in the evaluation process, and have limited access to the required information to make decisions [26, 28].

Additionally, whilst in some states this process may be centralised where statewide formularies are in use, in others it is conducted at the local hospital level. State-based or hospital-based evaluations often do not have access to the data that is needed to make these evaluations, with data sharing between hospitals and the PBAC rare and limited by commercial protections [9, 26]. Of particular concern is the assessment of medicines used for off-label indications, which is a practice common in hospitals for various legitimate reasons. DTCs are required to evaluate these medicines with incomplete information due to data sharing and governance limitations [29]. This has resulted in inefficacious and harmful medicines being approved for use and funding by hospitals and has been noted as not aligning with the National Medicines Policy Objectives [29]. These limitations may also result in variation in the cost-effectiveness of medicines use across states and hospitals. The Productivity Commission has noted variability in the cost-effectiveness of medicines use for non-PBS listed medicines, and has examined the case for establishing a statutorily independent PBS price-setting authority [6].

### ***Fragmentation of medicines funding across acute and primary care***

The delivery of health care services is changing, including hospital provided services. Whilst it has been easy to differentiate between hospital-based services and community-delivered services in the past, this traditional separation is becoming more and more unclear. Access to newer technologies and

changes in consumer expectations with a shift in focus to patient-centred care mean that many ‘acute’ hospital services are increasingly being provided in settings outside the hospital walls. Examples of this are Hospital in the Home programs, which allow public hospital patients to receive chemotherapy and intravenous antibiotics in their homes under the supervision of hospital outreach staff. In these cases, the patient is considered a public hospital admitted patient, and is utilising services that are funded through the state government despite physically being treated in the community. By residing and being treated in the community the patient is able to access their ongoing regular medicines through a community pharmacy and funded by the federal government through the PBS. At the same time, the patient would be accessing medicines for the condition related to their acute treatment, which would be supplied by hospital outreach staff and consequently funded by the state government. In these cases, medicines may be funded for a patient through a combination of patient contribution, and state and federal government funding, where the funding source for the medicine more appropriately matches the funding source for the associated health service. These programs have been developed due to the acknowledgement that integration in health service delivery is needed. However, current funding arrangements do not incentivise and may actually stifle both federal and state and territory governments from innovatively redesigning services.

### *Continuity of patients’ regular medicines in hospitals and at transitions of care*

Unlike patients receiving public hospital services in the community, patients receiving public hospital services within the walls of a public hospital have limited access to medicines funded by the federal government. This has implications for continuity of care, especially in the case of access to ongoing regular medicines. The utilisation of ongoing regular medicines that people bring in to hospital (also known as Patient’s Own Medicines or POMs) in Australia is a particularly grey area when it comes to access, supply and responsibility of funding. These medicines are typically accessed from community pharmacies and include all prescription and non-prescription medicines. Because of this, these medicines are funded by both the federal government through the PBS, and by patient contributions. In some cases, the medicines may be wholly funded by the federal government, or wholly by patients, and in many cases partially funded by both parties. The National Health Reform Agreement explicitly requires state governments to fund medicines for use by admitted public patients, but POMs sit outside this arrangement. Private hospitals, which have access to the PBS, routinely use POMs and only resupply these medicines when they are exhausted. The benefits of utilising POMs in hospitals have been evidenced in the literature as the following [30-34]:

- Promotes continuity of care
- Improves the accuracy of prescribing
- Reduces the number of dispensing errors
- Reduces the number of missed doses of medication
- Improves the accuracy of medication histories
- Reduces patient confusion regarding their therapy

The benefits need to be balanced against potential risks, which may include the incorrect identification of medications, the use of erroneously dispensed, expired, damaged or incorrectly stored medicines, increased risk of diversion and the increased potential for inadvertent self-administration by patients. Without effective organisational policies and processes around POM management, these risks can

result in real patient harm. The reduction of costs may come from reducing medicines wastage and reducing unnecessary processes such as the repeated supply of medicines. Due to this evidence, the incorporation of POMs use into hospital practice has been well established internationally, including in Canada and the UK [35, 36].

In Australia, there is significant variation in the utilisation of POMs across hospitals and within states, as well as across states. For example, the Victorian Department of Health and Human Services encourages the routine use of POMs that are not related to the reason for hospital admission [37]. The South Australian Department of Health instructs hospitals to use POMs where necessary and until hospital supply can be established [38]. The Tasmanian Department of Health and Human Services instructs the acceptable use of POMs, [39] and some states like Western Australia provide no direction to hospitals. This is in contrast to private hospitals where due to funding agreements, POMs are used routinely.

The implications of funding responsibility separation are potential limitations in cost effectiveness of care, and significant variability in equity of medicines access, especially between private and public hospitals and across states. Although data is limited, there are concerns that this results in harmful effects on patient outcomes through constraints in the continuity of care at admission, during hospitalisation and at discharge [9].

### ***Continuity of medicines management at transitions of care for Aboriginal and Torres Strait islander people***

For Aboriginal and Torres Strait Islander people, medicines access may be particularly complicated. In addition to being more likely to reside in rural and remote areas with the associated challenges for medicines access, there are deficiencies with the schemes originally designed to support medicines access and quality use of medicines. Seemingly arbitrary restrictions and limitations in the eligibility criteria of the program have caused further confusion for these patients [40]. Administrative restrictions in both the CTG and HSD schemes result in prescribers potentially unable to prescribe for these patients. Meeting the requirements of these schemes is difficult when patients move across rural, remote and metropolitan areas, limiting the access of medicines with no co-payment [40].

Aboriginal and Torres Strait Islander patients who are discharged from hospitals are also unable to access their discharge medicines under the schemes, reducing access to PBS medicines, including the usual medicines the patient may have been regularly taking. As a result, individual hospitals have developed workarounds such as transcribing medicines multiple times to facilitate the writing of CTG prescriptions or providing patients with interim supplies of medicines until the schemes again become accessible, however these are inherently inefficient [40]. In these circumstances, the schemes that are intended to facilitate improved compliance, may in fact hinder access to medicines for these patients. In these cases, some evidence suggests that standard co-payments are charged, reducing patient access and compliance [40].

### ***The impact of funding arrangements on budget pressure and medicines use***

The current system of federal government funding of medicines has created an environment where common medicines are generally available in a timely manner in the community. This is particularly

so in primary care where the medicines used in treatment are those listed on the PBS. The development of this universal and ubiquitous system results in many patients being treated with a similar list of medicines, and pharmacies being able to alter their inventory to any local patient needs. As a result, community pharmacies are generally able to readily provide access to these medicines. However, this may not be the case in hospitals where formularies and inventory must include medicines used for acute care or surgeries, in addition to the variety of medicines to cover the most prevalent chronic conditions. In the case of public hospitals, medicines that are used for rarer or specialised conditions or that are high cost may have to be sourced when needed or may not be available at all, potentially delaying or preventing access to patients.

Funding of medicines between private and public hospitals differs, as well as what medicines are funded in inpatient and non-admitted patient settings. Current public hospital funding incentivises hospitals to minimise the amount of medicines supplied to a patient whilst they are admitted, where hospitals cannot utilise PBS funding for medicines supplied to the patient. PBS funding can however be accessed for alternate admission statuses, including where patients are treated as outpatients, day patients or when they are discharged, and in private hospitals. This results in variation in what funding is available to hospitals to provide potentially the same medicines. Patients may experience an identical clinical indication and need for a medicine, but as a result of attendance at a public or private hospital, or the patient being admitted or not, may result in access to different medicines. Chemotherapy has been particularly highlighted as being subject to particular variation in access depending on funding sources [41].

Whilst the PBS is effectively uncapped in its allowable expense, hospitals budgets and finances are not. Whilst this may promote financial responsibility, it also means that hospitals cannot fund medicines beyond their resourcing constraints, which may include high-cost medicines for cancer that are considered cost-effective. In these cases, medicines may be deemed cost effective by the PBAC, be added to the PBS list by the federal government, but with an expectation that the states may have to incur some of this cost. There is a risk that equity may be compromised if hospitals cannot afford to fund these medicines. In these cases, the financial pressure for a hospital to restrict or limit medicines access varies depending on the categorisation of the hospital and of patient admitted status. As a result access to indicated medicines may be affected, including delaying starting a medicine until discharge, delaying or missing doses of medicines due to unavailable supply, or delaying access to medicines during a hospitals evaluation or medicines use approval process [41].

### ***Fragmented and uncoordinated approaches to pricing and purchasing of medicines***

Evidence suggests that the method of medicines pricing and purchasing in use across the Australian hospital and community pharmacy sectors results in higher costs of medicines [6]. Modelling has previously predicted this amount to be as high as 14% of the total PBS expenditure amount [29]. Whilst the federal government negotiates the price for medicines listed on the PBS, it does not purchase them, leaving this responsibility up to community and hospital pharmacies. The large volume of medicines ordered by hospitals reflects the need for PBS listed and non-listed medicines for both admitted and non-admitted patients. Public hospitals generally purchase generic branded medicines in large volume through state and territory government tender contracts [29]. This is in contrast to purchasing in community pharmacies that involves purchase of multiple branded medicines from a

variety of suppliers at variable volumes [40]. Private hospitals generally outsource their pharmacies to private companies with different hospital buying arrangements, or supply hospital-purchased medicines to local community pharmacies with whom they have a contract to support a targeted patient group voiding the need for the contracted pharmacy to purchase hospital medicines if inconvenient [40]. Broadly speaking, hospitals have the flexibility to purchase large volumes of medicines using a tender in order to obtain the lowest price for any particular medicine.

Comparisons between public hospital purchased prices and the PBS negotiated price highlight significant price variation, with hospital tender and negotiation processes resulting in much lower prices [9, 29]. In addition to this, comparisons to the New Zealand model, where the government purchases medicines using a tender, and to examples of state-wide tendering in Queensland, also shows the positive impact through lower prices [9, 29]. The fragmented pricing and purchase of medicines limits the cost-effectiveness of care, and whilst this affects smaller purchases of medicines such as independent community pharmacies or small states or territories unequally, coordination has the potential to result in cost savings. Additionally, the duplication of tendering and purchasing that occurs between state and territory governments and individual hospitals compounds the issue of unnecessary costs [9].

### ***Regulatory deficiencies associated with medicines registration and reimbursement***

The processes evaluating medicines safety and cost-effectiveness utilised within Australia have been widely praised by national and international experts. However, these processes have more recently been described as potentially out-dated, failing to adapt to changes in medicines development [42]. Whilst affecting all medicines, these issues are particularly relevant for high-cost medicines, and highlight a number of regulatory constraints. The timeline for funding decisions is becoming longer, the result of longer timelines for both TGA registration and PBAC evaluation processes [43, 44]. Submissions to the PBAC are also increasing in number due to the nature of newly developed medicines resulting in difficulty accumulating appropriate evidence. Medicines are becoming increasingly targeted and complex, which makes them more expensive and challenging to assess using current methods [43]. Even following a positive recommendation from the PBAC the ultimate decision to list a medicine on the PBS rests with the Minister for Health. In the past, decisions *against* both positive and negative PBAC recommendation have been made, which has been identified as undermining the process itself [41, 44]. Longer timelines, complexity of processes, and unreliable ultimate approvals have all been noted to create an environment of uncertainty and risk for medicines industry [1]. This environment discourages pharmaceutical companies to undertake long-term innovative medicines research and development, and makes seeking approval and registration in Australia less attractive, potentially limiting access to medicines [43]. Prior to regulatory approvals, early access may still be achieved through participation in clinical research trials, or other early access programmes funded by the medicines manufacturer. This type of access is usually intended to be temporary, with most of these programs used to cover the access gap between TGA registration and PBS reimbursement [42]. Given the increasingly long time for approvals and listing on the PBS, the sustainability of these programs is a growing issue for industry, which has important consequences for access and continuity of patients who rely on this funding source [42].

Hospitals are incentivised to use PBS listed medicines as often as possible in order to reduce their costs, particularly when federal government funding is available. This practice supports the use of cost-effective medicines and is in line with the NMP. However, value may be limited in situations when the PBS listed item has been evaluated to be cost-effective, but is not *the most* cost-effective option. This is the case with bevacizumab and ranibizumab, two similar medicines both clinically used and equally as effective for wet macular degeneration. Whilst bevacizumab is significantly cheaper medicine, only ranibizumab is approved and funded for wet macular degeneration [45]. By using the more expensive option in eligible hospital patients, federal government funding is available, whereas using the cheaper option would end up reducing total health system expenditure, but would cost the hospital more. Despite wide acknowledgment of this issue, current regulatory constraints result in little motivation or ability for clinicians, the pharmaceutical company, or government bodies to progress approvals for funding. The high cost of applications and the small likely financial gain means low appeal for the pharmaceutical company to progress the listing, and there are no means for the government or any other parties to apply for listing themselves. This limits applications that are primarily in the public interest [28, 45].

## International approaches to medicines funding and lessons learned

International models of hospital medicines funding vary, however in all OECD countries both public and private funding plays a role. Similar to the Australian healthcare system, medicines for hospital use in the British and Canadian healthcare systems are primarily publicly funded [16]. Without the presence of an additional layer of government, the funding model for medicines in the United Kingdom resembles that of a single funder. Funds are distributed by the government to area health services or 'trusts' to manage the delivery of services, a system that inherently reduces cost-shifting [36]. In contrast to the Australian system, trusts fund all medicines in their area regardless of whether they are delivered in a hospital or in the community. Despite these differences in funding models, OECD data shows that Australia and the United Kingdom health expenditures are similar at 9.6 and 9.7 % GDP respectively; which is slightly above the average of OECD countries at 9 % GDP [46].

The health system in Canada more closely resembles that of Australia's, with provincial governments funding and delivering hospital based services, including medicines. However, the Canadian system does not include universally public funded medicines for use in the community, with private insurance instead the main funder. There is significant variation in the coverage of publicly funded medicines between provinces, and health insurance to cover non-government funded medicines is optional in most provinces. The result is significant differences in patient medicines costs, which has been shown to result in poor adherence to medicines and consequently, poorer patient outcomes. Similar to the Australian system, the complex relationship between legislation and the funding responsibilities of multiple levels of government has limited evidence based quality use of medicines initiatives [33]. Although the federal and provincial governments have separate responsibilities in the Canadian medicines funding model, the decisions of each often has unintended consequences for the other, resulting in a system described as fragmented, inefficient and leading to increased costs to both patients and the government [47]. This fragmentation and inefficiency in medicines funding has been

identified as a contributing factor in the 10.6 % of GDP that Canada spends on healthcare, which is above the OECD average [46, 48].

In contrast, the United States has a much more significant proportion of its healthcare privately funded. Additionally, the US model has significant variation specifically in medicines funding as a result of state level legislation and similar to Canada, a lack of consistent public funding of medicines. Growing costs of medicines have been identified as a concern in the US and the lack of universal coverage in medicines funding, whether it be public or private, has been identified as an issue [49]. Despite accessibility and affordability issues which have been noted to negatively impact adherence and patient outcomes, the US still comparatively spends more of its GDP on health (17.2 %) than any other OECD country [46, 50].

New Zealand enjoys a medicines funding model similar to that of Australia's, with medicines listed on a national formulary similar to the PBS. Responsibility for deciding which medicines are subsidised by the government for use in public hospitals and the community rests with an independent agency. This agency is responsible for assessing whether medicines should be publicly subsidised, negotiating with pharmaceutical industry on prices, and deciding whether to list medicines on the publicly subsidised list [51]. In contrast to Australia, the New Zealand publicly subsidised medicines scheme operates under a fixed budget set by the New Zealand Government [51]. A range of commercial purchasing strategies, including tendering, direct negotiation and reference pricing have been considered to deliver substantial savings to the government [6]. Although the prices paid for medicines in this model are comparatively cheaper than in Australia, it is considered to be at the expense of delays to medicines being funded and sometimes medicines not being funded at all [52, 53].

The Australian healthcare system and more specifically Australia's NMP and medicines funding model are generally considered effective and high quality. Despite this, there is still scope for improvement. Whilst there are differences between international medicines funding models, there are still important lessons to learn. Comparisons to other models suggest that the more consistent and universal the coverage within a funding model, and the fewer funders for that coverage, the more cost-effective the funding model may be. Qualitative evidence also suggests that unnecessary variation and bureaucracy provides scope for inefficiencies and the potential for cost shifting to emerge, as is seen in the state and provincial based health systems of Australia, the US and Canada.

## The impact on meeting objectives of the National Medicines Policy

Figure 1. The effect of current medicines funding arrangements mapped against objectives of the National Medicines Policy.

### ***Timely access to the medicines that Australians need, at a cost individuals and the community can afford***

- Medicines access is dependent on where a patient lives, what hospital they attend, their private health insurance status, and hospital admitted status. Inequity exists within and across states, and can be greater for some patient groups [42].
- Due to capped budgets, hospitals must evaluate the cost-effectiveness of some medicines using state or hospital-based processes; however may lack expertise to do this effectively.
- Work duplication and cost-shifting incentives promote inefficiency and limit medicines funding affordability and sustainability.

### ***Medicines meeting appropriate standards of quality, safety and efficacy***

- Hospitals must evaluate the safety of some medicines using state or hospital-based processes, but lack access to sufficient data and expertise to do this effectively.
- Regulation processes may not adequately evaluate the safety and efficacy of newer personalized, targeted and complex medicines being developed.

### ***Quality use of medicines***

- Variation in medicines policies and guidelines, medicines formularies, and processes around medicines use limit consistent safe and quality use of medicines.
- Limited data sharing impedes hospitals and clinicians from making robust decisions regarding the safe and cost-effective use of non-PBS listed and off label medicines.

### ***Maintaining a responsible and viable medicines industry***

- An uncertain policy environment limits investment into the pharmaceutical industry.
- Regulatory restrictions and lengthy approval and evaluation timelines compound uncertainties and reduce incentives for pharmaceutical companies to develop new medicines and seek approval for government funding of medicines.

## Rationalising current funding arrangements

The NMP was established over 15 years ago and contains objectives for medicines use in Australia that are still relevant and important. However, our current medicines funding model has become more fragmented and complicated over time, compromising the achievement of the NMPs objectives. A report by the Australian Government Productivity Commission argued that funding structures and performance indicators should be evidence-based and linked to health outcomes [6]. The report identifies that reform in medicines funding to better align financial incentives for hospitals to health policy objectives is needed, whilst other reports have highlighted that integrated funding should be considered in order to encourage integrated care provision [6, 21]. While medicines funding reform has occurred before, there are barriers which have limited the success of previous reforms, including:

- The historically difficult negotiations between the federal and state governments about how much funding will be provided, and for the delivery of which services. In some cases, political tension between state and federal governments and unclear responsibilities may have stifled effective reform [19, 21].
- The multitude of invested parties, including state and federal governments, the pharmaceutical industry, consumers, and community pharmacy. It is difficult to align the interests of all these parties and negotiate a mutually agreed solution for a functional and sustainable medicines funding model.

Whilst the intention of reforms has been to improve the systems efficiency and effectiveness, previous medicines funding reforms have contributed to current inefficiencies, fragmentation and limited the ability to meet objectives of the NMP.

## **Working towards sustainable solutions in medicines funding reform**

Despite interest in hospital medicines funding reform, there is a lack of robust evidence to guide improvements. Whilst there is some expert consensus regarding the features of an effective medicines funding model, other information is conflicting [9]. Ultimately, any reform to hospital medicines funding should be coordinated across the health system, be patient-centred and driven by outcomes, and should result in care that is not dependant on a patient's ability to pay, where they live, their choice of hospital or their admission type [9]. This supports moving towards integrated medicines funding, with funding linked across the health system and to health outcomes, reinforcing the objectives of the NMP [54].

Medicines funding reform should firstly aim to reduce unnecessary variation and inefficiencies. Currently, funding is determined by patient and medicines factors, which can themselves be drivers of variation and as a result make identifying legitimate variation challenging. Integrating funding may allow the data that is available to more effectively be used to identify unnecessary variation, allowing the focus to shift to developing consistent best practice models of medicines use management [55]. This is illustrated by the partially implemented public hospital pharmaceutical reforms that aimed to reduce cost shifting and promote quality use of medicines [13]. To reinforce these benefits, and more importantly the notion of equity, coordination of continued implementation of these reforms should be considered. Early concerns over unknown financial risk to state governments was cited as a should now be alleviated by the experiences of participating states resulting in predictable and manageable risk [13, 40]. In addition to these reforms, various other incremental reforms have added further complexity and resulted in variable and unequal access to federal government funded PBS medicines for hospital patients. A comprehensive review of current practices related to use of PBS funded medicines would assist in understanding the issues related to supply of usual medicines to patients whilst they are admitted patients. This review should take into account lessons learned from the experience of private hospital utilisation of a PBS system of reimbursement for medicines used for admitted patients [56]. Administrative and operational streamlining had also been identified as necessary when the public hospital PBS reform was initially implemented [13]. These have been managed in various ways to minimise operational and administrative burdens, and have included changes over time to the way medicines are ordered and funding is claimed.

Recommendations from experts have urged that a broader and nationally coordinated approach to hospital medicines funding be taken [28]. A national hospital medicines formulary was initially proposed during reforms that began to incorporate the PBS in hospitals. It was recognised that the applicability of the PBS for use in hospital settings was limited by a focus on pack sizes and the range of medicines available [54]. A supplementary national hospital medicines formulary could incorporate and manage these issues, and could include arrangements for federal government funding, supporting the integration of services across health care settings. Most importantly, it would establish equitable access to all hospital inpatients and encourage a single hospital formulary for all hospitals, supporting the quality use of medicines as patients increasingly receive care from across health care settings. A national hospital medicines formulary would also promote cost-effective use of medicines, by transferring decisions regarding the best use of hospital medicines that are not on the PBS list from individual DTCs to a centralised reviewing body that would take into consideration the needs of the health system, not an individual hospital [26]. Establishing a single committee to make decisions on medicines formulary listing also supports equity and cost-effective use of medicines, particularly in medicines for off-label use, which can be more difficult for DTCs to evaluate due to the poorer availability of efficacy data [6, 9]. Regardless of any approach to reform evaluation and formulary management of hospital medicines, there may be opportunities to reduce unnecessary fragmentation and duplication of work. For example, this might include routinely sharing PBAC assessments and hospital utilisation and cost data reciprocally between states and territories governments and the federal government, or by coordinating DTC evaluations across states [6].

Although reforming medicines purchasing and pricing policy has the potential to result in significant cost savings, conflicting evidence makes it unclear what needs to change and how. Improvements in Australia's negotiating position with the pharmaceutical industry may be able to be achieved, giving the government greater control over PBS spending. Other proposed changes include implementation of a capped budget to the PBS; and ongoing evaluations to incentivise removal of less cost-effective medicines from the PBS, and adoption of national pharmaceutical tendering to improve value in pricing, however evidence from New Zealand has raised concerns these changes may reduce access and flexibility [6, 9, 26]. Whilst the reinvestment of efficiencies and use of other safeguards could ensure medicines access, reform in this area must importantly consider the effect on the viability and sustainability of the medicines industry, balancing potentially competing interests [57].

In order to promote funding integration, funding reforms need to acknowledge that no single entity is currently accountable for the delivery of any patient's health care and that the incentives facing hospitals and clinicians do not necessarily incentivise better patient outcomes and improved efficiency. Reform to establish a single funder of medicines would represent a truly integrated model. The concept of a 'single funder' of medicines describes a single source of the public proportion of medicines funding, and has been repeatedly identified as an option for reform [9, 20, 26, 40, 58, 59]. An integrated funding model would support the establishment of clearer accountability for the effectiveness and efficiency of service provision. International evidence suggests that removing the separation of responsibilities associated with medicines funding would not only reduce inefficiencies and cost-shifting incentives, but would encourage the delivery of value [59]. This option has been proposed in various forms, including sole responsibility of funding and service delivery by the federal government, or the more moderated option of pooled or shared funding with service delivery by

regional health services [21]. However, concerns have been raised about the potential effects of failing to integrate medicines funding with other health funding. Additional safeguards ensuring cost-effective, quality and safe medicines may need to be established, especially in the context of federal government medicines funding with an uncapped budget, and state government responsibility for care [21].

### ***Key considerations for hospital medicines funding reform***

*Figure 2. Considerations for future reform to hospital medicines funding*

- Full implementation of public hospital pharmaceutical reforms equally across all states and territories
- Review of the access to medicines funded through the PBS between private and public hospital admitted patients
- Establishment of a national hospital-specific medicines formulary, with expert national support in cost-effectiveness and safety evaluations
- Review of pricing and purchasing methods to ensure value for money and sustainability of the system
- Review of the regulatory framework for approval and registration of medicines to ensure timely, equitable and cost-effective access to medicines is achieved while supporting a viable and sustainable medicines industry
- Consideration of an integrated funding model with either shared or pooled funding between the federal government and the states and territories, or to that of a single funder of medicines model

Despite its complexity and fragmentation, reform may be achieved through cooperative negotiations between governments or through unilateral action by single government. Whilst medicines funding arrangements directly affect the ability to meet National Medicines Policy objectives, evidence highlights that the benefits are not always realised, illustrated by the limited effectiveness of past negotiations and reform. Hospital medicines funding reform should be considered more broadly in the context of all health funding in order to avoid creating any further fragmentation. Consideration must also be given to the sustainability of any reforms, where all parties involved must recognise the mutual necessity and role of others. It is vital to ensure that any future reforms to medicines funding arrangements are fiscally and politically sustainable, reduce current complexity and fragmentation, and are aligned with the National Medicines Policy.

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