8 April 2022

Mr James Downie
Chief Executive
Independent Hospital Pricing Authority
PO Box 483
Darlinghurst NSW 2300
By email to: submissions.ihpa@ihpa.gov.au

Dear Mr Downie,

Re: IHPA Work Program and Corporate Plan 2022-2023 Public Consultation

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 6,100 hospital pharmacists, and their hospital pharmacy intern and technicians working across Australia's hospitals and health system. Hospital pharmacists are core to medicines management and optimising the safe and quality use of medicines in all setting of a hospital, whilst also contributing to system-wide governance activities to reduce medicine complications and hospital-acquired complications (HAC) stemming from medicines. The role of hospital pharmacists are highlighted in 12 out of the 16 HAC information kits published by the Australian Commission for Safety and Quality in Health Care (the Commission).

SHPA welcomes the opportunity to provide feedback on the Independent Hospital Pricing Authority's (IHPA) draft *Work Program and Corporate Plan 2022-2023*. SHPA broadly supports the proposed draft work plan, however would like to bring to IHPA's attention several reviews and policies pertaining to medicines that will impact the following strategic objectives outlined in *Work Program and Corporate Plan 2022–23*:

- Strategic Objective One: Perform pricing functions
- Strategic Objective Three: Refine and improve hospital costing
- Strategic Objective Four: Determine data requirements and collect data
- Strategic Objective Five: Resolve disputes on cost-shifting and cross-border issues

Currently, there are simultaneous reviews being undertaken by the Commonwealth into the

- National Medicines Policy (extended until after 2022 Federal election)
- Section 100 Efficient Funding of Chemotherapy (EFC) (reporting 30 June 2022)
- Pharmaceutical Reform Agreements (PRA) (reporting 30 June 2022)

Both the Section 100 EFC and PRA are essential for attempts by hospitals and hospital pharmacists to facilitate equitable, timely and affordable access to medicines subsidised on the Pharmaceutical Benefits Scheme (PBS) for cancer patients, and hospital patients receiving medicines upon discharge or from outpatient clinics. Since Section 100 EFC and PRAs have been enabled throughout most jurisdictions,

hospital pharmacists have never been provided appropriate or equitable remuneration compared to community pharmacists for supplying the same PBS medicines. Furthermore, access to the PBS medicines and non-PBS medicines is variable across hospitals due to confounding factors which are explored in SHPA's submissions to these reviews. (attached)

IHPA's *Pricing Framework for Australian Public Hospital Services 2022–23* requires the agency to discount Commonwealth funding provided to public hospitals through programs other than the National Health Reform Agreement. SHPA believes that IHPA must consider the outcomes of these reviews as part of its *Work Program and Corporate Plan 2022-2023* as their findings and recommendations will have an impact on the cost of medicines, and the level of clinical pharmacy service required in hospitals to support safe care and quality use of medicines.

The recently signed Strategic Agreements between the Commonwealth and Generic and Biosimilar Medicines Association (GBMA) and Medicine Australia also contain various major changes to drug pricing policies. SHPA believes IHPA should undertake an impact assessment of these Strategic Agreements on hospital drug pricing, given the cost of medicines for each admission type or procedure is factored into National Weighted Activity Unit (NWAU) determinations. Most notably is the unknown impact of public hospitals being compelled to participate in Price Disclosure for PBS medicines, with data collection commencing on 1 October 2022. Given the commercial arrangements for medicines procurement in hospitals, it is anticipated that this major policy change will likely lead to an increase to the cost of lower cost medicines for hospital purchasers.

Finally, the Commission will publish the *Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard* on 27 April 2022, which is anticipated to significantly increase the level of necessary hospital pharmacy input for admissions relating to surgery and perioperative medicine, critical care and emergency medicine, to reduce opioid-related harm. SHPA recommends that the pricing and weighting of the impacted admission types should be updated to reflect these additional requirements pertaining to opioid stewardship, which will make hospital care safer for patients receiving treatment with high-risk opioid medicines.

If you have any queries or would like to discuss the matters raised above, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au

Yours sincerely,

Kristin Michaels
Chief Executive

SHPA's Response to the Review of the Efficient Funding of Chemotherapy (EFC) Program Discussion Paper

Introduction

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,200 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

Hospital pharmacists account for just over 20% of the entire pharmacy workforce. According to Services Australia, in 2019-20, hospital pharmacists managed over 23% of Pharmaceutical Benefits Scheme (PBS) expenditure, including a majority (58%) of Section 100 EFC expenditure. They further note that, in 2019-20, a total of $1.59 billion in Section 100 EFC pharmaceutical benefits was paid to pharmacies, almost double that of the $835 million just five years ago, which represents the largest growth of all PBS categories in this period.

SHPA commends the government on its Review into the Efficient Funding of Chemotherapy (EFC) Program and welcomes the opportunity to contribute member experiences to support the development of a more contemporary, patient-centric, and sustainable model that places patient access and safety and quality of care as the top priorities. Various reports stemming from both the 2016 *Inquiry into Off-protocol prescribing of chemotherapy in New South Wales*[1] and *Independent Review into the Incorrect Dosing of Cytarabine to ten patients with Acute Myeloid Leukaemia at Royal Adelaide Hospital and Flinders Medical Centre*[2] in South Australia, demonstrate the critical nature of hospital pharmacists acting as a safeguard for the quality and safety of cancer care.

Our submission is informed by our member's expertise; those who practice at the frontline of oncology and haematology wards, chemotherapy day treatment centres, and chemotherapy compounding suites providing care to patients receiving cancer therapies in hospitals and health service facilities nationally. This includes several SHPA Specialty Practice Leadership Committees including:

- Oncology and Haematology
- Leadership and Management
- Electronic Medication Management
- Medication Safety
- Rural and Remote Health
- Compounding Services
- Dispensing and Distribution
- Transitions of Care and Primary Care
- Aboriginal and Torres Strait Islander Health

Clinical pharmacists are experts in complex medication management for people who are acutely unwell. Pharmacists providing oncology and haematology clinical pharmacy services are clinical pharmacists with expertise in cancer therapies, practicing within a hospital's multidisciplinary team with a key focus on promoting safe and effective use of cancer medications, reducing the incidence of serious adverse events and toxicities, and improving patient care. Depending upon the capacity and preferences of the hospital, Oncology and Haematology Pharmacists work with multidisciplinary committees to support effective governance including policies and procedures to drive improved patient care. Pharmacists managing the manufacturing of these cancer therapies are also clinical pharmacists with expertise in the compounding of cytotoxic medications.

In this submission SHPA makes a range of recommendations to support a funding framework for the provision of cancer therapies to Australians that recognises its specialised nature, and places access and safety and quality of care as the top priorities. If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

Recommendations

Recommendation 1: **Funding models should recognise the overheads, ongoing costs uniquely associated with the provision of Section 100 EFC medicines separate to other PBS medicines to support sustainability and access to chemotherapy.**

Recommendation 1a: **For smaller hospitals, particularly in regional, rural and remote settings, funding models should recognise that these overheads and ongoing costs, are much more pronounced and less affordable, negatively impacting the viability of cancer services.**

Recommendation 2: **Funding models and/or remuneration fee structures for provision of Section 100 EFC medicines should be tiered to recognise the varying economies of scale and marginal costs of chemotherapy services provided in hospitals of different sizes and capacities, to facilitate improved patient access in regional and rural settings.**

Recommendation 3: **New South Wales and Australian Capital Territory should become signatories to the Pharmaceutical Reform Agreements, allowing public hospitals to directly supply Section 100 EFC medicines and chemotherapy services more efficiently and improve access.**

Recommendation 4: **Digital health infrastructure investment into electronic medical records design and implementation should consider the safety and workflow requirements of chemotherapy services and support the enabling and delivery of TeleChemotherapy services to increase access in rural and remote areas.**

Recommendation 5: **Improve chemotherapy service delivery and access to Aboriginal and Torres Strait Islander People by addressing health literacy and developing culturally appropriate resources on chemotherapy medicines and cancer care in hospitals, through co-design and consultation with Aboriginal and Torres Strait Islander Peoples and Indigenous Health peak bodies and practitioners.**

Recommendation 6: **Chemotherapy pharmacy services should be recognised as a specialty area of practice in recognition of its unique requirements, arrangements and expertise.**

Recommendation 7: **The provision of Section 100 EFC medicines should be delivered alongside best-practice clinical pharmacy services for oncology and haematology services with the following ratios according to SHPA's *Standard of practice in oncology and haematology for pharmacy services*:**

- **1 full-time equivalent (FTE) pharmacist to 20 medical oncology inpatients**
- **1 FTE pharmacist to 15 haematology inpatients**
- **1 FTE pharmacist to 20 same-day admitted or home-based care patients**

Recommendation 8: **Chemotherapy pharmacy services should be delivered by appropriately experienced and trained pharmacists in cancer services, with health services provided dedicated support for recruitment, retention and training of this specialised workforce, such as training pharmacists through SHPA's Cancer Services Advanced Training Residency Program.**

Recommendation 9: **Allow hospital inpatients to be eligible for subsidy for Section 100 EFC medicines where a hospital admission is unavoidable due to deteriorating patient condition and/or acute condition.**

Recommendation 10: **Any potential changes to the renumeration model for Section 100 EFC medicines should not result in a net-negative funding scenario compared to existing renumeration models as to not threaten the safety and quality of chemotherapy care.**

Recommendation 11: **Explore the appropriateness and feasibility for using dose banding and dose rounding strategies for chemotherapy medicines to minimise wastage.**

Recommendation 12: **Quality assurance programs should be embedded into existing frameworks accrediting and assessing hospitals and services against NSQHS Standards, and they should specifically assess the quality of chemotherapy pharmacy services against SHPA's Standard of Practice in Oncology and Haematology for Pharmacy Services.**

Recommendation 13: **To better support equitable patient access to cancer therapies, the maximum claimable doses for Section 100 EFC medicines should correspond with the evidence and established chemotherapy protocols to accommodate patients with larger body mass index.**

Recommendation 14: **The implementation of electronic prescriptions and electronic chemotherapy medication charts (eCMCs) should be undertaken in collaboration with hospital pharmacy stakeholders to ensure safety and quality of chemotherapy services whilst also reducing the administrative burden associated with paper-based prescriptions.**

Topic 1: Patient Access to Chemotherapy Services

Recommendation 1: **Funding models should recognise the overheads, ongoing costs uniquely associated with the provision of Section 100 EFC medicines separate to other PBS medicines to support sustainability and access to chemotherapy, particularly in smaller hospitals in regional and rural settings.**

Recommendation 1a: **For smaller hospitals, particularly in regional, rural and remote settings. Funding models should recognise that these overheads and ongoing costs, are much more pronounced and less affordable, negatively impacting the viability of cancer services.**

Recommendation 2: **Funding models and/or remuneration fee structures for provision of Section 100 EFC medicines should be tiered to recognise the varying economies of scale and marginal costs of chemotherapy services provided in hospitals of different sizes and capacities, to facilitate improved patient access in regional and rural settings.**

Chemotherapy medicines and services are highly specialised and complex, such that facilitating patient access to safe and high-quality chemotherapy services in hospitals is generally challenging and requiring thorough planning and comprehensive investment. These challenges are exacerbated in rural and remote areas on multiple fronts, including:

- Access to, funding, recruitment and retention of hospital pharmacists with specialisation or appropriate training or qualifications in oncology and haematology pharmacy services and compounding services
- Lack of recognition and renumeration for the provision of Section 100 EFC medicines
- Access to specialist medical staff in rural and regional hospitals
- Reduced economies of scale and cost-efficiency compared to urban hospitals, thus increasing exposure to financial risk associated with unavoidable medicine wastage
- Large overhead and ongoing costs associated with cytotoxic compounding services and chemotherapy services, resulting in reliance on metropolitan hospitals and metropolitan-based third-party compounding facilities

The majority of PBS medicines are low-cost packaged capsules or tablets that only require a clinical review to be dispensed safely to the patient, and can have a shelf-life of over three years. This differs with high-cost chemotherapy medicines provided under Section 100 EFC, where compounding services are required to manufacture chemotherapy doses, tailored to patient-specific characters and according to complex chemotherapy treatment protocols. These additional costs are not recognised meaningfully by current funding models, where a $40 per compounded Section 100 EFC medicine is paid to non-TGA-licensed compounders, which the majority of hospitals are. Where Section 100 EFC compounded items require subsequent dose modification, or for non-Section 100 EFC chemotherapy requiring compounded, no applicable fees are paid for these compounding services. These compounded medicines also have very short expiries, often less than 48 hours, which increases the financial risk and exposure if these medicines are unable to be delivered or administered to patients due to missed appointments, logistical delays, temperature and storage excursions or requirement for dose modification after compounding.

	Public hospitals	Private hospitals	Community pharmacy
Section 85 medicines	Ex-manufacturer price + 7.52% wholesale mark-up	Ex-manufacturer price + 7.52% wholesale mark-up + 1.4% pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 7.52% whole-sale markup + AHI fee + Dispensing Fee
Section 100 medicines	Ex-manufacturer price	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee

Table 1. Public and private hospital pharmacy renumeration fee structure for Section 85 and Section 100 medicines
Adapted from Review of Pharmacy Remuneration and Regulation Discussion Paper and updated with 2019 Federal Budget reduction to hospital pharmacy wholesale mark-up[3]

Furthermore, per Table 1, public hospital pharmacies that supply Section 100 EFC medicines are only able to claim for the approved ex-manufacturer price from Services Australia. This contracts with community pharmacies and private hospitals who, when dispensing Section 100 medicines, are remunerated per item, with a dispensing fee of $7.74 and a 4-tier pharmacy mark-up worth up to $40, on top of the approved ex-manufacturer.

Thus, when factoring in all associated costs of chemotherapy services, of which only a portion are provided under Section 100 EFC as hospitals are also responsible for non-Section 100 EFC chemotherapy medicine provision, SHPA members conclude that these services are often provided at an operational loss to pharmacy departments in larger urban hospitals, which is exacerbated in smaller hospitals without the economies of scale.

The large overhead costs are associated with the establishment and ongoing maintenance of chemotherapy compounding suites to meet *Australian Standards 2252: Controlled environments, Part 5: Cytotoxic drug safety cabinets (CDSC) - Design, construction, installation, testing and use*[4]*.* According to compounding pharmacists, commissioning and construction costs of a standard 20m^2 cytotoxic cleanroom suite typically found in metropolitan hospitals would be $160,000 alone, based on a per metre square cost of $8,000 per m2.

The annual staff cost of recruitment, employment, training and validation of compounding pharmacists and compounding pharmacy technicians would easily exceed $500,000 annually for a team of two pharmacists and four pharmacy technicians.

The equipment required is also expensive, with cytotoxic drug safety cabinets costing around $45,000, and approximately $65,000 for a two-hatch negative pressure isolator unit. Additionally, depending on the size and capacity of the hospital, there are ongoing annual costs that can reach just under $100,000 for cleaning consumables and disinfectants, microbiological media plates and validation kits, personal protective equipment and regular cleaning.

Thus, it is apparent that a one-size-fits-all approach to funding of chemotherapy services does not recognise the large fixed and ongoing costs of chemotherapy service and compounding operations, to the detriment of smaller hospital sites that have a role in facilitating access to regional, rural and remote populations. SHPA supports further work by the Australian government and associated stakeholders to understand these costs fully, to implement a tiered funding model that at minimum provides cost recovery to public hospital chemotherapy services. Any changes current funding and investment levels to increase access in rural and remote areas, should not – either intentionally or unintentionally – come at the expense of support for chemotherapy services in urban hospitals, who will continue to treat the vast majority of Australians requiring chemotherapy. Urban services often support rural and remote sites and will continue to do so; any reduction in funding or level of investment for urban services is likely to negatively impact on access to chemotherapy services for regional, rural and remote patients.

1. **Does access to chemotherapy services vary in rural and remote areas compared to urban areas? What, if anything, could be changed about current access arrangements? Please provide a case example if possible.**

Access to chemotherapy services in rural and remote areas varies greatly from that in urban areas of Australia. Patients requiring chemotherapy in rural and remote areas are often unable to receive treatment near their residence due to the challenges and costs associated with safe and high-quality chemotherapy services and the lack of economies of scale. This results in a reliance on patients to travel and receive treatment at urban centres, often at their own cost. This has downstream effects on increased out-of-pocket costs associated with travel and accommodation if necessary.

The large overheads and ongoing costs associated with providing chemotherapy services that include in-house chemotherapy compounding, renders it nonviable for smaller regional, rural and remote hospital pharmacy departments to provide comprehensive chemotherapy services akin to their urban counterparts. The *Final report: Review of the Pharmaceutical Compounding Operating Model in the Tasmanian Health Service*[5] presents a high-level analysis of the compounding services' cost-effectiveness using the 'operational cost per product' as an indicator. This analysis shows that the total operating cost in an urban hospital is approximately $84 per product whereas, the operating cost in a rural and remote hospital can be up to $305 per product. It is for this reason that only limited chemotherapy infusions with short expiries that cannot be transported from urban areas, are compounded in-house in regional, rural and remote settings, and almost certainly without the ability to cost recover.

Distance and the logistics of transportation, at times via plane or boat, necessitate increased lead up times for ordering compounded chemotherapy from TGA-licenced compounding facilities. This means that last minute changes to therapy cannot be accommodated in rural and remote hospitals and result in increased wastage of therapy since low patient volumes limits possibility of medications being used for another patient. Transport delays also cause significant operational and logistical issues in getting chemotherapy medicines to rural and remote sites and can cause delay to treatment. This has been most evident during the COVID-19 pandemic resulting in substantial flight scheduling disruptions and border restrictions.

Most additional costs incurred due to distance and poor economies of scale regional, rural and remote facilities, are absorbed by the hospital pharmacy departments rather than passed onto the patients. However, additional costs incurred by patients receiving cancer therapy in rural and remote areas include the PBS co-payment which is often waived in urban services, and cost of travelling to regional hubs from remote areas.

SHPA members observe that there is limited access to private chemotherapy services in rural and remote settings, likely due to significant costs and requirement for economies of scale to achieve viability.

2. **Are there differences in the costs or processes for receiving chemotherapy services in rural and remote areas? How do access arrangements vary between public and private sectors, States and Territories and what is the effect on accessibility of services? Please provide any details you have to support your position.**

Recommendation 3: New South Wales and Australian Capital Territory should become signatories to the Pharmaceutical Reform Agreements, allowing public hospitals to directly supply Section 100 EFC medicines and chemotherapy services more efficiently and improve access.

There are different costs and processes in rural and remote areas, stemming from the scalability issues examined above given the large overheads, fixed and ongoing costs of delivering chemotherapy. However, there are further variations between public and private sectors and between States and Territories that impact negatively on access in regional, rural and remote areas, which are examined below.

As stated in the introduction, hospital pharmacies account for a majority, 58%, of Section 100 EFC expenditure in 2019-20 per Table 2. However, this is an underrepresentation and hospitals account for a larger portion than 58%, as a portion of the Section 90 community pharmacies accounting for 42% of Section 100 EFC expenditure, are providing chemotherapy services and medicines directly to private hospitals. This is because private hospitals that exceed a certain size (SHPA members report a criterion is having 150

overnight beds or more) can elect to have a Section 90 community pharmacy on premise, instead of being a Section 94 private hospital pharmacy.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	National
Section 90 approved pharmacists (community pharmacy)	0%	80%	2%	15%	14%	61%	23%	38%	42%
Section 94 approved private hospital authorities	100%	20%	3%	36%	36%	27%	20%	28%	26%
Section 94 approved public hospital authorities	0%	0%	95%	49%	50%	12%	57%	34%	32%

Table 2. Proportion of Section 100 EFC expenditure attributed to pharmacy types, 2019-20 (Source: Services Australia)

This has commercial benefits as Section 90 community pharmacies are able to dispense prescription medicines and supply non-prescription medicines and other pharmacy products to the general public, which Section 94 hospital pharmacies are prevented from undertaking. Furthermore, Section 90 community pharmacies are also provided a larger renumeration fee structure when dispensing general Section 85 PBS medicines compared to hospital pharmacies both public and private as per Table 1. This renumeration impacts on the viability of chemotherapy services which have comparably larger fixed and ongoing costs compared to other PBS medicines. The lower the renumeration for supplying PBS medicines, the less funding there is for high quality clinical pharmacy services, dispensing services and compounding services to be delivered to patients requiring chemotherapy.

Given that private hospitals in regional, rural and remote areas would be smaller in size, their smaller patient load and subsequent lower renumeration impacts the viability of these services, resulting in many patients having to travel to urban areas to receive treatment.

For regional, rural and remote sites that do provide chemotherapy services, most often the compounding of Section 100 EFC medicines is outsourced to third-party compounding facilities as in-house compounding is cost-prohibitive. This presents an additional challenge as chemotherapy orders need to be made to third-party compounders in advance of up to a week, a longer lead time compared to urban areas, to factor in the travel and delivery schedules outside of urban centres. As mentioned above, this means that last minute changes to therapy cannot be accommodated in rural and remote hospitals and result in increased wastage of therapy since low patient volumes limits possibility of medications being used for another patient.

As per Table 2, it is apparent that the different pharmacy sectors in each state and territory account for a varying proportion of Section 100 EFC expenditure and chemotherapy services. In Queensland, South Australia and Victoria, approximately half of all Section 100 EFC is provided by public hospitals. In Tasmania and Western Australia, the private sector accounts for a majority of Section 100 EFC expenditure. Northern Territory, New South Wales and Australian Capital Territory have less variation, with virtually all of Northern Territory's Section 100 EFC provided by public hospitals, and the latter two states exclusively by the private sector. This is not to suggest that any certain sector is the preferred sector to deliver chemotherapy services, but rather that chemotherapy services across Australia have developed organically, responsive and at times, restricted by, jurisdictional healthcare systems and infrastructure.

A clear concern from SHPA members is that New South Wales as the only state to be non-signatory to the Pharmaceutical Reform Agreements, prevents New South Wales public hospitals from having meaningful participation in supplying PBS medicines. The impact of this on chemotherapy services in New South Wales public hospitals is that it hinges on workarounds where the dispensing and manufacturing of Section 100 EFC medicines is undertaken by a community pharmacy – who likely outsources the compounding – and delivers the prepared product to the public hospital for administration. This model of care to deliver chemotherapy, involves three different stakeholders to co-ordinate the supply and administration of a high-risk chemotherapy medicine safely and efficiently. The clinical review process of chemotherapy orders is also devolved in the absence of a singular chemotherapy clinical software system that all parties have access to, thus increasing the risk of error caused by transcription of chemotherapy order details, patient details and particulars

regarding their chemotherapy protocol and cycle. These challenges are exacerbated where last minute dose modification is required due to changing patient status, causing potential delays to treatment and/or wastage of high-cost chemotherapy medicines.

This contrasts with public hospitals in all other states that are signatories to the Pharmaceutical Reform Agreements, where they have the option to have in-house compounding services for chemotherapy medicines, as larger public hospitals with higher volumes of chemotherapy patients are able to make these compounding services more viable. The benefits from this include:

- More timely responsiveness and capacity to undertake any dose changes or modifications for chemotherapy orders, thus limiting risk of wastage of a high-cost medicine
- Increased safety and quality of chemotherapy services through access to patient file and notes within the hospital to undertake clinical review of chemotherapy orders to ensure it is accurate, safe and appropriate for the patient

Thus, SHPA recommends that New South Wales and the Australian Capital Territory become signatories to the Pharmaceutical Reform Agreements, allowing public hospitals to directly supply Section 100 EFC medicines and chemotherapy services.

3. What additional factors may limit access to chemotherapy services in rural and remote areas?

For hospital pharmacies in rural and remote areas, a limiting factor is having the requisite hospital pharmacy workforce for chemotherapy services. Recruitment and retention of specialised and experienced hospital pharmacy staff is significantly more challenging than in ,urban settings, due to a smaller pool of available pharmacists with the requisite skills. Additionally, a flatter hierarchy of hospital pharmacy departmental structures in rural and remote health services means qualified and experienced pharmacists seek more attractive opportunities in urban areas. Although increased remuneration can potentially attract the requisite oncology and haematology pharmacists to regional, rural and remote areas, this is difficult for hospitals who operate within fixed resourcing budgets that are also subject to efficiency dividends annually. These issues associated with hospital pharmacists providing specialised chemotherapy services, are further explored in Topic 2: Chemotherapy Services as ‘Speciality Services’.

Furthermore, as chemotherapy medicines are cytotoxic, cytotoxic waste disposal must be disposed of at specific waste facilities. These facilities are located in urban areas which incurs a significant additional cost in transportation and poses potential safety concerns when they are stored and transported from regional, rural and remote areas to urban areas.

4. What changes, if any, could be made to current pharmacy arrangements to improve access to chemotherapy services in rural and remote areas? Can you suggest ways in which those changes could be managed?

As per our first two recommendations, SHPA recommends a funding model that properly recognises the overheads, ongoing costs uniquely associated with the provision of Section 100 EFC medicines separate to other PBS medicines to support sustainability and access to chemotherapy, particularly in smaller hospitals in regional and rural settings.

Given the importance of economies of scale on the viability of chemotherapy services, funding models and/or remuneration fee structures for provision of Section 100 EFC medicines should be tiered to recognise this and the marginal costs of chemotherapy services provided in hospitals of different sizes and capacities, to facilitate improved patient access in regional and rural settings. This would aim to reflect and cost-recover for increased workload relating to logistics of ordering, transportation, receiving, storing and dispensing of chemotherapy in rural and remote settings. This increased funding will also support the recruitment of appropriately skilled and trained pharmacists that have experience in or specialise in chemotherapy services.

This could come in the form of targeted service fees for regional, rural and remote specialised chemotherapy services to improve viability and access of these services. These types of targeted remuneration arrangements are not new to Australia’s healthcare system, as evidenced by the nine Rural Support

Programs funded under the Seventh Community Pharmacy Agreement to support access to PBS medicines and pharmacy services for people living in rural and remote regions of Australia[6], and pricing adjustments based on remoteness in activity based funding for public hospital services[7].

Recommendation 4: Digital health infrastructure investment into electronic medical records design and implementation should consider the safety and workflow requirements of chemotherapy services and support the enabling and delivery of TeleChemotherapy services to increase access in rural and remote areas.

Australian hospitals are currently on an electronic medical records journey, with different hospitals, states and territories at varying levels of design, scoping and implementation, with varying state-wide versus local approaches to this. Investment in electronic medication management systems that are integrated with procurement, scheduling and dispensing systems and processes would reduce the risk of errors, administrative burden, and promote safe and quality use of medications.

On top of electronic medical records software, chemotherapy-specific software programs such as Charm Evolution and Episoft are also used by hospitals to deliver chemotherapy services. These software programs have the capacity to provide end-to-end management of chemotherapy services, with chemotherapy protocols loaded into the software, allowing for calculation of doses and monitoring of chemotherapy cycle to ensure patients receive the right dose at the right time. These software programs supplant paper-based chemotherapy services where paper-based medication charts, infusion administration charts and clinical notes prevail. Paper-based systems require transcription of clinical information at each step, is a known risk area contributing to errors in care.[8] Many hospitals still use paper-based systems, due to significant investment, design and training required to switch to chemotherapy electronic software. If they are not implemented without a strong focus on design, user-testing and user-training, this can cause serious risks to patient safety and quality of care.

Electronic medication management systems can also possibly aid the establishment of innovations such as TeleChemotherapy that would improve patient access to specialised cancer care, especially in rural and remote areas where it is difficult to or not feasible to recruit dedicated pharmacist resources for very small patient cohorts. Funding and enabling of TeleChemotherapy could allow for patients based in regional, rural and remote areas to receive their chemotherapy without travelling to an urban area, whilst still receiving comprehensive pharmacy care by suitably trained and experienced pharmacists. One such example is the Western Australia Country Health Service TeleChemotherapy Pharmacy Service, which has received national recognition for its innovation in delivering chemotherapy treatment to regional, rural and remote patients. Thus far, this service has allowed dozens of patients in these regions receive lower-risk chemotherapy locally with the support of specialist metropolitan-based clinicians via telehealth services.

5. **Describe the challenges you have faced with current access arrangements to chemotherapy for Rural and Remote areas, Aboriginal and Torres Strait Islander People, and older Australians. How could these be improved?**

Recommendation 5: Improve chemotherapy service delivery and access to Aboriginal and Torres Strait Islander People by addressing health literacy and developing culturally appropriate resources on chemotherapy medicines and cancer care in hospitals, through co-design and consultation with Aboriginal and Torres Strait Islander Peoples and Indigenous Health peak bodies and practitioners.

SHPA members have reported several challenges with the current access arrangements to chemotherapy for Aboriginal and Torres Strait Islander People across Australia. Hospitals are considered culturally unsafe institutions and places to go when dying in Aboriginal and Torres Strait Islander communities. Better messaging is required to improve health literacy around the role of hospitals in healing, and of chemotherapy in the treatment of cancer.

Culturally and linguistically diverse medication information resources are not currently available for chemotherapy and supportive non-chemotherapy medications. These resources would support these important conversations and help improve cultural perspectives on hospitals and cancer treatment options. SHPA supports development of these resources through co-design and consultation with Aboriginal and Torres Strait Islander Peoples and Indigenous Health peak bodies and practitioners, such as SHPA's Aboriginal and Torres Strait Islander Health Leadership Committee and National Aboriginal Community Controlled Health Organisation.

Additionally, there is limited access to supportive non-chemotherapy medications (i.e. pain medicines, anti-nausea medicines) in Remote Area Aboriginal Health Services (RAAHS) and the PBS co-payment for supportive medications is also a barrier to receiving these medicines.

SHPA members also note that referral of complex and often marginalised Aboriginal and Torres Strait Islander patients from urban centres to rural and remote centres, to better place them closer to home and their support networks, has cost implications on rural and remote centres to provide a level of complex care usually only reserved for urban centres.

6. **When compared to urban/metro areas, are there significant differences in treatment facilities which may impact chemotherapy services for rural and remote areas? Please provide any details you have to support your position.**

As discussed above, chemotherapy treatment facilities in rural and remote areas are limited with respect to hours of operation and staffing due to low patient volumes, which can impact on the timely delivery of varying treatment plans (i.e. long infusions, multiple infusions on one day and/or multi-day regimens) especially when dose changes are required. The lack of on-site or local chemotherapy compounding facilities has significant implications on patient care since, as last-minute changes to therapy cannot be accommodated in a timely manner.

Topic 2: Chemotherapy Services as 'Speciality Services'

Recommendation 6: Chemotherapy pharmacy services should be recognised as a specialty area of practice in recognition of its unique requirements, arrangements and expertise.

SHPA supports the discussion paper's notion of recognising chemotherapy pharmacy services as a specialty area of practice in recognition of its unique requirements, arrangements and expertise. The hospital pharmacy sector has long recognised chemotherapy pharmacy services provided to oncology and haematology patients as a specialty given the complexity and expertise required to provide safe and quality care to this at-risk patient cohort with expensive and high-risk medicines. As mentioned in the introduction, both the 2016 *Inquiry Off-protocol prescribing of chemotherapy in New South Wales*[1] and *Independent Review into the Incorrect Dosing of Cytarabine to ten patients with Acute Myeloid Leukaemia at. Royal Adelaide Hospital and Flinders Medical Centre*[2] in South Australia, demonstrate the specialised and complex nature of chemotherapy separate to other medicines, and the critical nature of hospital pharmacists to act as a safeguard for quality and safety of cancer care.

SHPA has also supported this through establishing the Oncology and Haematology Specialty Practice Group, which at present has almost 1,000 members dispersed through its Leadership Committee, Practice Group and Interest Group. Similarly, SHPA also convenes a Compounding Services Specialty Practice Group to support its members who specialise in the compounding of medicines, including Section 100 EFC and non-Section 100 EFC medicines.

In hospitals that have medical oncology and haematology wards, generally more experienced, senior pharmacists take on the role of oncology and haematology pharmacist. In smaller hospitals where departmental structures have a flatter hierarchy with very limited capacity or funding for senior hospital pharmacists, the role of cancer services pharmacists is preferentially recruited at a senior level. Similarly for private hospitals where there is generally lower coverage of clinical pharmacy services provided overall to patients compared to public hospitals, clinical pharmacy services for patients receiving chemotherapy treatment are the top priority when allocating limited resources.

As mentioned earlier, most PBS medicines are tablets and capsules and have simpler requirements with respect to its safe prescribing, dispensing, storage and administration, and the only healthcare practitioners required to safely supply general PBS medicines to patients are a doctor and a pharmacist. This differs greatly to the provision of Section 100 EFC medicines and cancer treatment, where there are more healthcare practitioners required to be involved in delivery of safe and quality chemotherapy pharmacy services, including:

- Specialist oncologist/haematologist to prescribe chemotherapy medicines on the appropriate medication/infusion chart on paper-based system or electronic oncology software system, as well as supportive non-chemotherapy medications
- Oncology/haematology clinical pharmacist to review prescription against the chemotherapy protocol, including reviewing patient details that impact dosing such as height, weight, renal and hepatic function to ensure dose is safe and appropriate, and that the infusion rate, infusion and administration times are also appropriate
- Dispensing pharmacist and pharmacy technician to dispense the Section 100 EFC medicine and supportive non-chemotherapy medications, ensuring the prescription fits all requirements of a PBS prescription to be claimed successfully, including the relevant Authority Required codes
- Compounding pharmacist and compounding pharmacy technician to compound chemotherapy
- Oncology nurse to administer infusible chemotherapy to patient
- Electronic medication records pharmacist to implement electronic medical records software and/or chemotherapy-specific software programs safely, if used

Recommendation 7: The provision of Section 100 EFC medicines should be delivered alongside best-practice clinical pharmacy services for oncology and haematology services with the following ratios according to SHPA's *Standard of practice in oncology and haematology for pharmacy services*:

- **1 full-time equivalent (FTE) pharmacist to 20 medical oncology inpatients**
- **1 FTE pharmacist to 15 haematology inpatients**
- **1 FTE pharmacist to 20 same-day admitted or home-based care patients**

Given the complex and specialised nature of chemotherapy services, SHPA's Oncology and Haematology Leadership Committee has published the *Standard of practice in oncology and haematology for pharmacy services*[9] to describe how best-practice clinical pharmacy services for oncology and haematology patients should be provided. It defines the pharmacist-to-patient ratio that should not be exceeded to ensure the full suite of clinical pharmacy services are delivered to ensure safe and quality care for patients receiving chemotherapy. These ratios are as per the recommendation above, and the Standard also describes a slightly smaller ratio for paediatric oncology patients. Adhering to the limits of these ratios allows the comprehensive range of clinical cancer pharmacy services and quality improvement activities to be delivered, which include:

- Medication history and reconciliation on admission
- Assistance with cancer therapies planning and review
- Clinical verification of cancer therapies and supportive care, and coordination of compounding and/or dispensing of cancer medicines
- Medication chart review and monitoring of cancer therapies
- Monitoring of cancer therapies and optimisation of supportive care plan
- Optimisation of graft-versus host-disease management
- Participating in multidisciplinary ward rounds and multidisciplinary team meetings
- Patient and/or carer education on cancer therapies and supportive care medicines including appropriate administration and handling of cancer medicine
- Discharge prescription review and reconciliation in the context of cancer therapies and disease
- Preparation and delivery of discharge medicine information for patients and/or carers
- Provision of information about medicine changes to patients and/or carers
- Facilitation of post-transplant vaccines administration
- Development and review of cancer therapy protocols, procedures and guidelines, and patient education materials on cancer therapy
- Participation in cancer therapy governance committee and Quality Use of Medicines activities such as audits and staff education
- Participation in research projects

However, SHPA members report that a majority of hospitals and health services, are not sufficiently funded or resourced to provide comprehensive clinical pharmacy care for cancer patients. This means that instead of a 1.0 FTE cancer services pharmacist being responsible for 15-20 patients as per SHPA's standard, they are allocated a patient load of more than 20 patients, sometimes even over 50 patients depending on the hospital. SHPA believes this is inappropriate, as it means cancer services pharmacists with inappropriate patient loads are unable to provide the full suite of clinical pharmacy services described above. This places the safety and quality of care for cancer patients at great risk.

In the worst case scenario, some hospitals and health services may not have any dedicated cancer services pharmacist at all, and any opportunity for clinical review and check for appropriateness of therapy rests with the dispensing and/or compounding pharmacist who are much less likely to have comprehensive access to patient clinical notes to inform care.

The absence of providing comprehensive clinical pharmacy services for patients receiving chemotherapy only increases the risk of treatment errors, reduces the quality of care and decreases patient safety. A literature review on chemotherapy medication errors[10] focusing on prescription orders and pharmacy practices spanning 1980 to 2017 published in The Lancet Oncology, demonstrated that chemotherapy errors occur at a rate of about one to four per 1000 orders, affect at least 1–3% of adult and paediatric oncology patients, and occur at all stages of the medication use process. According to Services Australia data, in 2019-20, there were 1.24 million Section 100 EFC prescriptions successfully claimed by all community and hospital pharmacies. Extrapolating the literature review's findings means that in 2019-20, there would be anywhere between 1,240 to 4,960 Section 100 EFC prescriptions – 5 to 19 prescriptions each weekday – that contained an error that may or may not have reached the patient, and would require a hospital pharmacist to detect, escalate and manage the error, to prevent or minimise the harm caused to the patient.

The NSW *Inquiry into off-protocol chemotherapy prescribing for head and neck cancers: Final report*[1], highlights the risks associated with limited access to clinical pharmacy oncology and haematology services. A recommendation from this Inquiry was that the Ministry of Health, with the Cancer Institute NSW, examine ways to ensure that all people diagnosed with notifiable cancer in NSW have their care overseen by a Multidisciplinary Cancer Care Team that includes all relevant healthcare professionals including pharmacists, after patients were prescribed off-protocol flat doses of 100 mg carboplatin. However, the limited workforce of oncology and haematology pharmacists makes it difficult to provide high-quality cancer services and deliver on these government recommendations.

Recommendation 8: Chemotherapy pharmacy services should be delivered by appropriately experienced and trained pharmacists in cancer services, with health services provided dedicated support for recruitment, retention and training of this specialised workforce, such as training pharmacists through SHPA's Cancer Services Advanced Training Residency Program.

Given the complex and specialised nature of chemotherapy services and the comprehensive clinical pharmacy services required to deliver safe and quality care, it is appropriate that these services should be delivered by appropriately experienced and trained pharmacists. However, hospital pharmacy directors and clinical leads often report that recruitment for pharmacists specialising in oncology and haematology is difficult even in urban areas, and these difficulties are exacerbated in regional, rural and remote areas. Recent challenges brought on by the COVID-19 pandemic and overall increased demand for health expertise, has been another additive challenge for recruitment.

SHPA operates a hospital pharmacy jobs board for the sector and hosts regular Director of Pharmacy forums, and our first-hand evidence indicates that it can take up to a couple of months to recruit for these positions in urban areas. In non-urban areas, this can take up to and over six months depending on the location.

Similar challenges also exist for compounding pharmacists and compounding pharmacy technicians, where it can take several months to provide experiential training to become fully trained and be able to validate a candidate's competencies.

Even when successfully recruiting for these positions, retention and turnover presents another challenge as when experienced staff leave, it is difficult to replace them as well as allocate further resources for training new staff. This is particularly relevant and pertinent in smaller hospitals, typically in regional and rural areas, where pharmacists seek job opportunities in larger hospitals in urban areas where there are more senior job opportunities, a symptom of the different hospital pharmacy department structures and hierarchies discussed in Topic 1: Patient Access to Chemotherapy Services.

As discussed earlier, the under-resourcing of cancer wards at many hospitals leading to cancer services pharmacists having patient loads that are in excess of SHPA's standard, also contributes to pharmacist's negative job satisfaction, stress and burnout, and is a risk factor for retention of this skilled workforce.

Thus, SHPA recommends that there are specific workforce recruitment and retention strategies, as well as provision of training for clinical and compounding pharmacists that provide chemotherapy medicines and cancer services, to support safe and quality care for high-risk cancer patients.

To support this specifically, SHPA launched its Cancer Services Advanced Training Residency Program in 2021. The Cancer Services Advanced Training Residency program offers an accredited two-year experiential learning pathway for specialty practice development in cancer services. As per the Cancer Services Advanced Training Residency Practice Area Framework and Knowledge Guide[11], Advanced Training Residents are supported by a Program Residency Leader as well as their Advanced Training mentor and a second external mentor. In this two-year program, Cancer Services Advanced Training Residents must undertake a minimum of 18-months' of direct patient care of adult cancer patients (includes malignant haematology and solid tumour oncology) with:

- a minimum of 6 months in direct patient care of adult solid tumour oncology patients
- a minimum of 6 months in direct patient care of adult malignant haematology patients
- work undertaken in inpatient and outpatient clinical settings

As the Cancer Services Advanced Training Residency Program has just launched in 2021 amidst the COVID19 pandemic, there are two public hospitals participating in the program, however with dedicated resourcing, there is scope and capacity to implement and provide this program to more hospitals in all states and territories. This Residency is not currently supported by State or Federal funding.

There are no specific compounding courses for pharmacists and pharmacy technicians that have are available on a national scale, there are just a small handful of consultancies or hospitals that can provide training packages locally at request. In the main, hospitals have to individually manage their own training and skills development for compounding pharmacists and pharmacy technicians.

1. **Describe what regulatory and quality challenges you have faced when delivering chemotherapy services. What, if anything, could be changed to improve chemotherapy services?**

SHPA members report considerable regulatory challenges associated with the fragmented healthcare system that administers, funds and manages hospital care and community care differently. Fragmented funding streams and systems do not put the patient at the centre of care and contribute to inequitable access to cancer therapies.

Recommendation 9: Allow hospital inpatients to be eligible for subsidy for Section 100 EFC medicines where a hospital admission is unavoidable due to deteriorating patient condition and/or acute condition.

The Pharmaceutical Reform Agreements and PBS rules dictate that PBS medicines can be provided to patients who are in the community or outpatient setting. For patients receiving Section 100 EFC medicines, this is manageable as cancer patients typically receive chemotherapy at day treatment centres, and are not overnight admitted patients, thus the medicine is eligible for claiming from Services Australia.

This supports however, ceases when cancer patients become too unwell and need to be admitted to hospital as an inpatient, and their inpatient admission coincides with their chemotherapy treatment day. Given the critical nature of delivering timely chemotherapy medicines according to prescribed chemotherapy protocols, hospitals are forced to choose between administering these high-cost medicines to hospitalised patients and forgo the eligibility to claim for these medicines from Services Australia, or wait until the patient has been discharged and provide delayed chemotherapy treatment. These medicines can cost into the thousands of dollars per dose, and despite them being non-PBS as it is inpatient use, these costs are not passed on to the patient in public hospitals. Rather, hospitals absorb these costs from their already constrained budgets.

It follows larger urban hospitals with larger budgets are more able to absorb these costs, but this is not possible for smaller and/or regional, rural and remote hospitals. People being treated for cancer are often in

and out of hospital and these arbitrary rules can compromise their continuity and quality of care. Thus, to avoid unnecessary delays to treatment caused by these rules, SHPA recommends that hospital inpatients should be eligible for subsidy for Section 100 EFC medicines where a hospital admission is unavoidable due to deteriorating patient condition and/or acute condition.

An additional regulatory challenge reported by SHPA members is the unnecessary complexity and administrative burden created by the exclusion of certain infusible cancer therapies from the Section 100 EFC schedule. An example of this is azacitidine which is an Authority Required medicine and listed in the Section 100 Highly Specialised Drugs program.

Another regulatory challenge faced by hospital pharmacy compounding services are the significant and costly changes required to their compounding facilities based on changes to standards for manufacturing which are enforced by governing pharmacy bodies. These additional costs are challenging for larger urban hospitals to fund but are near on impossible for smaller regional, rural and remote hospitals and health services. A rural hospital in Victoria reported that upgrades to their sterile compounding suite to meet current standards for manufacturing, would cost approximately $75,000, but they could only make changes worth $5,000 to date. The ever-changing standards of manufacturing, whilst important in providing patients with a high-quality service, can also act as a barrier to service provision and access to cancer therapies, particularly to those in rural and remote areas.

2. **How have the unique characteristics of chemotherapy services (including but not limited to unique requirements, arrangements and expertise in the compounding/handling of these medicines) challenged you over the past years?**

SHPA members report that growing regulatory requirements along with increasing fiscal constraints have made it extremely challenging to maintain an appropriate, up-to-standard cytotoxic compounding facility. Access to in-house cytotoxic compounding services are essential to support access to cancer therapies with short expiries in rural and remote areas and to accommodate last minute changes to therapies in all settings. As per our first two recommendations, we support changes to the funding models and remuneration structures to recognise the true costs of delivering chemotherapy and the challenges when there are poor economies of scale in smaller, non-urban hospitals.

Additional challenges with supply of consumables, closed system transfer devices and PPE experienced by members have been compounded by the recent COVID-19 pandemic.

3. **What strategies have been used to overcome these challenges? Describe any implementation challenges you faced.**

A significant number of Australian hospitals, including larger urban hospitals, have outsourced the manufacturing of their cancer therapies to a third party TGA-licenced compounder. Whilst this can minimise compounding costs and remove the need for unfunded capital investments to bring existing facilities in line with standards, there is a trade-off with timeliness and responsiveness, that can ultimately impact on the quality of care. Third party manufactures require orders to be made at least two days, sometimes up to a week, in advance depending on location and therefore are less responsive and cannot frequently accommodate last minute changes to therapy when clinically required. To contrast, in-house compounding services only need as little as a few hours' notice to receive a chemotherapy order and compound it.

4. **How have you aimed to minimise wastage and improve cost-effectiveness of infusible chemotherapy medicines over recent years. Which strategies have been practical and why? Are there other strategies you could use, but have not been able to implement? If not, why?**

The entire healthcare sector, including hospitals and hospital pharmacies, have a strong aversion to unnecessary wastage of any resource and have strategies to minimise wastage of any procured resource to maximise cost-efficiency. Waste mitigation strategies utilised by hospitals focus on maximising cost-efficiency, not cost-effectiveness.

This is particularly relevant for high-cost chemotherapy medicines, whether they are eligible for subsidy under Section 100 EFC or not. Infusible chemotherapy medicines require compounding to specific calculated doses that depend on the patient's height, weight, body surface area, renal and hepatic function, and other factors, and thus on any given day, a hospital may need to compound varying doses of the same medicine for the patients that are receiving chemotherapy that day. As they are able to calculate how many milligrams or grams in total of a certain chemotherapy medicine they require for compounding for the patient load that day, it follows they can maximise the cost-efficiency of their compounding operations as well as minimising unnecessary wastage of an expensive medicine.

SHPA is aware of the potential unintended consequences their efforts to minimise wastage and improve cost -efficiency can have on other parts of the medicines supply chain, and understands this very review was borne from attempted changes to remuneration arrangements for medicines with special pricing arrangements. Prior to this review, there was also a wide-ranging review into Section 100 EFC in 2013 which resulted in fundamental and wholesale changes to Section 100 EFC renumeration. SHPA did not oppose those changes then in 2013, and in the last few years when discussing potential changes to renumeration arrangements for medicines with special pricing arrangements with the Department of Health and other stakeholders, SHPA was open and receptive to work with each model presented and discussed.

Recommendation 10: Any potential changes to the renumeration model for Section 100 EFC medicines should not result in a net-negative funding scenario compared to existing renumeration models as to not threaten the safety and quality of chemotherapy care.

Our main priorities have remained consistent and unwavering, in that hospital pharmacists are supported to provide best-practice clinical pharmacy services for oncology and haematology patients to ensure safe and quality care. The renumeration for Section 100 EFC medicines only contains the approved ex-manufacturer price for public hospitals. Thus, the entire scope of chemotherapy services, when factoring in the provision of the necessary clinical pharmacy services, is delivered at an operational loss to pharmacy departments as discussed in Topic 1: Patient Access to Chemotherapy Services, and this threatens safety and quality of care as well as the viability of these services across Australia.

Given literature reviews indicate error rates in chemotherapy medication orders range between 1-4%[10], any changes to renumeration models that provide less funding to hospital pharmacy departments for the supply of Section 100 EFC medicines will likely have a direct negative impact on the safety and quality of clinical chemotherapy services, exacerbated in smaller hospitals in regional, rural and remote areas. As discussed in our response to Topic 2: Chemotherapy Services as 'Speciality Services', the majority of hospitals are already not meeting pharmacist-to-patient ratios as outlined in SHPA's *Standard of practice in oncology and haematology for pharmacy services*[9], and pharmacists have patient loads that prevent them from providing the full suite of chemotherapy clinical pharmacy services. It follows that any changes to renumeration models that place hospitals at further disadvantage, would mean even less safe and less comprehensive clinical services are provided to this high-risk patient cohort, and increase the risk of chemotherapy treatment errors.

Any such negative changes would only further entrench the inequities in funding for public hospital pharmacies supply PBS medicines as outlined in Table 1.

Recommendation 11: Explore the appropriateness and feasibility for using dose banding and dose rounding strategies for chemotherapy medicines to minimise wastage.

Some larger urban hospitals in Australia have aimed to minimise wastage via adopting the United Kingdom's model of dose banding. Dose banding is when chemotherapy doses are fitted into predefined dosage ranges, as opposed to a fixed dosage. Batch preparation of standardised dosage ranges can reduce drug wastage drastically. One major United Kingdom cancer centre that implemented dose banding reduced drug wastage

to zero.[12] This method is particularly successful in the United Kingdom as it has been adopted as a nationwide initiative. A similar approach across Australian chemotherapy services should be explored.

SHPA members inform us of another initiative to reduce wastage known as dose rounding. Dose rounding is prevalent in the United States of America and is the process of rounding of medication doses to the nearest vial size when the difference is less than an established percentage. This initiative is a relatively simple cost -saving measure that minimises wastage and according to cost analyses, the estimated savings range from tens of thousands to millions of dollars, depending on the medication and the number of doses dispensed per patient per year.[13-20]

SHPA members have reported that both the initiatives mentioned above, dose banding and dose rounding, are often met with resistance from medical and nursing staff concerned about the accuracy and efficacy of the dose being provided, despite assurances provided by the literature. These strategies are broadly used internationally and should be further explored in Australia.

5. **In terms of improved access to these medicines for patients, what implementation challenges have hindered the use of innovative technologies, such as chemotherapy compounding automation solutions, in the EFC supply chain? How could these be resolved?**

Whilst chemotherapy compounding automation solutions can increase the efficiency of the manufacturing process, they have limited applicability for many hospital pharmacy departments with cytotoxic compounding suites. Chemotherapy compounding automated solutions or robots are expensive, easily costing into the tens and hundreds of thousands of dollars. Apart from the exorbitant costs associated with purchasing and installing and the requirement for structural changes to existing building facilities, these robots come with their own reliability, scale and scope of practices issues.

They do not have any impact on the necessary staffing levels since trained and experienced pharmacists are still required to instruct the robot as it is not integrated with hospital electronic systems, this of course introduces the risk of error. They also require their own consumables, adding to the ongoing costs of maintaining them. Chemotherapy compounding robots are more suited to larger scale operations such as TGA-licensed compounding services with better scalability of operations as opposed to hospital pharmacy departments.

Other innovations SHPA members believe are more suited to hospital pharmacy departments include, automated inventories, oncology electronic prescribing software with embedded protocols and closed system drug transfer devices for manufacturing. Automated inventories would support better stock management and therefore minimise wastage and improve costings. Oncology electronic prescribing software with integrated protocols would reduce errors and improve safe and quality use of medications. Closed system drug transfer devices protect staff from hazardous medications whilst also protecting the products being compounded from microbial contaminations, hence extending their expiries and reducing wastage.

Lack of capital investment funds is the most significant barrier to the adoption of these automations in the hospital pharmacy setting, and the cost of these innovative technologies only add to the already significant overheads for providing chemotherapy services. SHPA reiterates its first two recommendations regarding remuneration and funding models genuinely accounting for the true cost of chemotherapy services, and this includes the implementation of these innovative technologies and solutions that can support safe and quality use of medications in cancer therapy.

Topic 3: Terminology and Definition of Medicine Types

1. **Is "Efficient Funding of Chemotherapy" the most appropriate name for this program? If not, what alternative name would you suggest for a program that covers injectable/infusible anti-cancer medications?**

No. Whilst SHPA members do support efficiency in delivery of health services, of greater importance is the safety and quality of chemotherapy services and chemotherapy medicines delivered to patients, and an appropriate name for this program should reflect this.

As noted in the discussion paper, members also agree despite Section 100 EFC having the term 'chemotherapy' in its name, it does not encompass all other chemotherapy medicines, particularly oral chemotherapy medicines, that are otherwise listed in the general Section 85 PBS schedule. It is unclear whether these need to continue to be separated, however SHPA members would prefer more simplicity in the system that also prioritises safety and quality.

Topic 4: Referencing Standards, Guidelines and Policies

All patients share a right to fundamental safe and high-quality cancer care. Standards, guidelines, and policies are essential to the delivery of consistent and evidence-based cancer services that prioritise safety and quality for the patient. Oncology and haematology pharmacy services ensure the provision of safe and effective cancer and supportive therapies, based on current evidence-based practice, and to limit unintended consequences for patients, such as toxicities and adverse drug reactions. These services should be delivered against relevant SHPA standards of practice to ensure quality provision of cancer services and therapies. National standards for cancer services along with greater quality assurance requirements are also essential in providing Australians with safe and high-quality cancer care.

1. **What guidelines and standards apply to the preparation, supply, and administration of chemotherapy services across States and Territories? How are these standards regulated?**

The following guidelines and standards apply to the preparation, supply and administration of chemotherapy services across Australia:

- SHPA's Standard of Practice in Oncology and Haematology for Pharmacy Services[9]
- SHPA's Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments[21]
- Clinical Oncology Society of Australia (COSA) Guidelines for the Safe Prescribing, Dispensing and Administration of Systemic Cancer Therapy[22]
- National Safety and Quality Health Service (NSQHS) Standards Version 2; Medication Safety Standard [23]
- NSQHS Standards Version 2; User Guide for Medication Management in Cancer Care[24]
- Pharmacy Board of Australia (PBA) Guidelines on Compounding of Medicines[25]
- Guiding principles to achieve continuity in medication management[26]

Standards are not currently well regulated in the cancer services space, there is no external validation or assessment and no formal accreditation process.

2. **Is further development of current standards required? If so, in which area is work needed?**

Yes. SHPA members believe there is a need for national standards for cancer service delivery to be developed and established in Australia, and for uniform standards and processes at the State level. These standards would support a consistent approach to the delivery of cancer services across various settings. Ideally national standards for cancer services would address elements pertaining to the setting up of a cancer clinic, staff training required in various roles, etc.

3. **Is other work, such as the development of quality assurance programs, required?**

Yes. SHPA members believe that quality assurance programs and their requirements are essential in maintaining high-quality, comprehensive, safe and quality cancer services. These quality assurance programs should be built into the existing quality assurance frameworks accrediting and assessing hospitals and health services against current NSQHS standards. When assessing the appropriateness, safety and quality of chemotherapy pharmacy services, these should be assessed against SHPA's Standard of Practice in Oncology and Haematology for Pharmacy Services[9].

Recommendation 12: Quality assurance programs should be embedded into existing frameworks accrediting and assessing hospitals and services against NSQHS Standards, and they should specifically assess the quality of chemotherapy pharmacy services against SHPA's Standard of Practice in Oncology and Haematology for Pharmacy Services.

4. **Should meeting any of these standards be a mandatory requirement for Commonwealth funding under the EFC program? If so, which? How would this be managed or enforced?**

Yes. The following standards should be a mandatory requirement for Commonwealth funding under the Section 100 EFC program to ensure cancer patients are receiving safe and quality chemotherapy cancer care.

- SHPA's Standard of Practice in Oncology and Haematology for Pharmacy Services[9]
- Clinical Oncology Society of Australia (COSA) Guidelines for the Safe Prescribing, Dispensing and Administration of Systemic Cancer Therapy[22]
- National Safety and Quality Health Service (NSQHS) Standards Version 2; Medication Safety Standard [23]
- NSQHS Standards Version 2; User Guide for Medication Management in Cancer Care[24]

This could be managed or enforced by current accreditation frameworks and processes for hospitals and healthcare services. Dedicated government agencies for cancer services could also be established to manage or enforce these standards, similar to existing frameworks for aged care.

Topic 5: Funding of EFC across the Supply Chain

The discussion paper discusses in this section, the possibility of alternate funding models to support different modes of chemotherapy medicine treatment delivery may improve patient access, as well as an appetite for gaining a better understanding and transparency of product flow and funding including through systems and data flows used by Government and supply chain participants. As such, we reiterate Recommendations 1, 2 and 10 in response to this section.

Recommendation 1: Funding models should recognise the overheads, ongoing costs uniquely associated with the provision of Section 100 EFC medicines separate to other PBS medicines to support sustainability and access to chemotherapy, particularly in smaller hospitals in regional and rural settings.

Recommendation 1a: For smaller hospitals, particularly in regional, rural and remote settings. Funding models should recognise that these overheads and ongoing costs, are much more pronounced and less affordable, negatively impacting the viability of cancer services.

Recommendation 2: Funding models and/or remuneration fee structures for provision of Section 100 EFC medicines should be tiered to recognise the varying economies of scale and marginal costs of chemotherapy services provided in hospitals of different sizes and capacities, to facilitate improved patient access in regional and rural settings.

Recommendation 10: Any potential changes to the renumeration model for Section 100 EFC medicines should not result in a net-negative funding scenario compared to existing renumeration models as to not threaten the safety and quality of chemotherapy care.

SHPA understands this review was borne from attempted changes to remuneration arrangements for medicines with special pricing arrangements. In the last few years when discussing potential changes to renumeration arrangements for medicines with special pricing arrangements with the Department of Health and other stakeholders, SHPA was open and receptive to work with each model presented and discussed.

Our main priorities have remained consistent and unwavering, in that hospital pharmacists are supported to provide best-practice clinical pharmacy services for oncology and haematology patients to ensure safe and quality care. The renumeration for Section 100 EFC medicines only contains the approved ex-manufacturer price for public hospitals. Thus, the entire scope of chemotherapy services, when factoring in the provision of the necessary clinical pharmacy services, is delivered at an operational loss to pharmacy departments as discussed in Topic 1: Patient Access to Chemotherapy Services, and this threatens safety and quality of care as well as the viability of these services. Given literature reviews indicate error rates in chemotherapy medication orders range between 1-4%[10], any changes to renumeration models that provide less funding to hospital pharmacy departments for the supply of Section 100 EFC medicines will likely have a direct negative impact on the safety and quality of chemotherapy services.

As discussed in our response to Topic 2: Chemotherapy Services as ‘Speciality Services’, the majority of hospitals are already not meeting pharmacist-to-patient ratios as outlined in SHPA’s *Standard of practice in oncology and haematology for pharmacy services*[9], and pharmacists have patient loads that prevent them from providing the full suite of chemotherapy clinical pharmacy services. It follows that any changes to renumeration models that place hospitals at further disadvantage, would mean even less safe and less comprehensive clinical services are provided to this high-risk patient cohort, and increase the risk of chemotherapy treatment errors.

Any such negative changes would only further entrench the inequities in funding for public hospital pharmacies supply PBS medicines as outlined in Table 1.

1. **What are the main challenges in having medicines listed in the EFC program compared to non-EFC drugs/other PBS listed drugs?**

SHPA members report that some medications not currently included in the Section 100 EFC program such as azacitidine, require the same level of clinical pharmacy and compounding expertise to supply as other medications included in the Section 100 EFC program. These medications at times may have an added cost to patients depending on their indication and condition, which requires detailed explanation and justification to help patients understand why this medication, although not subsidised through the Section 100 EFC program, is best for their cancer therapy. To the consumer, these parameters appear to be arbitrary as their focus is being able to access the medicines they require in a timely and affordable manner.

The exclusion of subcutaneous chemotherapy such as azacitidine and trastuzumab from the Section 100 EFC program, may factor into prescribing decisions based on cost-efficient therapies such as intravenous chemotherapy which may be more of an inconvenience to the patient, rather than the most suitable or convenient treatments for patients.

There are also an increasing number of immunotherapy agents administered in hospitals that required the same handling and management as chemotherapy medications with similar risk and toxicity profiles, such as infliximab, natalizumab and alemtuzumab, yet there is no funding for the preparation of these agents as they are not listed in the Section 100 EFC program.

SHPA members also reported that some chemotherapy items require compounding in two separate preparations, for instance, requiring more than one infusion bag or syringe, due to stability or dosing issues. These items however, are only eligible for a single compounding payment despite requiring additional compounding services, leaving pharmacy departments to bear the costs of preparing the second infusion bag or syringe.

SHPA members report other administrative challenges faced in the provision of cancer therapies through the current Section 100 EFC program including a significant administrative burden in identifying compounder codes, Authority Required (Streamlined) codes and Authority Required approval numbers. Errors in selection of these codes result in rejection of payment, exposing the pharmacy department to bearing the financial risk and loss. SHPA members believe the prescribing of medications through the Section 100 EFC program should move to Authority Required (Streamlined) codes where possible, to reduce financial risk and administrative burden.

Another administrative challenge is associated with the dispensing of cancer medication prescriptions. Paper-based prescriptions present a burden brought about by the need to manage repeats and co-payments is still an ongoing challenge for hospital pharmacy departments. SHPA members also noted that in an environment where dose changes are a frequent occurrence, the requirement for a new prescription for dose changes that are more or less than 10% of that prescribed, is another added administrative burden requiring pharmacists to procure a new prescription. This is notoriously difficult as the prescribers are not always present and accessible, and these issues are further exacerbated in smaller hospitals where the prescribing doctors may be visiting medical officers. SHPA members believe that there should not be a need for a new prescription in the case of dose reductions, in line with the general PBS policy where pharmacists have the ability to supply less than what is prescribed if that is appropriate for the patient's needs and welfare.

2. **What are the key barriers for wholesalers in ensuring equitable access to EFC medicines for all Australians?**

Whilst this is a question best addressed by wholesalers, SHPA members report that wholesalers do not readily stock low-usage, high-cost medications since they are at a risk of expiring before being sold and

hence are a financial risk to wholesalers. This however, results in treatment delays and does not provide Australians with timely and equitable access to all cancer therapies on the Section 100 EFC program.

3. **Are there significant differences in the costs or processes for providing chemotherapy services in rural and remote areas compared to urban areas? If yes, what are they?**

Yes. Refer to responses in Topic 1: Patient Access to Chemotherapy Services.

The costs and processes associated with the provision of cancer therapy services in rural and remote areas is significantly different compared to those delivered in urban areas. Rural and remote cancer services incur substantial costs due to their geographical distance from TGA licensed compounders. These costs include added transport and courier costs, costs of compounded stock that expired due to delays in transportation, increased wastage due to the low volume of patients, and managing environmental challenges such as humidity issues in rural and remote compounding facilities in places such as Northern Australia. Increased lead times are also required for orders of cancer therapy from TGA licensed compounders, this means there is reduced responsiveness to changes made to a patient's cancer therapy.

In addition to the costs listed, rural and remote facilities providing cancer therapies must compound low stability or short-expiry medications in-house. This adds costs associated with commissioning compounding facilities, maintaining and staffing these facilities with a suitably trained pharmacy workforce for a limited number of patients.

Another cost differential is related to funding through the Section 100 EFC program being linked to the dispensing location with no recognition of the clinical pharmacy services involved in supplying the medication if this is to occur in a separate setting. This is most relevant to smaller hospitals in regional, rural and remote areas who outsource the dispensing, compounding and claiming of a medicine to a larger hospital with compounding capacity. However, in this example, there is no funding provided to the smaller hospital site who is actually delivering chair-side chemotherapy pharmacy services.

4. **How do arrangements vary between the public and private sectors, States and Territories and what is the effect on accessibility of services? Please provide any details to support your position.**

Refer to responses in Topic 1: Patient Access to Chemotherapy Services.

5. **Do consumers or providers have additional costs or other factors that limit access to services in rural and remote areas (excluding ancillary costs such as travel and accommodation, and oral chemotherapy medicines)? Please provide any details to indicate the difference in costs or other factors for consumers.**

There are certainly several factors that limit access to cancer services in rural and remote areas, these include limited workforce expertise due to the challenges in attracting specialised prescribers and pharmacists to these settings. A limited expert workforce and skillset of local staff directly impacts the number of services able to be provided in rural and remote settings, their hours of operation and the complexity of regimens being offered. Certain regimens cannot be offered due to the limited stability of the prescribed medications once compounded not able to withstand transportation from urban TGA licensed compounders. Another point of difference in rural and remote settings is limited access to patient follow-up between cycles of chemotherapy to ensure patients are well post chemotherapy administration due to the limited workforce access in these settings, which can decrease the quality of care.

6. **Do you hold, or are you aware of, any datasets, analyses, databases, or registries that might inform recommendations of the review? If yes, please provide the details for the relevant person/s to contact regarding access to those data if possible.**

No.

Topic 6: PBS Access and Claims Processing of EFC Medicines

1. **What concerns are there in relation to the current administrative processes surrounding the provision and claiming of EFC medicines?**

Whilst claiming through the Section 100 EFC program is relatively straightforward in a system that utilises paperless prescribing which is afforded to Section 100 EFC, there is a high administrative burden where hardcopy prescriptions or medication charts are required. For example, the supportive non-chemotherapy medicines used for pain, nausea and vomiting, cannot be prescribed paperless and require a separate paper-based prescription. This essentially increases the workload for all pharmacists and prescribers involved by operating two systems concurrently, and thus also introduces risk for error. In smaller hospitals with limited workforce resources, there is limited capacity to handle this breadth of administrative burden whilst attempting to maintain a comprehensive clinical pharmacy service.

Recommendation 13: To better support equitable patient access to cancer therapies, the maximum claimable doses for Section 100 EFC medicines should correspond with the evidence and established chemotherapy protocols to accommodate patients with larger body mass index.

Another concern raised by SHPA members is regarding the claiming of certain PBS agents with maximum claimable doses such as rituximab. The upper limits of these claimable doses that do not always align with evidence-based chemotherapy protocols and the patient's required dosage based on their body mass index. Claiming for these medications at the necessary doses require burdensome administrative workarounds such as obtaining written Authority Required prescriptions, or otherwise high-cost Section 100 EFC medicines are provided without remuneration.

2. **What could be addressed in relation to these matters?**

Recommendation 14: The implementation of electronic prescriptions and electronic chemotherapy medication charts (eCMCs) should be undertaken in collaboration with hospital pharmacy stakeholders to ensure safety and quality of chemotherapy services whilst also reducing the administrative burden associated with paper-based prescriptions.

SHPA supports minimising the diversity of different prescriptions and charts used concurrently for a single patient care episode, as this contributes to the administrative burden caused by operating multiple systems simultaneously, as well as increasing the risk of error. As the healthcare system is increasingly digital, SHPA commends the Australian Commission on Safety and Quality in Health Care on the impending development of a national eCMC to improve safety, quality and efficiency in the provision of cancer therapies to Australians. SHPA however, strongly recommends that this development and the implementation and design process is done in consultation with hospital pharmacy stakeholders to ensure it is fit-for-purpose and enhances safety and quality.

3. **Are there other matters not mentioned in this paper that could be considered in developing a sustainable, transparent and equitable model for access to chemotherapy medicines?**

No. Please refer to response in Topic 1: Patient Access to Chemotherapy Services.

4. **Are there other consumer issues that could be considered in developing a sustainable, transparent and equitable model for access to chemotherapy medicines?**

No.

5. **What are the key administrative challenges in relation to prescribing and claiming EFC medicines? For example, via the Private vs Public settings?**

Please refer to responses in Topic 1: Patient Access to Chemotherapy Services.

Current arrangements do not allow for compensation or support for unintentional errors or spillages of medicines during the compounding process which contributes to wastage. This cost is bore by the pharmacy department alone, and as discussed above, it is the smaller hospitals in regional, rural and remote areas who have the least capacity to wear this cost and are most exposed to financial risk.

6. **Are the current remuneration arrangements appropriate? Should they be amended, and how? What strategies could be implemented to create greater equity in remuneration across the EFC supply chain?**

As per our response and recommendations in Topic 1: Patient Access to Chemotherapy Services, SHPA believes remuneration arrangements and funding models should recognise the overheads, ongoing costs uniquely associated with the provision of Section 100 EFC medicines separate to other PBS, and that these arrangements should be tiered to recognise the varying economies of scale and marginal costs of chemotherapy services provided in hospitals of different sizes and capacities.

This could come in the form of targeted service fees for regional, rural and remote specialised chemotherapy services to improve viability and access of these services. These types of targeted remuneration arrangements are not new to Australia's healthcare system, as evidenced by the nine Rural Support Programs funded under the Seventh Community Pharmacy Agreement to support access to PBS medicines and pharmacy services for people living in rural and remote regions of Australia[6], and pricing adjustments based on remoteness in activity-based funding for public hospital services[7].

Additionally, as discussed in Topic 2: Chemotherapy Services as 'Speciality Services', SHPA believes hospital inpatients should be eligible for subsidy for Section 100 EFC medicines where a hospital admission is unavoidable due to deteriorating patient condition and/or acute condition. The Pharmaceutical Reform Agreements and PBS rules dictate that PBS medicines can be provided to patients who are in the community or outpatient setting. This supports however, ceases when cancer patients become too unwell and need to be admitted to hospital as an inpatient, and their inpatient admission coincides with their chemotherapy treatment day. Given the critical nature of delivering timely chemotherapy medicines according to prescribed chemotherapy protocols, hospitals are forced to choose between administering these high-cost medicines to hospitalised patients and forgo the eligibility to claim for these medicines from Services Australia, or wait until the patient has been discharged and provide delayed chemotherapy treatment. These medicines can cost into the thousands of dollars per dose, and despite them being non-PBS as it is inpatient use, these costs are not passed on to the patient in public hospitals. Rather, hospitals absorb these costs from their already constrained budgets.

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SHPA's Response to the Review of the National Medicines Policy (NMP) Discussion Paper 2021

Introduction

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for more than 5,200 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system, advocating for their pivotal role in improving the safety and quality of medicines use. SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care. SHPA is committed to facilitating safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the review into the NMP as the medicines landscape has significantly changed in the last twenty years. In recent years, a majority of PBS expenditure and listings are for biologicals, high-cost and complex medicines used to treat cancers and autoimmune diseases, which are often initiated and supplied in hospital settings. This contrasts with when the NMP was introduced, where listings were dominated by medicines for lifestyle-related non-communicable diseases.

About hospital pharmacy

Hospital pharmacists account for just over 20% of the entire pharmacy workforce and are the fastest growing sector of the pharmacy workforce. It is in hospital where hospital pharmacists treat patients at their most unwell, often having a significant health event such as strokes, heart attacks and organ transplants. Patients are usually prescribed multiple new medicines in hospitals during their admission, many of which are taken for many months or years after discharge, relying on regular care by their community-based practitioners.

At the inception of the NMP twenty years ago, hospital pharmacy and the PBS were mutually exclusive, and hospital prescribers and pharmacists could not prescribe or dispense medicines to patients with PBS subsidy. In most recent 2019-20 data, hospital pharmacy accounted for 23% of all Pharmaceutical Benefit Scheme (PBS) expenditure, which included a majority of Section 100 Efficient Funding of Chemotherapy (EFC) and Highly Specialised Drugs Program (HSDP) expenditure. This is the result of Pharmaceutical Reform Agreements (PRAs) entered into by all Australian jurisdictions with the exception of New South Wales and Australian Capital Territory with the Commonwealth.

The PRAs enabled hospital prescribers and pharmacists to prescribe and dispense PBS subsidised medicines to hospital patients upon discharge from hospital, outpatients and patients receiving care from day-treatment services. They supported the transitions of care for patients discharging from hospital back into the community and allowed for patients to be supplied the standard PBS quantity of one-months' supply of discharge medicines. Previously, hospital patients received as little as three days' worth of discharge medicines, which placed pressure on them to see their primary healthcare provider very soon after discharge to continue receiving key medicines.

The inclusion of the hospital pharmacy sector in the PBS has enabled it to further support the key objectives of the NMP, specifically with respect to timely access and quality use of medicines. In this submission, SHPA makes a range of recommendations to further support access equity and quality use of medicines for all Australians. If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

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SHPA Recommendations to the Review of the NMP

Recommendation 1: **In order for the NMP to be reflective of a national strategy, New South Wales and the Australian Capital Territory should become signatories of the Pharmaceutical Reform Agreements to achieve the proposed principle of equity and access to medicines.**

Recommendation 2: **The NMP should recognise the necessity of the 'continuity of care' as a fifth objective focusing on the exchange of health information across the transitions of care to facilitate safe and effective medicine use and access.**

Recommendation 3: **The NMP's definition of medicines should be expanded to include vaccines and medical devices which are used to deliver or administer medicines, and future-proofed to include emerging therapies and technologies.**

Recommendation 4: **The NMP should acknowledge digital health technologies as important elements of the healthcare sector which impacts medication safety and quality use of medicines and strive for a connected, interoperable digital health ecosystem.**

Recommendation 5: **The principles and objectives of the NMP relating to access and equity should include patient access to novel and high-cost unsubsidised medicines used in hospitals to treat complex and rare diseases.**

Recommendation 6: **Consumer centricity and engagement should be strengthened in the NMP through greater diversity and inclusion, understanding of their expectations of healthcare delivery and health literacy levels.**

Recommendation 7: **Existing forums between state and federal governments, such as the COAG Health Council and HCEF should be formally recognised as stakeholders in future governance arrangements for the NMP.**

Recommendation 8: **To inform policies and investments to achieve the objectives of the NMP, consistent and high-quality data on medicines use, medicines-related outcomes and pharmacy services should be collected systematically.**

Terms of Reference 1: Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.

A. Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?

SHPA supports the proposed principles of equity, consumer centred approach, partnership based, accountability and transparency, and stewardship for inclusion in the refreshed NMP.

To meet the principle of equity for consumers, SHPA believes that the Commonwealth should make the PRAs a uniform policy in Australia and enter into PRAs with New South Wales and Australian Capital Territory. This would ensure a consistent standard of care for vulnerable patients who have just had a major health event requiring hospitalisation and reduces the need for individuals to immediately seek an appointment with their general practitioner on discharge from hospital to continue receiving vital medicines. Patients being discharged from public hospitals in NSW and ACT are currently supplied 3-7 days' worth of discharge medicines, which contrasts with the other jurisdictions who are able to supply a months' worth of discharge medicines. The expansion of PBS into public hospitals has allowed more hospital pharmacists to be employed and provide clinical pharmacy activities to patients, as well as allow investment into specialised pharmacy services, such as pharmacists specialising in oncology, paediatrics, emergency medicine and geriatric medicine. These services are necessary to safeguard and maximise the federal government's investment into new PBS medicines that treat complex conditions.

Recommendation 1: In order for the NMP to be reflective of a national strategy, New South Wales and the Australian Capital Territory should become signatories of the Pharmaceutical Reform Agreements to achieve the proposed principle of equity and access to medicines.

The principle of equity should also not just be limited to effective, safe, high-quality, and affordable medicines, but also expanded to be complemented by clinical pharmacy services delivered which are necessary to support the quality use of medicines and patient safety. Medicines have the capacity to cause harm either through side effects, drug interactions or inappropriate dosing. Literature suggests that there are 250,000 hospital admissions resulting from medication-related problems each year, costing the healthcare system $1.4 billion annually.[1] However, several inequities exist with respect to funding that prevents patients from receiving the comprehensive suite of clinical pharmacy services in SHPA's Standards of Practice for Clinical Pharmacy Services[2], which include:

- taking a medication history and ensuring medications are charted correctly and available at admission to be administered in a timely manner
- regular review of the safety, quality, storage and supply of medications during hospital stay
- review of discharge prescriptions, dispensing a sufficient supply of medications to take home, counselling patients on their medications and communicating changes to primary healthcare providers
- ensuring appropriate follow-up and monitoring of medications post-discharge including in specialised clinics and outpatient services and checking for adverse reactions to medications

The inequities in remuneration for the supply of PBS medicines to hospital pharmacists as per Table 1, have downstream impacts on hospital pharmacy departments capacity to deliver comprehensive clinical pharmacy services to patients. The lack of dispensing fees, wholesale mark ups and administrative handling and infrastructure (AHI) fees means fewer hospital pharmacists are employed to deliver key services to patients that are vital to medication safety and quality use of medicines.

SHPA supports recognition of and funding for clinical pharmacy services in all settings of care and should be devolved from the cost of the medicine. Consumers expect to receive the same quality of care regardless of the healthcare setting, however different funding and service levels across different care settings prevent this.

	Public hospitals	Private hospitals	Community pharmacy
Section 85 medicines	Ex-manufacturer price + 7.52% wholesale mark-up	Ex-manufacturer price + 7.52% wholesale mark-up + 1.4% pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 7.52% whole-sale markup + AHI fee + Dispensing Fee
Section 100 medicines	Ex-manufacturer price	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee

Table 1. Public and private hospital pharmacy renumeration fee structure for Section 85 and Section 100 medicines
Adapted from Review of Pharmacy Remuneration and Regulation Discussion Paper and updated with 2019 Federal Budget reduction to hospital pharmacy wholesale mark-up[3]

Another inequity is the exclusion of public hospitals from participating in the Closing the Gap (CTG) PBS Co-payment Measure (the Measure). Whilst the Measure provides co-payment relief for concessional patients in the community, indigenous patients discharging from hospital are not eligible for co-payment relief and are often discharged without any medicines. SHPA members have observed that the need to pay a co-payment per PBS medicine, where treatment regimens sometimes exceed ten medications for complex needs patients, is a significant financial hurdle to many Aboriginal patients. The lack of discharge medicines greatly increases their risk of readmission.

Without access to the Measure, individual hospital policies (which require a co-payment as specified by PBS procedures) often prevent Indigenous patients from receiving their medicines at discharge to avoid incurring operational cost. If patients are unable or unwilling to pay the co-payment, they must attend a community pharmacy to receive discharge medicines. Research shows that these patients have lower medicines adherence compared to other population groups[4], and that over a quarter of patients fail to make it to a local pharmacy until days later to have their discharge prescription dispensed.[5]

B. Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?

SHPA believes the four objectives of the NMP remain highly relevant, and that the NMP should consider a fifth objective of 'continuity of care' to reflect the importance of maintaining and protecting safe and quality use of medicines at transitions of care. The World Health Organisation's (WHO) third Global Patient Safety Challenge: Medication Without Harm also identified that in order for preventable medicine-related harm to be reduced, focus should be given to polypharmacy, high-risk medicines and high-risk situations which specifically includes transitions of care.

Recommendation 2: The NMP should recognise the necessity of the 'continuity of care' as a fifth objective focusing on the exchange of health information across the transitions of care to facilitate safe and effective medicine use and access.

Medicine use throughout transitions of care is complex. There is often involvement of multiple clinicians at any given time as patients transition between community and healthcare services. Half of all medication errors in hospital occur upon admission, during transfer and on discharge from hospital, of these medication-related errors, 30% have the potential to cause patient harm.[6]

Medication reconciliation by pharmacists remains the most important means of reducing errors in medication use.[7] Without continuity of care, optimal health outcomes cannot be achieved, and patients are at risk of medication-related harm. Pharmacists have demonstrated that they possess the skills to obtain the most accurate medication histories compared to other health professionals[8,9] and are highly valued by doctors[10] as this ensures patients do not unintentionally skip doses of vital medicines when unexpectedly admitted to hospital. In September 2020, broadcast of the *Sixty Minutes: The Greatest Loss* report on the tragic deaths of

Mr Bryan Ryan and Mr Allan Wells highlighted worst possible impacts of absent and poor medication reconciliation practices, where preventative medicines for stroke and cardiovascular disease were omitted during transitions of care.

Upon discharge, hospital pharmacists are integral to ensuring continuity of care through providing updated medicines lists for patients who often have significant changes to their medicines during their admission, including initiation and cessation of medicines, increased or reduced dosage of medicines, and uptitrating or downtitrating of medicines to achieve stability. Increasingly in Australian hospitals, hospital pharmacists are responsible for the medication summary section of the patient's discharge summary and are integral to providing information to the patient's community-based care providers to ensure a safe transition back into care.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) in their report on Safety Issues at Transitions of Care recognised transitions of care as a substantial risk of harm to patients including harms directly caused by medication errors.[11] They identified six areas where prioritisation needed to occur and these correlate to the principles proposed under the NMP, all of which hospital pharmacists are integral to achieving.

- Improvement in person-centred care
- Better responsibility and accountability for communication at transitions of care
- Better engagement of patients in care planning and communications
- Better access to complete and current health and social information
- Better opportunities for medication reconciliation
- Better discharge planning

Additionally, the Australian Pharmaceutical Advisory Council (APAC) Guiding Principles to Achieve Continuity in Medication Management[12] provides the framework for clinicians on how to provide optimal continuity of care with respect to patient's medicines as they transition between different care settings. However, due to funding challenges in hospital pharmacy departments exacerbated by remuneration inequities, it is difficult for the vast majority of hospitals to deliver all ten Guiding Principles systematically across their entire health service for every patient.

Terms of Reference 2: Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

A. **Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?**
B. **Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?**

SHPA supports the expansion of the NMP's current definition to include vaccines and medical devices which are used to deliver or administer medicines. The objectives in the NMP with respect to timely access and quality use of medicines are highly applicable to vaccines and medical devices.

Recommendation 3: The NMP's definition of medicines should be expanded to include vaccines and medical devices which are used to deliver or administer medicines, and future-proofed to include emerging therapies and technologies.

The COVID-19 pandemic has demonstrated the importance of vaccines to the Australian community to prevent disease and is the most important line of defence against a global pandemic. Given the high demand and complexities of manufacturing vaccines, it is appropriate that they are included in the purview of the NMP to ensure timely access for Australians.

Medical devices which are used to deliver or administer medicines should also be under the remit of the NMP as without them, as there are extremely limited alternatives when they are unavailable. For example, syringes are recognised by the Therapeutic Goods Administration (TGA) as medical devices and are critical to the delivery of medicines via intravenous, subcutaneous and intramuscular injection. These include anti-cancer therapies, biological medicines, antimicrobials and vaccines just to name a few.

During the initial stages of the COVID-19 vaccine program rollout, there were concerns from Australian hospitals that the specific low dead space syringes required for COVID-19 vaccines approved in Australia were unable to be procured in the quantities required, necessitating the use of other syringes which would increase the unnecessary wastage of vaccine doses. Recently the WHO reiterated that global shortages of syringes remain a real possibility in the short to medium term future based on projected need and manufacturing capacities[13].

Additionally, devices such as nebulisers, metered dose inhalers and dry powder inhalers commonly used to administer inhaled medicines to treat respiratory diseases are critical and should be considered by the NMP.

To future-proof the National Medicines Policy, the definition of medicines under the NMP should also include emerging medicines and technologies such as gene therapies (i.e. chimeric antigen receptor (CAR) T-cell therapy), immunotherapies, and personalised medicine. These emerging technologies are high-cost, complex and have the capacity to revolutionise how genetic diseases, autoimmune diseases and cancers are treated. Given their specialised nature, these therapies are administered in hospitals and sit alongside conventional therapies when treatment options are decided upon, thus it is imperative the entire continuum of medicines and therapies are included under the NMP's consideration.

Terms of Reference 3: Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

A. **How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?**

B. **How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?**

The NMP has maintained relevance over time as its objectives remain desirable and appropriate in setting out how Australians are able to access safe and high-quality medicines in a timely manner. SHPA also believes the NMP should acknowledge the increasing importance of digital health technologies which have a major impact on how patients use and access medicines, quality use of medicines and healthcare outcomes. SHPA is pleased to see the discussion paper acknowledges the Australian Digital Health Strategy and the My Health Record, which is increasingly utilised by hospital pharmacists to undertake medication reconciliation upon entry into hospitals and to support safer transitions of care.

Beyond My Health Record, digital health investments into electronic medical records (EMR) around Australian hospitals have in the last decade, shifted hospitals from paper systems to electronic systems. EMRs aim to improve the safety and quality of healthcare, and hospitals have been able to introduce electronic medication management as part of EMR systems to improve the quality and safety of prescribing, ordering and administering medicines to hospital patients.

However, many hospitals are implementing EMR systems in a fragmented approach, without integrating clinical decision-making software, pathology and laboratory data systems, medication administration charts, prescribing and dispensing systems or covering all areas of the hospital which provide medicines. This prevents the implementation of best practice closed loop medication management[14] and necessitates transcription and parallel systems (i.e. paper-based, and electronic medical records), ultimately limiting the benefits an integrated system intended to improve efficiency and reduce prescribing and dispensing errors.

EMRs, which have been implemented in public hospitals operated by state governments, sit alongside the My Health Record's implementation at a federal level without strong awareness of one another. These dual systems still have varying levels of interoperability which require significant investment from hospitals to connect their EMRs to a patient's My Health Record. For example, hospital pharmacists routinely provide updated medication lists/charts and medication management plans to patients and primary care providers upon discharge, but currently have no mechanism to upload these important documents to a patient's My Health Record to ensure a safer transition of care. Much of the transitions of care in relation to digital health technologies at the moment, currently differs greatly between hospitals, depending on the level of hospital pharmacy resourcing available, the time of discharge and what local arrangements exist between the hospital and community pharmacies.

Recommendation 4: The NMP should acknowledge digital health technologies as important elements of the healthcare sector which impacts medication safety and quality use of medicines and strive for a connected, interoperable digital health ecosystem.

Rapidly evolving treatment options which have changed the profile of new medicines being brought to market, have increasingly highlighted issues around access and equity. As stated earlier, twenty years ago at the inception of the NMP, new medicines were predominantly small molecules for lifestyle-related non-communicable diseases. In recent years, advancements in medical technology and research have seen

more complex and high-cost medicines being brought to market to treat diseases requiring acute hospital or outpatient care, such as cancers, autoimmune diseases and genetic diseases.

Public hospitals and hospital pharmacy departments play a crucial role in access to novel, usually high-cost and/or off-label medicines to treat complex and uncommon diseases before these medicines are registered on the Australian Register of Therapeutic Goods (ARTG) and well before they are listed on the PBS. They are also integral to patient access to clinical trials.

Due to the complex and specialised nature of these medicines, as well as their cost, patient access to these medicines differs greatly between hospital networks and between jurisdictions. They are subject to various factors including:

- fixed hospital pharmaceutical budget constraints
- varying access to compassionate access schemes
- local Drug and Therapeutic Committee policies and decisions
- access to specialist clinicians
- proximity to large hospitals
- varying out-of-pocket expenses determined by local and jurisdictional policies

This issue of access inequity for new and specialised medicines in hospitals is also explored in Pharmacy Forecast Australia 2021[15], and calls for structural funding reforms to reduce access inequities and ensure they are fit-for-purpose and sustainable.

Recommendation 5: The principles and objectives of the NMP relating to access and equity should include patient access to novel and high-cost unsubsidised medicines used in hospitals to treat complex and rare diseases.

Terms of Reference 4: Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations

A. How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?

SHPA believes consumers should be central not only in the development of the NMP as indicated in the proposed principles but rather be recognised as an empowered participant in their healthcare continuum in line with the Australian Charter of Healthcare Rights. There needs to be recognition that consumers are more active and informed in the context of broader health policy through the readily available access of general and personal health care information and have increased expectations on health services and health professionals.

Consumers who navigate between different care settings such as hospitals, aged care and community care, have the same expectation of service delivery regardless of their setting of care. For pharmacy services, this means consumers expect doctors and pharmacists to be working together to provide multidisciplinary care, irrespective of whether it is in a hospital or community setting, to enhance their quality use of medicines.

The NMP must acknowledge consumer diversity and broad representation on consultations including Aboriginal and Torres Strait Islander people. The Medication Safety Forum: Informing Australia's 10th National Health Priority Area[16] recognised certain populations should be part of national health priority strategy to achieve improved medication safety and quality use of medicines.

Recommendation 6: Consumer centricity and engagement should be strengthened in the NMP through greater diversity and inclusion, understanding of their expectations of healthcare delivery and health literacy levels.

SHPA believes the NMP should also acknowledge the importance of health literacy and that varying levels of health literacy will impact on a consumer's ability to make informed decisions and take medicines in a safe and quality manner.

It is recognised that poor health literacy results in worse health outcomes and health behaviours due to[17]:

- lower engagement in health services and preventative measures
- higher hospital readmissions rates
- poorer understanding of medication instructions (including non-adherence, improper usage)
- lower ability to self-manage care

A longstanding example of health literacy issues is the current provision of Consumer Medicines Information (CMI) leaflets with medicines. CMIs need to be shorter, more concise summaries of medicine information which cater to varying health literacy levels in the community. Current CMIs are impractical at communicating key pieces of medicines information to patients and are under-utilised despite being compulsory and readily available. They are lengthy, complex and difficult to use and can cause confusion and be overwhelming. Some hospital pharmacies and hospital pharmacy departments have instead developed their own medicines information leaflets for high-risk medicines – such as oral anticoagulants and opioid medicines – which are maximum two pages long and written in plain English.

Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

A. What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?

SHPA believes that to strengthen governance arrangements for the NMP, there should be more robust and dedicated engagement between state and federal counterparts to ensure consistent policies and aims around medicines access and quality use of medicines to achieve the objectives of the NMP.

Currently there is significant discrepancy in the access of medicines on discharge in non-PRA jurisdictions, as well as for Aboriginal and Torres Strait Islander patients who would otherwise have access to PBS medicines with co-payment relief. As mentioned above, there are also inequities in access to complex, high-cost specialised therapies from public hospitals, where access varies according to geographical location and hospital networks.

As discussed earlier, there also exists variations in the provision of hospital pharmacy services delivered to patients at the bedside, upon discharge and for outpatients. These are caused by piecemeal funding approaches and exacerbated by an imbalance of remuneration for dispensing medicines for hospital pharmacies.

At the government level, there exists the Council of Australian Governments (COAG) Health Council which is comprised of health ministers. The COAG Health Council is supported by the Health Chief Executives Forum (HCEF), formerly the Australian Health Ministers' Advisory Council (AHMAC), comprised of the heads of federal and state health departments.

Despite this, a review of all meeting communiques published[18] do not show inequities of medicines access or clinical pharmacy services for patients – either by jurisdiction or metropolitan/non-metropolitan – being discussed at these meetings. SHPA believes these bodies should form an important part of the governance arrangements of the NMP.

Recommendation 7: Existing forums between state and federal governments, such as the COAG Health Council and HCEF should be formally recognised as stakeholders in future governance arrangements for the NMP.

SHPA also believes that consistent and high-quality data on medicines use, medicines-related outcomes and pharmacy services should be collected to inform policy actions designed to achieve principles and objectives of the NMP. This would build on the work undertaken by the Independent Hospital Pricing Authority (IHPA) who collect data on sentinel events, hospital acquired complications and avoidable hospital readmissions, all of which can implicate the inappropriate use of medicines to cause harmful outcomes.

At present, data on PBS medicines use is systematically collected by Services Australia and the Department of Health, however there is no data collection on non-PBS medicines use in all settings of care, including the use of unregistered medicines and off-label medicines.

Data relating to medicine-related outcomes is also not collected systematically, with key statistics such as the 250,000 medicine-related hospital admissions annually being pieced together by an extensive literature review. The reporting of adverse events caused by medicines is also undertaken on a voluntary basis. For hospital pharmacists, when adverse events are reported, this often requires a duplication of the same report to both the TGA as well as local incident management reporting systems, which may then be further examined by state governments.

There is also no mechanism to measure or collect data on what extent hospitals are delivering the clinical services described by the SHPA Standards of Practice for Clinical Pharmacy Services to ensure medicines

safety and quality use of medicines. Data collection and benchmarking on service provision would allow health policymakers to further understand where service gaps exist and make strong links between how service provision impacts on the quality use of medicines and medicines access around Australia. SHPA believes that at a minimum, the following data points relating to medicines use in hospitals should be collected at the individual hospital level:

- Rate of medication reconciliation undertaken within 24 hours of admission
- Rate of daily medication chart review for inpatients
- Incidence of adverse drug events
- Rate of updated medication list/chart provided to patients, carers, and community care providers upon discharge
- Rate of discharge medicine counselling being provided to patients and/or carers

At present, the ACSQHC is undertaking the National Baseline Report on Quality Use of Medicines and Medicine Safety, which is focusing on medicines use in aged care and medication safety in vulnerable populations. The possibility of these reports to be expanded to include data collection on the above parameters in hospitals and health services should be explored.

Recommendation 8: To inform policies and investments to achieve the objectives of the NMP, consistent and high-quality data on medicines use, medicines-related outcomes and pharmacy services should be collected systematically.

B. How can communication about the NMP be enhanced or improved?

C. What would be effective mechanisms to support communication about the policy?

SHPA recommends that there is more engagement, opportunity and resourcing for hospital pharmacy representatives to participate in programs and policies relating to the NMP. This would improve the communication around the NMP and the policies and programs designed to achieve its objectives, where all stakeholders can play an active role in communicating updates to their membership cohorts and professional communities.

In recent years, SHPA has increased the representation of hospital pharmacy stakeholders on the Medicines Shortages Working Party convened by the TGA, the Health Services Medication Expert Advisory Group (HSMEAG) convened by ACSQHC, several NPS MedicineWise committees as well as the Pharmacy Profession Compliance Roundtable convened by the Department of Health. Representation on these groups has informed the work of government to be more aware and understanding of the role of hospital pharmacists and medicines use, and in turn has allowed SHPA to provide timely updates and news to its hospital pharmacist members regarding medicines policy.

This could be broadened to include representation of, or dialogue with hospital pharmacy representatives, on existing bodies convened by the Federal government such as the Pharmaceutical Benefits Advisory Committee and its sub-committees, Australian Technical Advisory Group on Immunisation (ATAGI), TGA advisory groups, Access to Medicines Working Group, Generic Medicines Working Group and others.

Terms of Reference 6: Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

A. How should the NMP's 'partnership-based' approach be defined?

B. What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?

SHPA supports the groups which are identified in the discussion paper as being responsible for advancing the NMP's objectives, however believes some groups that are missing from the listed partners include:

- automation industry (robotics, automated dispensing cabinets, webster packing etc.)
- medicines compounding services
- medical software industry stakeholders and EMR vendors
- individual healthcare organisations such as hospitals, aged care facilities and general practices

Whilst individual healthcare practitioners, federal and state governments are identified, SHPA believes individual healthcare organisations such as hospitals, aged care facilities and general practices are a significant omission as healthcare facilities will often have varying local policies and programs which impact on medicines access and quality use of medicines. As such, they should be explicitly recognised separately as NMP partners.

C. How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?

Each partner should be acutely aware of their role in delivering the objectives of the NMP and be held accountable for their progress and contribution to this with clear recording and reporting on targets and key performance indicators. As discussed earlier, consistent and high-quality data pertaining to medicines use, medicines-related outcomes and pharmacy services should be collected systematically to inform work and accountability by partners and stakeholders. There also needs to be transparency across partners to build trust and prevent unnecessary duplication.

D. How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?

Conflicts of interests should be declared openly and transparently and documented in formal submissions to a governing body for review.

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SHPA submission to Review of Pharmaceutical Reform Agreements – March 2022

Introduction

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation representing the over 6,100 Hospital Pharmacists, their hospital pharmacy interns and hospital pharmacy technicians working across Australia's hospitals and healthcare system. SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care. SHPA is committed to facilitating safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the review into the Pharmaceutical Reform Agreement (PRA) and notes its context and timing with concurrent reviews with into the National Medicines Policy (NMP) and the Section 100 Efficient Funding of Chemotherapy (EFC) program, as a crucial opportunity to get policy settings for medicines access in hospital settings fit-for-purpose and achieving the needs and expectations of patients.

Since the first PRAs were implemented over twenty years ago, there have been significant reforms and changes in public hospital funding via establishment of National Health Reform Agreements (NHRA), medicines access and medication management programs in the primary care sector via Community Pharmacy Agreements (CPA), as well as for the pharmaceuticals sector via Strategic Agreements with major stakeholders. Each of these important agreements are openly available to the public and periodically reviewed to ensure they are appropriate and meet the anticipated needs of the next five years, however this is not the case for PRAs.

SHPA believes fundamentally, the PRA Review is an opportunity to change this and have more contemporary governance arrangements for a program that enables the supply of approximately $3 billion of Pharmaceutical Benefits Scheme (PBS) medicines to hospital patients at discharge, outpatient clinics and at day treatment facilities.

About hospital pharmacy

Hospital pharmacists account for just over 20% of the entire pharmacy workforce and are the fastest growing sector of the pharmacy workforce. It is in hospital where hospital pharmacists treat patients at their most unwell, often having a significant health event such as strokes, heart attacks and organ transplants. Patients are usually prescribed multiple new medicines in hospitals during their admission, many of which are taken for many months or years after discharge, relying on regular care by their community-based practitioners.

Hospital Pharmacists are integral to achieving the aims of Australia's NMP, and addressing Medicines Safety and Quality Use of Medicines, Australia's Tenth National Health Priority Area. Medication management services such as medicines reviews are proven to reduce hospital readmission rates and medication-related hospital admissions, of which there are 250,000 annually costing the Australian healthcare system $1.4 billion each year.

Prior to PRAs being established, hospital pharmacy and the PBS were mutually exclusive, and hospital prescribers and pharmacists could not prescribe or dispense medicines to patients with PBS subsidy. In most recent 2019-20 data obtained from Services Australia, hospital pharmacy accounted for 23% of all Pharmaceutical Benefit Scheme (PBS) expenditure, which included a majority of Section 100 EFC and Highly Specialised Drugs Program (HSDP) expenditure.

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The PRAs enabled hospital prescribers and pharmacists to prescribe and dispense PBS subsidised medicines to hospital patients upon discharge from hospital, outpatients and patients receiving care from day-treatment services. They supported the transitions of care for patients discharging from hospital back into the community and allowed for patients to be supplied the standard PBS quantity of one-months' supply of discharge medicines. Previously, hospital patients received as little as three days' worth of discharge medicines, which placed pressure on them to see their primary healthcare provider very soon after discharge to continue receiving key medicines.

Furthermore, the medicines landscape has significantly changed in the last twenty years. In recent years, a majority of PBS expenditure and listings are for biologicals, high-cost and complex medicines used to treat cancers and autoimmune diseases, which are often initiated and supplied in hospital settings. This contrasts with when the PRAs were introduced, where listings were dominated by medicines for lifestyle-related non-communicable diseases.

In this submission, SHPA makes a range of recommendations to improve the governance and policy settings of PRAs to support access, efficiency, equity and quality use of medicines for all Australians. If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

SHPA's Recommendations to the PRA Review

Recommendation 1: Enable public hospital pharmacies to supply PBS-subsidised medicines for public hospital inpatients to achieve equity and enhance quality use of medicines and medicines safety.

Recommendation 2: New South Wales and the Australian Capital Territory should become signatories of the Pharmaceutical Reform Agreements to achieve the proposed principles of a future PRA.

Recommendation 3: The governance arrangements for PRAs should be significantly improved to achieve the proposed principles of a future PRA of partnership based, accountability and transparency, and stewardship, via

a. **Establishment of five-year, nationally consistent PRAs for the public hospital pharmacy sector with the Commonwealth, jurisdictional governments and SHPA as signatories and aligned to National Health Reform Agreements**
b. **Publishing the PRAs to the general public similar to other major government programs and agreements**
c. **Regular consultative forums between Commonwealth, jurisdictions and SHPA on PRA implementation and delivery and impact of new PBS listings on hospital pharmacy sector**
d. **Inclusion of clauses for dispute resolution and variations to PRAs**

Recommendation 4: Enable hospital pharmacists to supply medicines to Indigenous Australians under Closing the Gap PBS Co-Payment Measure.

Recommendation 5: Provide consistent, appropriate and equitable remuneration for supplying PBS medicines to public hospital pharmacies that supports the delivery of the necessary clinical pharmacy services to ensure medicines safety, quality use of medicines and maximise investment into PBS medicines

Recommendation 6: The PRA should acknowledge digital health technologies as important elements which impacts medication safety and quality use of medicines, and prioritise and provide commensurate support to the hospital pharmacy sector

Recommendation 7: The PRAs should provide resourcing support to achieve hospital pharmacist staffing levels published in professional standards, to ensure full and meaningful adoption of the APAC guidelines.

Proposed principles for a future PRA

1. **Are these proposed principles appropriate? Is anything missing or needing to change?**

SHPA supports the five proposed principles of equity, person-centred, partnership-based, accountability and transparency, and stewardship. Whilst the discussion paper states these principles have been drawn from the current approach to PRAs, SHPA believes there are many existing gaps presently in achieving these under existing PRAs.

To achieve the principles of equity and person-centred, the PRAs should enable access to PBS-subsidised medicines for inpatient medicines, as is currently enabled for private hospital pharmacies. At present, public hospital inpatients are supplied and dispensed medicines without PBS subsidy, where public hospital pharmacists have to dispense two to fourteen days' worth of inpatient medicines depending on the expected length of admission. Upon discharge from hospital, hospital pharmacists are then able to and often do, resupply medicines at the point of discharge where PBS subsidy is enabled.

Recommendation 1: Enable public hospital pharmacies to supply PBS-subsidised medicines for public hospital inpatients to achieve equity and enhance quality use of medicines and medicines safety.

This is a major quality use of medicines (QUM) and medicines safety issue, which has been declared as Australia's Tenth National Health Priority Area in 2019. Where private hospital inpatients will have access to a PBS pack from admission, this assists with their overall medicines adherence and health literacy, as hospital pharmacists are able to counsel and educate patients on their regular, new or changed medicines using the medicine packaging as an important visual aid. For public hospital inpatients, given there is no PBS funding for medicines, patients will be supplied a blister strip or a small bottle of a few days' worth of medicines. This makes it very difficult for hospital pharmacists to educate and counsel patients meaningfully, if all their different inpatient medicines appear in the same packaging.

This is a QUM and medicines safety risk for nurses who administer the medicines, who again do not have the different visual aids of medicines primary packaging if PBS for inpatients were enabled, to discern between different medicines to ensure the correct medicine was administered. According to incident reporting data collected and reported within hospitals, SHPA members understand that this is a major risk area for nurses and patients who are administered the incorrect medicines against their medication chart.

Furthermore, the exclusion of PBS for public hospital inpatients is inefficient, as it means public hospital pharmacists have to dispense the same medicine twice, once upon admission and again upon discharge. This is inherently inefficient, especially for a workforce that has been experiencing workload pressures for a long time which have been exacerbated by the COVID-19 pandemic. By enabling public hospital inpatients to access PBS medicines, it brings forward dispensing of PBS medicines from the point of discharge to the point of admission, hence SHPA believes this would be at a relatively net-zero cost to the Commonwealth.

The improved efficiencies would also improve hospital bed flow through reducing the number of dispensing episodes required and also deliver a modest saving to public hospital pharmacy operations, which would be passed on to both the states and the Commonwealth.

The lack of PBS for public hospital inpatients also results in cost shifting incentives remaining at the expense of efficient, quality and safe healthcare delivery. Without PBS subsidy for public hospital inpatients, there are perverse incentives to delay initiation of certain higher cost treatments until the point of discharge to access PBS subsidy, such as antipsychotic drug depots, iron infusions, Hepatitis C medications and infusions for osteoperosis.

SHPA believes this can be achieved by existing governance arrangements in the Addendum to the NRHA 2020–25 for public hospital funding, where Commonwealth funding for blood products (through the National Blood Agreement) and Commonwealth pharmaceutical programs (PRA, S100 EFC and S100 HSD) is removed from public hospital funding calculations to avoid 'double-dipping'.

The lack of PBS for public hospital inpatients also causes issues for patients admitted to hospitals who are taking high-cost medicines in the community that are listed under S100 HSD or are high cost S85 medicines. If they present to hospital without their regular medicines, which is often the case due to public hospital admissions being unplanned, then public hospitals are faced with the choice of breaking PBS packs of very high cost medicines – such as newly listed medicines for cystic fibrosis – to ensure continuous therapy in hospital.

This is extremely inefficient and expensive for the public hospital, and in many instances, these vital medicines are not provided at all until a carer can bring in their PBS-dispensed pack from home, which does not always occur. Once a PBS pack is broken, it cannot be resupplied to another patient, and has a major risk of eventually expiring and having to be wasted. This is just another unintended consequence of this inequity that can be rectified by allowing PBS-subsidy for public hospital inpatient medicines.

Broken packs of medicines are also incompatible with dispensing robots and automated dispensing cabinets, which have been invested into by various hospitals around the country – well into the tens of millions, and increasing – to improve the accuracy and quality of dispensing. Where there are broken packs, parallel manual handling processes must occur which inadvertently cause issues with efficiency and safety.

Additional challenges in funding of medicines in public hospitals also stem from parallel procurement and funding systems for medicines supplied/procured under compassionate access schemes, clinical trials, Special Access Scheme, Authorised Prescriber Scheme and other niche and specialised access schemes.

Recommendation 2: New South Wales and the Australian Capital Territory should become signatories of the Pharmaceutical Reform Agreements to achieve the proposed principles of a future PRA.

To meet the principle of equity for consumers, SHPA believes that the Commonwealth should make the PRAs a uniform policy in Australia and enter into PRAs with New South Wales and Australian Capital Territory. This would ensure a consistent standard of care for vulnerable patients who have just had a major health event requiring hospitalisation and reduces the need for individuals to immediately seek an appointment with their general practitioner on discharge from hospital to continue receiving vital medicines.

Patients being discharged from public hospitals in NSW and ACT are currently supplied 3-7 days' worth of discharge medicines, which contrasts with the other jurisdictions who are able to supply a months' worth of discharge medicines. The expansion of PBS into public hospitals has allowed more hospital pharmacists to be employed and provide clinical pharmacy activities to patients, as well as allow investment into specialised pharmacy services, such as pharmacists specialising in oncology, paediatrics, emergency medicine and geriatric medicine. These services are necessary to safeguard and maximise the federal government's investment into new PBS medicines that treat complex conditions.

Recommendation 3: The governance arrangements for PRAs should be significantly improved to achieve the proposed principles of a future PRA of partnership based, accountability and transparency, and stewardship, via

a. Establishment of five-year, nationally consistent PRAs for the public hospital pharmacy sector with the Commonwealth, jurisdictional governments and SHPA as signatories and aligned to National Health Reform Agreements

b. Publishing the PRAs to the general public similar to other major government programs and agreements

c. Regular consultative forums between Commonwealth, jurisdictions and SHPA on PRA implementation and delivery and impact of new PBS listings on hospital pharmacy sector

d. Inclusion of clauses for dispute resolution and variations to PRAs

At present, SHPA and jurisdictions understand that each of the six PRA jurisdictions has a slightly different PRA to one another, depending on when the PRA was established. Furthermore, the PRAs cumulatively result in over $3 billion of annual PBS expenditure, representing just under a quarter of the PBS. Given the large scale of expenditure, and its impact on how medicines are used not just in hospitals but also beyond hospital discharge, SHPA believes this does not meet public expectations regarding governance, transparency and consistency.

It is recommended that the Commonwealth establishes five-year Pharmaceutical Reform Agreements for the public Hospital Pharmacy sector with the Commonwealth, jurisdictional governments and SHPA as signatories. Given the current NRHA expires on 30 June 2025, this provides ample time for the concurrent PRA, S100 EFC and NMP reviews to conclude, to inform these five-year PRAs in the next iteration of NHRAs from 1 July 2025.

This would be similar to existing, publicly viewable, five-year Agreements entered into the Commonwealth in the pharmacy and pharmaceuticals sector including:

- Seventh Community Pharmacy Agreement with The Pharmacy Guild of Australia and Pharmaceutical Society of Australia
- Strategic Agreement with Medicines Australia
- Strategic Agreement with Generic Biosimilar Medicines Association

Similar to these existing agreements, SHPA also recommends there be regular consultative forums between the Commonwealth, jurisdictions and SHPA on the implementation and delivery of PRAs. This would also provide an opportunity to discuss the impact of new PBS medicines listings on the hospital pharmacy sector. Newly listed PBS medicines are increasingly complex, specialised and high-risk, often requiring an admission to initiate medicines and monitor patients, such as blinatomumab, venetoclax, macitentan, clozapine, multiple myeloma medicines to name a few. However, the hospital pharmacy sector is not engaged by either Pharmaceutical Benefits Advisory Committee or Department of Health to discuss whether these new PBS listings requiring inpatient are and monitoring can or will be appropriately managed in the hospitals sector, and are also not provided sufficient advance notice to prepare for the arrival of new PBS listings which will alter care provided by hospitals and hospital pharmacies. The lack of impact assessment on public hospitals for new PBS listings, particularly S100 medicines, is a risk to QUM and achieving the principles of PRA and the NMP.

In this context, the PRAs should also have provisions for dispute resolution and variations to the agreements in the spirit of good governance. SHPA believes that historically, the lack of these clauses in PRAs has favoured the Commonwealth who have enacted changes without consultation, such as the 2019 Federal

Budget $44 million cut to hospital pharmacies via a cut and a cap to the wholesale mark-up for public hospital pharmacies, which were again revised down approximately a year later, again without consultation. That the remuneration terms in PRAs are somewhat dictated by or reference remuneration arrangements in CPAs, is also inappropriate with contemporary governance principles.

2. **In thinking about future PRAs, what should new arrangements achieve? What are the emerging areas of interest to focus on?**

The new PRA arrangements should enable hospital pharmacists to supply medicines under the Closing the Gap (CTG) Pharmaceutical Benefits Scheme (PBS) Co-payment Measure (the Measure). This policy currently excludes public hospitals from participating in these arrangements. The requirement for a co-payment to receive medications at discharge from a public hospital, has resulted in ongoing inequity in the provision of medications. Without access to the Measure, individual hospital policies (which often require a co-payment as specified by PBS procedures) often prevent Indigenous patients from receiving their medications at discharge. If patients are unable or unwilling to pay the co-payment, they must attend a community pharmacy to receive discharge medications.

Research shows that these patients have lower medication adherence compared to other population groups,[1] and that over a quarter of patients fail to make it to a local pharmacy until days later to have their discharge prescription dispensed.[2] Poor access to medications can potentially compromise a patient's health and cause preventable hospital readmissions. This also prevents the provision of expert advice related to the new medication regimen by the pharmacist who has counselled them during their inpatient stay.

Some states and territories have implemented PBS quantities on discharge and are using their hospital budget to absorb the co-payment costs, however this is not nationally consistent and defies the proposed PRA principles.

Recommendation 4: Enable hospital pharmacists to supply medicines to Indigenous Australians under Closing the Gap PBS Co-Payment Measure.

The new PRA arrangements should also achieve equitable funding arrangements for the supply of PBS medicines and medication management programs, as similarly provided in existing CPAs. The principle of equity should also not just be limited to effective, safe, high-quality, and affordable medicines, but also expanded to be complemented by clinical pharmacy services delivered which are necessary to support the QUM and patient safety. Medicines have the capacity to cause harm either through side effects, drug interactions or inappropriate dosing. Literature suggests that there are 250,000 hospital admissions resulting from medication-related problems each year, costing the healthcare system $1.4 billion annually.[3] However, several inequities exist with respect to funding that prevents patients from receiving the comprehensive suite of clinical pharmacy services in SHPA's Standards of Practice for Clinical Pharmacy Services[4], which include:

- taking a medication history and ensuring medications are charted correctly and available at admission to be administered in a timely manner
- regular review of the safety, quality, storage and supply of medications during hospital stay
- review of discharge prescriptions, dispensing a sufficient supply of medications to take home, counselling patients on their medications and communicating changes to primary healthcare providers
- ensuring appropriate follow-up and monitoring of medications post-discharge including in specialised clinics and outpatient services and checking for adverse reactions to medications

The inequities in remuneration for the supply of PBS medicines to hospital pharmacists as per Table 1, have downstream impacts on hospital pharmacy departments capacity to deliver comprehensive clinical pharmacy

services to patients. The lack of dispensing fees, wholesale mark ups and administrative handling and infrastructure (AHI) fees means fewer hospital pharmacists are employed to deliver key services to patients that are vital to medication safety and QUM.

SHPA supports recognition of and funding for clinical pharmacy services in all settings of care and should be devolved from the cost of the medicine, ensuring that remuneration supports the delivery of the necessary clinical pharmacy services to ensure medicines safety, QUM and maximise investment into PBS medicines. Consumers expect to receive the same quality of care regardless of the healthcare setting, however different funding and service levels across different care settings prevent this.

	Public hospitals	**Private hospitals**	**Community pharmacy**
Section 85 medicines	Ex-manufacturer price + 7.52% wholesale mark-up	Ex-manufacturer price + 7.52% wholesale mark-up + 1.4% pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 7.52% whole-sale markup + AHI fee + Dispensing Fee
Section 100 medicines	Ex-manufacturer price	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee	Ex-manufacturer price + 4-tier s100 pharmacy mark-up + Dispensing Fee

Table 1. Public and private hospital pharmacy renumeration fee structure for Section 85 and Section 100 medicines
Adapted from Review of Pharmacy Remuneration and Regulation Discussion Paper and updated with 2019 Federal Budget reduction to hospital pharmacy wholesale mark-up[5]

Recommendation 5: Provide consistent, appropriate and equitable remuneration for supplying PBS medicines to public hospital pharmacies that supports the delivery of the necessary clinical pharmacy services to ensure medicines safety, quality use of medicines and maximise investment into PBS medicines

The new PRAs should also acknowledge the 'patient journey' is no longer a simple pathway back and forth between hospital and community settings, and should be updated to enable quality access to medicines and pharmacy services in all the innovative models of care that have been, are in the process of, or will be developed as contemporary healthcare continues to evolve. Some examples are:

- Hospital in the home
- Hospital in the nursing home
- Pharmacist-led outpatient clinics
- Aged care outreach programs
- Post-discharge programs to prevent re-admission
- Models of care necessitated by COVID-19 pandemic
- Virtual care models, telehealth models
- District nursing services, community health services and Primary Health Networks

In this context, per our discussion around Recommendation 1, the exclusion of public hospital inpatient access to PBS medicines, but enabled for outpatient access and upon discharge, becomes increasingly not fit-for-purpose and fails to address contemporary needs as hospital care and delivery can no longer be simplified to the inpatient/outpatient binary. Rather, hospital and hospital pharmacy care has the flexibility to be delivered to patients in the setting and circumstances most appropriate to them via a patient-centred approach, and commensurate support from the PRAs is required to maximise investment, medicines safety and QUM of PBS medicines in all settings.

Recommendation 6: The PRA should acknowledge digital health technologies as important elements which impacts medication safety and quality use of medicines, and prioritise and provide commensurate support to the hospital pharmacy sector

The expansion and evolving nature of electronic and digital health provides another reason why PRAs should be periodically reviewed and consulted on to ensure contemporary developments in the healthcare and pharmacy sector are reflected in ongoing PRAs. Electronic and digital health technologies have a major impact on how patients use and access medicines, their QUM and healthcare outcomes.

PRAs should acknowledge policies and programs by the Australian Digital Health Agency (ADHA), including the Australian Digital Health Strategy, National Digital Health Strategy and Framework for Action and the My Health Record, to empower and provide support to hospital pharmacists to achieve medicines safety, QUM, especially at the transitions of care. The My Health Record is increasingly utilised by hospital pharmacists to undertake medication reconciliation upon entry into hospitals and to support safer transitions of care.

Beyond My Health Record, digital health investments into electronic medical records (EMR) around Australian hospitals have in the last decade, shifted hospitals from paper systems to electronic systems. EMRs aim to improve the safety and quality of healthcare, and hospitals have been able to introduce electronic medication management as part of EMR systems to improve the quality and safety of prescribing, ordering and administering medicines to hospital patients.

However, many hospitals are implementing EMR systems in a fragmented approach, without integrating clinical decision-making software, pathology and laboratory data systems, medication administration charts, prescribing and dispensing systems or covering all areas of the hospital which provide medicines. This prevents the implementation of best practice closed loop medication management[6] and necessitates transcription and parallel systems (i.e. paper-based, and electronic medical records), ultimately limiting the benefits an integrated system intended to improve efficiency and reduce prescribing and dispensing errors.

EMRs, which have been implemented in public hospitals operated by state governments, sit alongside the My Health Record's implementation at a federal level without strong awareness of one another. These dual systems still have varying levels of interoperability which require significant investment from hospitals to connect their EMRs to a patient's My Health Record. For example, hospital pharmacists routinely provide updated medication lists/charts and medication management plans to patients and primary care providers upon discharge, but are only just now beginning to be able to upload Pharmacists Shared Medicines List (PSML) to a patient's My Health Record to ensure a safer transition of care.

This also has significant implications for Electronic Prescribing (EP), which thus far has focused primarily on the community setting, where SHPA understands up to 98% of all community pharmacies have enabled EP, whereas no public hospitals are currently participating in EP from a federal PBS perspective, but are already running multiple different software and systems for digital prescribing at the intra-hospital level. SHPA supports consistency and priority in EP arrangements for the hospital pharmacy sector, to reduce further fragmentation and inconsistency.

The rollout thus far of EP has focused on community settings, with acute settings lagging behind, and this has been a noticeable trend with federal policies and programs pertaining to health where the community sector has been engaged more widely and earlier compared to the acute sector. A reformed PRA with renewed focus on the principles of partnership-based, accountability and transparency, and stewardship, would hopefully allow for improved engagement and consultation with the hospital sector, to ensure they are empowered to assist the Commonwealth to deliver its strategic policies, programs and aims, such as the many investments in digital health.

Term of Reference 1: The Review will examine the success of the current PRAs by evaluating their objectives and outcomes to date, including:

- **Leadership, responsibility, and accountability for medication management;**
- **Evidence of streamlined and consistent application of arrangements;**
- **Outcomes or evidence of improvements in medication access when transitioning between hospital and community settings**

1. **Have the PRAs met their objectives – providing easier and safer access to medicines for public hospital patients, ensuring adoption of APAC guidelines and reducing cost shifting incentives for state funded public hospitals? What does success look like? And if not, why not?**

The PRAs have met the objective of providing easier and safer access to medicines for public hospital patients on discharge, at outpatients and in day treatment facilities, particularly for patients requiring EFC medicines and other specialised, high-cost and complex medicines. It is time these provisions are also extended to the ACT and NSW whose hospital patients are at risk of poor QUM and medicines safety due to lack of easy and safe access to PBS medicines, particularly in the immediate discharge phase where readmission risk is higher, and a much more costlier outcome for the healthcare system if preventable readmissions are realised.

The PRAs have not met their objectives in ensuring adoption of APAC guidelines or reducing cost-shifting incentives. As discussed earlier, the exclusion of PBS-subsidy for public hospital inpatients has introduced new cost-shifting incentives that result in the delayed treatment of patients requiring higher cost PBS medicines. As per Table 1, the inequitable remuneration means in vast majority of cases, the remuneration provided for dispensing PBS medicines in hospitals does not provide cost recovery once the resources of pharmacists, procurement officers and pharmacy technicians are factored into overall cost of supply. Thus, to minimise the impact of this, it is typical for certain medicines to be delayed until the point of discharge to gain PBS subsidy. Beyond the cost-shifting issues this has created, it must also be noted this also can hold up discharge and provide a negative pressure on improving bed flow in hospitals, an issue that has been acutely felt during the COVID-19 pandemic.

There have been attempts by PRA states with varying success to adopt the APAC guidelines, however without dedicated staffing and resourcing, supported by the states and the Commonwealth, this makes it difficult and SHPA members report virtually all hospitals do not fully meet the APAC guidelines. These issues of workforce availability and funding must be addressed in partnership between the states and Commonwealth. SHPA has developed its Standards of Practice for Clinical Pharmacy Services in 2012 with pharmacist to patient staffing ratios in hospitals to support the full adoption of the APAC guidelines, however the vast majority of hospitals do not meet these staffing ratios, meaning the APAC guidelines are not adopted to their full extent, increasing the risk of medication-related harm for hospital patients.

Recommendation 7: The PRAs should provide resourcing support to achieve hospital pharmacist staffing levels published in professional standards, to ensure full and meaningful adoption of the APAC guidelines.

Furthermore, due to lack of governance, data collection and consultative forums on the PRA, it is extremely difficult for governments at all levels to even measure to what extent the APAC guidelines are being adopted, to identify gaps, which then makes providing targeted solutions beyond additional hospital pharmacy workforce investment, even more difficult.

Finally, the lack of staffing and resourcing also inhibits hospital pharmacy departments from meeting National Safety and Quality Health Service (NSQHS) Standards, particularly the Medication Safety Standard.

2. **Are there any population groups that are not receiving equitable access to medicines under the PRAs? What could be changed to improve access for these patients?**

As per Recommendation 2 and 4, indigenous patients, and patients in the ACT and NSW are not receiving equitable access to medicines due to inconsistent policies with the PRA.

Due to the lack of PBS-subsidy for public hospital inpatients, public hospital long-stay patients are typically disadvantaged when they require treatment of a high cost PBS medicine, however the hospital is unable to fund this treatment for inpatients. Public hospital long-stay patients can typically be geriatric patients and mental health patients.

It is in long-stay mental health patients where this issue is most apparent, where some patients on these wards may have a history of intravenous drug use and are subsequently diagnosed with Hepatitis C. However, given the cost of these medicines are in excess of $10,000, they are unable to be supplied to these vulnerable patients until they are discharged, which can take a long time.

3. **How has the risk sharing arrangement under the PRAs worked in practice? Does it remain an effective mechanism? Are there other useful approaches to risk sharing?**

SHPA understands the risk sharing arrangements under the PRAs have never been practically enforced, and exceptions were made when the listing of high-cost Hepatitis C medicines occurred.

This is an area where improving the transparency and governance of the PRAs as per Recommendation 3, can produce meaningful cooperation on risk sharing arrangements. The lack of consultative forums also means issues arising from risk sharing arrangements, analysis of forecasts and projected expenditure, is unable to be discussed in a consultative manner with all stakeholders involved. As discussed earlier, engagement with hospital pharmacy sectors, who are increasingly called upon to supply, dispense and administer newly listed complex and high-cost PBS medicines, is crucial ahead of PBS listings occuring, not only so they can prepare their clinical practices for new PBS medicines, but also to discuss any implications it will have on hospital pharmacy's PBS expenditure and subsequent impact on risk sharing arrangements.

There is also a risk that the existence of risk-sharing arrangements can again, inadvertently encourage cost-shifting incentives, where supply of PBS medicines are delayed or avoided to avoid reaching the ceilings, which end up contributing to care that is not patient-centred and potential adverse health outcomes. Hospital pharmacists are champions for reducing unnecessary use of medicines and work with doctors to deprescribe where possible, and by virtue of their clinical pharmacy services, improve PBS sustainability by improving healthcare outcomes. As such, given the focus of our sector already to reduce unnecessary medicines use, the need for risk sharing arrangements and their role should be examined further between the jurisdictions and the Commonwealth.

4. **How has medication management in public hospitals changed since the introduction of PRAs and how might the adoption of a PRA have affected this?**

As per our response to Question 1 in this section, the introduction of PRAs has improved medication management in public hospitals by enabling additional hospital pharmacy resource investment to implement the APAC Guidelines, address QUM and medicines safety which is a National Health Priority Area, and to meet NSQHS standards. However, due to lack of governance, data collection and consultative forums on the PRA, it is extremely difficult for governments at all levels to even measure to what extent the APAC guidelines

are being adopted, to identify gaps, which then makes providing targeted solutions beyond additional hospital pharmacy workforce investment, even more difficult.

It is clear when looking at hospital pharmacy workforce statistics published in the National Health Workforce Data Set, that a non-PRA state such as NSW, has the least hospital pharmacists per capita compared to all other PRA-states, and according to the Productivity Commission, has a higher rate of adverse events related to medicines.

	NSW	VIC	QLD
2011-12	2.4	2.1	2.1
2012-13	2.5	2.3	2.4
2013-14	2.6	2.2	2.4
2014-15	2.8	2.2	2.4
2015-16	2.8	2.1	2.4
2016-17	2.8	2.2	2.4
2017-18	3.1	2.1	2.4

Table 2. Adverse effects of drugs, medicaments and biological substances, events per 100 separations
Source: Productivity Commission, Report on Government Services

5. **How does the patient experience in a PRA hospital versus non-PRA hospital differ, including their experience of the continuum of care between hospital and community care?**

As discussed earlier, patients being discharged from public hospitals in NSW and ACT are currently supplied 3-7 days' worth of discharge medicines, which contrasts with the other jurisdictions who are able to supply a months' worth of discharge medicines. This requires patients in ACT and NSW to immediately seek an appointment with their general practitioner (GP) on discharge from hospital to continue receiving vital medicines, such as preventative anticoagulants, antihypertensives and anti-cholesterol medicines to reduce the risk of another heart attack or stroke.

This is extremely difficult for patients who have just had a major – oft traumatic – healthcare event and are still transitioning back to home life, and further exacerbated for patients living in areas, - particularly rural and regional – where access to general practitioner services are challenging with wait times of up to three weeks for an appointment. This is a major QUM and medicines safety issue that contributes to hospital readmission.

By closing this gap and reducing the need for some patients to access GP services on discharge, it also improves Medicare Benefits Schedule (MBS) sustainability by reducing the need for MBS consultations simply to obtain another prescription in the immediate discharge phase, with another MBS consultation in another one to two weeks to conduct the post-discharge follow-up.

6. **What is the experience of hospital administrators and practitioners in a PRA hospital versus a non-PRA hospital? How has having a PRA in place impacted on system processes and hospital administration.**

Whilst PRAs have overall improved access to PBS medicines, PRA hospitals, by virtue of being able to supply PBS quantities on discharge, have had to make necessary adjustments to their layout and storage facilities to accommodate more medicines. Many hospitals can often find obtaining more floor space for storage facilities challenging due to the increased demand for healthcare services.

As discussed above, the lack of PBS medicines for inpatients can often lead to many inefficiencies with respect to dispensing robots and automated dispensing cabinets being incompatible with broken packs. Broken packs, particularly for high-cost medicines which have limited patient cohort, are at risk of being wasted and severely impact the operating budget of hospitals, particularly smaller hospitals with smaller overall budgets are wastage of high cost medicines account for a higher proportion of drug budgets.

The lack of PBS medicines for inpatients also causes issues with two parallel medicines funding systems occurring in hospitals, which makes it extremely difficult for administrators and managers to track expenditure and how medicines are used. SHPA has been engaged on discussions over the years on Special Pricing Arrangements and their proposed reforms, and reiterates that these parallel funding systems of medicines listed on the PBS that do not attract PBS subsidy when used for public hospital inpatients, makes the tracking of medicines throughout the supply chain extremely difficult.

7. **How consistent are PRA arrangements across jurisdictions? What are some examples of consistent or inconsistent implementation?**

PRA arrangements are variable across jurisdictions with respect to how much they can meet the APAC guidelines, which is a reflection the differing levels of hospital pharmacy workforce resourcing. An example of this is the extent to which hospital pharmacy departments have hospital pharmacy services provided after traditional business hours and on weekends, where patients are discharged. Without pharmacists present during these discharges that occur outside of business hours, this can contribute to unsafe discharges, medication errors on the discharge prescriptions not being detected, and contribute to hospital readmission.

Another example of this are PBS co-payment policies for Indigenous patients, given the exclusion of public hospital pharmacies to participate in the CTG PBS Co-payment Measure. SHPA understands some states charge the PBS co-payment to Indigenous patients, but some states do not and elect to absorb the cost themselves. This is inconsistent and inequitable, and we reiterate the need for Recommendation 4 to be adopted to include public hospital pharmacies in this measure.

Term of Reference 2: The Review will examine 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

1. **Should future PRAs include more flexible language to ensure all approved prescribers can participate in PBS access in hospitals? If so, what is the best way to reflect this flexibility in a PRA?**

SHPA believes this should be further explored and supports this in-principle to introduce consistency in PBS prescribing across the Australian healthcare system. It is also inefficient to allow PBS prescribers to prescribe medicines in certain circumstances but not others, and does not provide for a patient-centred approach to hospital care.

Additionally, ensuring this consistency and thus expanding the prescribers under the PRA where appropriate, can also potentially alleviate some of the workforce shortages and pressures experienced by our medical colleagues.

2. **How might Biosimilar uptake and electronic medication management be best supported under a future PRA. What performance measures could be incorporated to encourage best practice?**

Hospital pharmacists are champions of PBS sustainability and analysis of PBS data should demonstrate higher conversion and use of biosimilars compared to community pharmacists. Hospitals often have internal or state-wide policies that ensure the use of biosimilars wherever possible, and have robust enforcement mechanisms to ensure originator biologicals are only used in limited and clinically appropriate circumstances, due to adverse reaction or lack of evidence for switching to a biosimilar.

Hospitals often only stock one brand of medicine, and thus when biologicals are initiated in hospital, overwhelmingly it is the biosimilar that is prescribed and dispensed by hospital doctors and pharmacists, regardless of any preference a prescriber may have as the policy and guidelines must be adhered to. SHPA understands this contrasts with practices in the community sector.

Biosimilar uptake can be further supported with dedicated and additional research capacity for hospitals and hospital pharmacists to examine the safety of biosimilar switching protocols, to provide further evidence base for these clinical decisions which will enhance PBS sustainability.

As discussed earlier, the rollout thus far of EP has focused on community settings, with acute settings lagging behind, and this has been a noticeable trend with federal policies and programs pertaining to health where the community sector has been engaged more widely and earlier compared to the acute sector. The PRAs must acknowledge and provide support for EP to integrate seamlessly with existing EMRs, which have been implemented in public hospitals operated by state governments.

The rollout thus far of EP has focused on community settings, with acute settings lagging behind, and this has been a noticeable trend with federal policies and programs pertaining to health where the community sector has been engaged more widely and earlier compared to the acute sector.

SHPA understands there are incentives under the CPA for community pharmacists to take up electronic and digital health initiatives, and these should be considered under future PRAs to foster maximal engagement and provide sufficient resourcing to implement these key programs.

3. **What other key policy and program drivers might be incorporated into a future PRA? What performance measures could be incorporated to encourage best practice?**

As discussed earlier, the enabling of PBS-subsidy for hospital inpatients would close the gap on having parallel medicines funding systems occurring in public hospitals, which cause a lot of inefficiency and waste

that does not place the patient at the centre of care. This would also ensure that QUM, medicines safety and medicines access will be fit-for-purpose for all the contemporary healthcare models that continue to evolve. Some examples are:

- Hospital in the home
- Hospital in the nursing home
- Pharmacist-led outpatient clinics
- Aged care outreach programs
- Post-discharge programs to prevent re-admission
- Models of care necessitated by COVID-19 pandemic
- Virtual care models, telehealth models
- District nursing services, community health services and Primary Health Networks

In this context, per our discussion around Recommendation 1, the exclusion of public hospital inpatient access to PBS medicines, but enabled for outpatient access and upon discharge, becomes increasingly not fit-for-purpose and fails to address contemporary needs as hospital care and delivery can no longer be simplified to the inpatient/outpatient binary. Rather, hospital and hospital pharmacy care has the flexibility to be delivered to patients in the setting and circumstances most appropriate to them via a patient-centred approach, and commensurate support from the PRAs is required to maximise investment, medicines safety and QUM of PBS medicines in all settings.

The future PRA should also have a refreshed focus on transitions of care, as it is the immediate post-discharge phase where patients are most at-risk of hospital readmission. The ACSQHC in their report on Safety Issues at Transitions of Care recognised transitions of care as a substantial risk of harm to patients including harms directly caused by medication errors.[7] They identified six areas where prioritisation needed to occur, all of which hospital pharmacists are integral to achieving. These provide a template for where performance measures could be built upon to encourage best practice.

- Improvement in person-centred care
- Better responsibility and accountability for communication at transitions of care
- Better engagement of patients in care planning and communications
- Better access to complete and current health and social information
- Better opportunities for medication reconciliation
- Better discharge planning

SHPA also believes that consistent and high-quality data on medicines use, medicines-related outcomes and pharmacy services should be collected to measure success of PRAs and implementation of APAC guiding principles. This would build on the work undertaken by the Independent Hospital Pricing Authority (IHPA) who collect data on sentinel events, hospital acquired complications and avoidable hospital readmissions, all of which can implicate the inappropriate use of medicines to cause harmful outcomes.

Data relating to medicine-related outcomes is also not collected systematically, with key statistics such as the 250,000 medicine-related hospital admissions annually being pieced together by an extensive literature review. The reporting of adverse events caused by medicines is also undertaken on a voluntary basis. For hospital pharmacists, when adverse events are reported, this often requires a duplication of the same report to both the TGA as well as local incident management reporting systems, which may then be further examined by state governments.

There is also no mechanism to measure or collect data on what extent hospitals are delivering the clinical services described by the SHPA Standards of Practice for Clinical Pharmacy Services to ensure medicines safety and quality use of medicines. Data collection and benchmarking on service provision would allow the Commonwealth and jurisdictions to further understand where service gaps exist and make strong links

between how service provision impacts on the quality use of medicines and medicines access around Australia to achieve the objectives of the PRA and the Guiding Principles. SHPA believes that at a minimum, the following data points relating to medicines use in hospitals should be collected at the individual hospital level:

- Rate of medication reconciliation undertaken within 24 hours of admission
- Rate of daily medication chart review for inpatients
- Incidence of adverse drug events
- Rate of updated medication list/chart provided to patients, carers, and community care providers upon discharge
- Rate of discharge medicine counselling being provided to patients and/or carers

At present, the ACSQHC is undertaking the National Baseline Report on Quality Use of Medicines and Medicine Safety, which is focusing on medicines use in aged care and medication safety in vulnerable populations. The possibility of these reports to be expanded to include data collection on the above parameters in hospitals and health services should be explored.

Finally, a future PRA should also provide sufficient funding and access to hospital pharamcies to provide dose administration aids (DAAs) which are currently a major transitions of care gap, where hospitals are not supported or funded to do so, even when a patient's usual community pharmacy is unable to provide this service on demand, particularly outside of business hours.

Term of Reference 3: Examine recommendations from the Australian Healthcare Associates report PBS Pharmaceuticals in Hospitals Review

SHPA notes there are no questions under this term of reference, however would like to voice in-principle support of the Australian Healthcare Associates report on PBS Pharmaceuticals in Hospitals Review with respect to its findings and recommendations, particularly its suggested consideration of developing a single funder model of medicines in public hospitals, which our Recommendation 1 aims to address.

Term of Reference 4: The Review will examine the patient journey into and out of the public health setting, ensuring consistency with the principles of the quality use of medicines

1. **How has the patient's experience of the continuum of pharmaceutical care changed in the life of current PRAs? Has this experience varied across public hospitals or jurisdictions? If so why?**

As discussed earlier, the continuum of pharmaceutical care has evolved significantly over the life of the PRAs, and contemporary healthcare can no longer be simplified to the inpatient/outpatient binary. The 'patient journey' is no longer a simple pathway back and forth between hospital and community settings, and should be updated to enable quality access to medicines and pharmacy services in all the innovative models of care that have been, are in the process of, or will be developed as contemporary healthcare continues to evolve. Some examples are:

- Hospital in the home
- Hospital in the nursing home
- Pharmacist-led outpatient clinics
- Aged care outreach programs
- Post-discharge programs to prevent re-admission
- Models of care necessitated by COVID-19 pandemic
- Virtual care models, telehealth models
- District nursing services, community health services and Primary Health Networks

Hospital and hospital pharmacy care has the flexibility to be delivered to patients in the setting and circumstances most appropriate to them via a patient-centred approach, and commensurate support from the PRAs is required to maximise investment, medicines safety and QUM of PBS medicines in all settings.

Overall, this experience has varied across different public hospitals and jurisdictions, due to different levels of hospital pharmacy staffing and resourcing investment which are impacted by PRAs, as well as other policies such as Price Disclosure that impact on revenue. In the absence of dedicated funding for hospital pharmacist staffing as per our Recommendation 7, this will continue to be varied to the detriment of patients, and hinder the PRA's ability to meet the principle of being patient-centred and equitable.

An example of this is the extent to which hospital pharmacy departments have hospital pharmacy services provided after traditional business hours and on weekends, where patients are discharged. The services provided at these hours are very variable across the country. Without pharmacists present during these discharges that occur outside of business hours, this can contribute to unsafe discharges, medication errors on the discharge prescriptions not being detected, and contribute to hospital readmission.

2. **To what extent does having access to PBS medicines affect the pharmaceutical continuum of care in public hospitals?**

Having access to PBS medicines improves the pharmaceutical continuum of care in public hospitals, however substantial gaps remain which have been explored in our submission, particularly for public hospital inpatients, Indigenous patients, and patients requiring hospital and hospital pharmacy care outside of

traditional business hours. Without closing these gaps, this will contribute to delayed or lack of access to PBS medicines and increase the risk of hospital re-admission in the immediate post-discharge phase, particularly for vulnerable populations, resulting in a much costlier outcome for the healthcare system if preventable readmissions are realised.

Over the life of the PRAs, due to increasing availability of medicines used for non-communicable diseases and in the prevention of acute healthcare events, patients are on average taking more medicines than patients twenty years ago before the first PRA came into existence. Thus, having access to PBS medicines in hospitals means hospital pharmacists can contribute to the QUM and medicines safety for these patients, ensuring compliance and adherence to medicines that keep patients healthier and reduce the incidence of a major healthcare event and hospital admission. Thus, to further support public hospital pharmacists to achieve these efficiencies and quality improvement for patients and the healthcare system, they must also be supported by the PBS and PRAs to supply PBS medicines to public inpatients.

3. **What data is available to measure the patient's experience of the continuum of pharmaceutical care when moving into and out of hospital?**

There is limited data and resourcing to undertake this work, however this is critical to measure the impact of the Commonwealth's investment into the PBS and PRAs. For many patients who experience a significant healthcare event such as a stroke or heart attack, or are diagnosed with conditions in hospital during an admission, the initial prescribing and supply of PBS medicines in the hospital settings has a major impact on subsequent PBS prescribing and supply in the community setting, which should be of immense interest to the Commonwealth.

SHPA believes theoretically, this could be undertaken by examining Services Australia claiming data with respect to which prescriber types and pharmacy types are prescribing medicines over a time period. This would also allow medicines adherence and compliance to be monitored via PBS data. Related to this, analysis of MBS data can also show whether post-discharge follow-up is occurring, and whether appropriate continuing supplies of PBS medicines are occurring. Theoretically, where non-compliance is occurring according to PBS and MBS data, this could then be linked to hospital admission and readmission rates, to evaluate the impact of these services.

It must also be stated that given many of these medicines are initiated in the public hospital inpatient setting, the use of inpatient medicines will not be reflected in the PBS and MBS data, which means data analysis of medicines use will not provide the complete picture. This would be another benefit of allowing public hospital inpatients access to PBS medicines.

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