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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