

Summary of Submissions
received in response to
the Review of Funding
Arrangements for
Chemotherapy Services:
Discussion Paper

August 2013

TABLE OF CONTENTS

| | | |
|-------|---|----|
| 1 | Purpose | 4 |
| 2 | Executive Summary..... | 4 |
| 3 | Background..... | 5 |
| 4 | Bilateral Discussions | 6 |
| 5 | Responses from Sector Organisations and other Collective Responses..... | 6 |
| 5.1 | Confidential information provided | 7 |
| 6 | General Feedback | 7 |
| 6.1 | General Statistics and Themes..... | 7 |
| 6.1.1 | Statistics | 7 |
| 6.1.2 | Themes | 8 |
| 6.2 | Data..... | 9 |
| 6.3 | Consumer Issues | 9 |
| 6.4 | Models of Care | 10 |
| 6.4.1 | Different Models of Care | 10 |
| 6.4.2 | Professional and Administrative Practices | 11 |
| 6.4.3 | Changes Over Time..... | 12 |
| 6.4.4 | Third-Party Compounding | 12 |
| 6.4.5 | Upstream and Downstream Relationships | 13 |
| 6.4.6 | Clinical Services..... | 14 |
| 6.4.7 | Possible Funding Model Options | 15 |
| 6.5 | Costs and Complexities | 16 |
| 6.5.1 | Differences in Costs and Complexities | 16 |
| 6.5.2 | Possible Options..... | 17 |
| 6.6 | Rural and Regional | 17 |
| 6.6.1 | Differences in Costs and/or Access..... | 17 |
| 6.6.2 | Differences in Consumer/Provider Costs and/or Access | 18 |
| 6.6.3 | Differences in Quality | 18 |
| 6.6.4 | Possible Options..... | 19 |
| 6.7 | Quality | 19 |
| 6.7.1 | Available Guidelines | 19 |
| 6.7.2 | Further Development Suggested | 20 |
| 6.7.3 | Mandatory Standards..... | 20 |
| 6.8 | Other Matters | 21 |
| 6.8.1 | Administrative Concerns | 21 |
| 6.8.2 | Suggested Improvements | 21 |
| 6.9 | Additional Issues Raised | 21 |
| 6.10 | Feedback Methodology..... | 22 |
| 7 | Summary/Conclusions..... | 22 |
| | Attachment A – Alternative Suggestions and Comments Raised Within Responses | 23 |

1 Purpose

The purpose of this report is to provide the executive with information on the themes and trends of responses to the public request for feedback on the Discussion Paper on the Review of Funding Arrangements for Chemotherapy Services.

2 Executive Summary

The Government has directed the Department of Health and Ageing to undertake a comprehensive review of chemotherapy funding arrangements. A Discussion Paper was released on 29 June 2013, seeking public comments, and key stakeholders provided submissions between 22 July 2013 and 31 July 2013.

Thirty submissions were received, including: fourteen responses from sector organisations; three responses from consumer groups; two responses from groups of medical specialists; two responses from compounders, and three State Government responses.

The pharmacy, hospital, medical, consumers and compounding sectors are well represented by the range of submissions received.

In general, the pharmacy sector and consumers welcomed the further review following the Senate Inquiry, seeking further, specific information as well as a consumer perspective.

There were a range of different models of care provided, and a host of different professional and administrative activities described to support these models.

Submissions also identified that there has been noteworthy change in chemotherapy arrangements over the last decade or so, with the majority enabling greater access for patients, and higher standards of safety.

While the majority of those that had a view about the fees currently paid for chemotherapy services consider them to be too low, there was limited data provided to support this. Key issues that will need to be explicitly addressed by the Review Team include:

- Compounding costs;
- Dispensing and administrative costs
- Clinical services;
- Consumables and devices; and
- Freight.

With regard to rural and regional differences, it is reassuring that providers are of the view that the quality of services does not differ generally between urban and regional areas, and that additional costs in relation to freight do not get passed on to regional cancer patients.

The range of standards and guidelines identified through these submissions was substantial, and it is clear that the pharmacy sector is active in this space, with further development underway.

There was support for mandatory standards to be linked to payment, and suggestions that this review take account the parallel review of the reform of the regulatory framework for pharmacy compounders underway by Therapeutic Goods Administration (TGA).

It is clear that any attempts by the Government to simplify administration would be well received by the sector. This could include: consideration of paperless claiming; consideration of extending streamlined authorities; clarifying business rules, such as ‘in good faith payments’ and unavailability of most efficient vials; and following up where drugs cannot be purchased at ex-manufacturer price.

3 Background

The Government has directed the Department of Health and Ageing to undertake a comprehensive review of chemotherapy funding arrangements (the Review), with a view to putting in place a longer term solution to recent issues that have been raised.

The aim of the Review is to maximise the benefits consumers receive from chemotherapy infusions by ensuring efficient and effective clinical processes and appropriate funding arrangements for the preparation and supply of chemotherapy medicine infusions.

Formal Terms of Reference for the Review are available on the Department’s website <http://www.health.gov.au/chemo-review#ToR>.

In October 2012, stakeholder groups started raising concerns about the possibility that upcoming price reductions to the drug Docetaxel in October 2012, and other drugs in the April 2013 round of Enhanced and Accelerated Price Disclosure, would make the delivery of chemotherapy services unviable. This spurred work by the Department to review the costs involved in delivering chemotherapy infusions, and the range of clinical and business services associated with chemotherapy services.

Subsequent to this, it was announced on 7 February 2013 that matters pertaining to the supply of chemotherapy drugs in Australia including the drug Docetaxel would be referred to the Senate Community Affairs Committee for inquiry. Many stakeholders made submissions and representations to this Senate Inquiry, and the submissions are publicly available on the [Senate Committee Website](#):

The Department commenced an extensive consultation process in the latter part of 2012 which is continuing through 2013. A Discussion Paper was released on 29 June 2013, seeking public comments. This Discussion Paper is also available on the Department’s website. Stakeholders were informed that the Department would be considering the information provided to the Senate Inquiry, so stakeholders would not need to duplicate their submissions.

The Discussion Paper sought information in relation to a wide range of issues, in order to inform future funding options for chemotherapy services, and also provided a template for the provision of data, to support the views provided.

Key stakeholders and other interested parties were asked to provide feedback to the Discussion Paper, either through formal submissions, or through meetings, by 29 July 2013. Responses were received between 22 July 2013 and 31 July 2013.

4 Bilateral Discussions

It should be noted that the Review Team has also undertaken extensive bilateral meetings and teleconferences with a significant number of respondents, as well as some stakeholders who did not provide a submission in response to the Discussion Paper. These bilateral discussions, which have provided more detailed information, context and insights to the provision of chemotherapy services, are not recorded as part of this summary.

5 Responses from Sector Organisations and other Collective Responses

There were eleven collective responses from pharmacy organisations:

- APHS Pharmacy Group
- Community Pharmacy Chemotherapy Services Group
- Joondalup and Southwest Hospital Pharmacies
- Mater Hospital Pharmacy
- Medicines Australia
- National Pharmacies
- The Pharmacy Guild of Australia (the Guild)
- Slade Pharmacy Services
- The Society of Hospital Pharmacies of Australia (SHPA)
- Sydney Adventist Hospital Pharmacy
- Wesley Pharmacy

There were three collective responses from the hospital sector:

- Australian Private Hospital Association (APHA)
- Catholic Health Australia (CHA)
- UnitingCare Health (UCH)

Collective responses were received from three consumer groups:

- Breast Cancer Network Australia
- Cancer Voices Australia
- CanSpeak

In addition, two joint submissions were provided by the following four groups of medical specialists:

- Clinical Oncological Society of Australia (COSA) and Cancer Pharmacists Group (CPG) – joint submission
- Medical Oncology Group of Australia (MOGA) and Private Cancer Physicians of Australia (PCPA) – joint submission

A response was provided by ICON Cancer Care, a vertically integrated practice where doctors, treatment, pharmacy and research are co-located at all of their day hospitals.

Two TGA-licenced compounders also provided submissions:

- Baxter
- Fresenius Kabi

Two collective responses were also received from other interested stakeholders:

- Cancer Australia
- Healthcare at Home

QLD, SA and TAS State Governments also provided submissions to the review, along with private health insurers, BUPA and Medibank Private.

The pharmacy, hospital, medical, consumer and compounding sectors were well represented by the range of submissions received.

5.1 Confidential information provided

While the majority of submissions provided were publicly available, there are some that have requested confidentiality. On this basis, the comments provided have been de-identified, or in some cases, removed from this report.

Each of the public submissions are available on the Department's website:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/chemotherapy-review>.

A summary of each group's response and a summary of each submission were developed, but are not provided as part of this public document due to the confidential information provided.

6 General Feedback

The analysis of the feedback provided in the submissions has been categorised under the key topics of the Discussion Paper, i.e:

- **Consumer issues:** Impacts to access or quality of chemotherapy medicine infusions;
- **Models of care:** How chemotherapy medicine infusions are provided, the role of each sector, and how services and funding roles have changed over time, and views on possible funding options;
- **Costs and complexities** involved in the provision of chemotherapy drugs;
- **Rural and regional** chemotherapy provision;
- **Quality** of infusion preparation; and
- **Other matters** pertinent to funding for chemotherapy infusion preparation.

A number of alternative suggestions and comments were also provided, and these are listed at **Attachment A**.

6.1 General Statistics and Themes

6.1.1 Statistics

There were 30 responses in total, consisting of:

| Number of responses | Percent of responses | Classification of respondent |
|---------------------|----------------------|--|
| 11 | 36.7% | Pharmacist/ pharmacy association |
| 4 | 13.3% | State government/ government agencies |
| 3 | 10.0% | Hospitals/ hospital association |
| 3 | 10.0% | Consumers/groups |
| 2 | 6.7% | Medical specialists/ medical association |
| 2 | 6.7% | Compounders/ third-party compounders (TPC) |
| 2 | 6.7% | Private Health Insurers |
| 2 | 6.7% | Profession not indicated/ other |
| 1 | 3.3% | Vertically integrated practice (providing a range of medical, pharmacy and hospital services under common ownership) |

Twenty nine responses were collective or organisational responses, with only one response from an individual. No drug companies or logistics firms provided submissions to the Discussion Paper.

All of the responses were received via e-mail, with some information also provided during bilateral discussions.

6.1.2 Themes

While there was significant and expected variation in models of care across health care settings, private and public sectors, and use of in-house or third-party compounders, there was a degree of consistency in relation to the proposed funding model preferred by the sector.

| Number of responses | Percent of responses | Topic |
|---------------------|----------------------|---|
| 22 | 73.3% | Views on possible funding options |
| 20 | 66.7% | Identifying other matters not specifically identified in the Discussion Paper |
| 18 | 60.0% | Describing model/s of care |
| 17 | 56.7% | Suggestions to improve administrative processes |
| 16 | 53.3% | Identifying changes over time |
| 15 | 50.0% | Describing components of dispensing and clinical services |
| 15 | 50.0% | Identifying the current range of guidelines and standards |
| 14 | 46.7% | Describing professional and administrative practices |
| 14 | 46.7% | Describing third-party compounder involvement |
| 12 | 40.0% | Describing upstream and downstream arrangements |
| 12 | 40.0% | Identifying further development of guidelines required |
| 11 | 36.7% | Identifying increased consumer costs in rural and regional areas |
| 10 | 33.3% | Identifying concerns about current administrative processes |
| 9 | 30.0% | Identifying different arrangements for rural and regional areas |
| 9 | 30.0% | Suggested changes to support rural and regional areas |
| 8 | 26.7% | Identifying differing compounding costs |
| 7 | 23.3% | Describing differences in quality services in rural and regional areas |

Summary of Submissions – Discussion Paper

| | | |
|---|-------|---|
| 7 | 23.3% | Views on whether standards should be mandatory |
| 6 | 20.0% | Describing change in access or quality for consumers |
| 6 | 20.0% | Views on possible options for different compounding costs |

Summary of each of the themes, below, is along the lines of the questions posed in the Discussion Paper.

6.2 Data

The Discussion Paper requested that respondents to substantiate their views by providing data. A template for collecting data was provided on the website so that consistent data could be captured.

Only a small number of submissions provided data in support of their views. Five of the thirty submissions provided information in the table provided, three of which completed all relevant sections of the template. Data was provided by:

- Two pharmacy compounders (one provided costs for compounding at two hospital sites);
- Two private hospitals; and
- One third-party compounder.

Data was not provided by public hospitals.

In addition to data provided in the template, some submissions included selective cost data, such as profit/loss information (on individual drugs, or overall business costs), the cost of infusions and suggestions for additional funding. Further, a number of submissions commented on what they believe to be the appropriate level of remuneration per chemotherapy infusion. One submission provided a commissioned report examining the impact of price disclosure on community pharmacies. Some additional data has also been received through bilateral discussions and requests to interested parties, however, the total amount of data provided remains low.

The paucity and spread of the data make it difficult to determine an accurate average cost per infusion. Further, for a number of reasons, different providers will have different costs associated with the preparation and provision of chemotherapy medicines. For example, large third-party compounders may have a lower cost per infusion than smaller compounding pharmacies.

6.3 Consumer Issues

Six respondents (20%) provided comment in relation to the consumer question seeking to understand whether there have been any issues that have impacted on access to or the quality of chemotherapy infusion medicines.

Three submissions referred to the achievements of Regional Cancer Centres and their potential to reduce geographic inequity, with one respondent encouraging government coordination to underpin their sustainability.

While none of the responses actually identified any specific issues, three respondents noted their concerns that further price reductions could impact on: the cost of care; patient access; and quality of services provided.

One submission noted a concern that public patients in NSW public hospitals and a single

public hospital in QLD are required to pay a PBS co-payment, while public hospitals in other jurisdictions are not levying this charge. The Review Team notes that there is only one PBS

co-payment¹ on each original chemotherapy prescription and no co-payments for PBS chemotherapy repeat prescriptions for public hospital patients.

To access any medicine through the PBS the medicines must be accessed through a community pharmacy, a private hospital or a public hospital in a jurisdiction that is a signatory to the Pharmaceutical Policy Reform Agreement. NSW is not a signatory to this Agreement, and so PBS-subsidised medicines, including for chemotherapy, are only accessible in NSW through community pharmacy or private hospitals.

6.4 Models of Care

6.4.1 Different Models of Care

Eighteen respondents (60%) describe the model of care for the provision of chemotherapy medicine infusions that apply in their respective healthcare sector or their particular institution or organisation. There are different models of care for patients receiving treatment in urban and regional/rural areas. Patient care models also differ between, public and private settings, hospitals and clinics, and states and territories. There is also variation based on individual business models. Universal elements of all models of care are preparation and dispensing of chemotherapy drugs. Chemotherapy funding arrangements vary by hospital, ownership, compounders, and case-mix, and financial outcomes vary accordingly.

Variation in providers that contributed information included:

- Public hospitals that provide public and private (day admitted) services.
- Private hospital offering a broad range of cancer treatments including bone marrow transplants, haematology, oncology and palliative services, which is also co-located with a day hospital that provides infusion services. The day hospital can refer a patient for admission if they require overnight care.
- Community pharmacy co-located with private hospital that engages specialised oncology pharmacists and a support technician to dispense outsourced chemotherapy drugs to hospital patients receiving treatment as inpatients in oncology ward or day patients through the day infusion centre.
- Community pharmacy with TGA-licensed compounding facility which provides compounded drugs to customers which include regional hospitals, day hospitals and other community pharmacies.
- Community pharmacies with TGA-licensed compounding facility that provides chemotherapy preparation, distribution, supply, management, clinical advice to patients and hospital staff, dispensing, counselling, coordinating, checking and monitoring of side-effects.
- Specialist provider of home infusion, injection and medication management services, designed to minimise the burden of travel for cancer patients.
- TGA-licensed compounding facility that manufactures chemotherapy products and delivers to other facilities.
- Vertically integrated practice where doctors, treatment, pharmacy and research are co-located at private day hospitals.

It is also clear that there is variation in treatment protocols, determined at local/hospital level.

¹ [PBS Website](#)

6.4.2 Professional and Administrative Practices

Fourteen submissions (46.7%), described the professional and administrative practices across the range of health care providers that contribute to the provision of chemotherapy medicine infusions, for their respective model/s of care in their specific healthcare sector or facility. However, it should be noted that many submissions were unable to sufficiently separate the core dispensing and PBS administration activities from the specialised clinical services appropriate for chemotherapy provision.

One submission claimed adherence to SHPA standards of care (oncology) and COSA guidelines, where: the oncologist determines treatment plan; the pharmacist checks the treatment regimen, interviews patient, orders, receives and checks medication, reviews patient parameters, and provides pre-treatment medicines, infusions and monitoring; and the nursing staff administer the drugs.

Two further submissions shared that the oncologist determines treatment plan on the medication chart, orders and later prescribes the chemotherapy drugs. The hospital oncology pharmacist liaises with the community pharmacist, and checks the order against medication chart and available history. The oncology nurse confirms patient parameters and provides pre-treatment medicines, administers the infusions and monitors for adverse events.

Three other submissions added that once the oncology order is transferred to the pharmacy, the pharmacy team checks the order for accuracy and completeness, reviews protocols against patient parameters, checks previous effects and other medications, interviews the patient to assess suitability, lodges the drug order with the compounder; double checks the infusion on return; educates patients (with one noting that the pharmacist visits patients in clinics to assess drug side effects), where the nursing team checks the drugs again prior to administration, provides the infusion, and coordinates patient scheduling and orders.

An alternative model was described as follows: Referrals from GPs are reviewed by a triage team of haematologist/oncologists. Patients referred to a multidisciplinary team (oncologists, radiologists and surgeons) for development of a treatment plan. The medical team book treatment and discuss plan with the clinical pharmacists and nurses. The clinical pharmacist provides verification process (up to 20 minutes per patient). The medicines are ordered and compounded. The doctor or nurse performs a toxicity assessment for each patient during treatment and before each new chemotherapy cycle.

It was also noted that in any model of care, preparation, dispensing and clinical costs are inextricably linked. As per the Pharmacy Board of Australia's guidelines for dispensing of medicines, checking chemotherapy protocols prior to ordering from a compounder must be considered as part of dispensing.

Professional activities undertaken by pharmacists were described in one submission as including: clinical verification of drug order; checking dose/protocol against patient parameters (height, weight, bloods, body surface area (BSA), etc.); clarification and resolution of issues; accurate dispensing and patient education; infusion preparation; and safety. Administrative activities undertaken by pharmacists were described as including: purchasing and storage; managing scripts and authorities; managing drug charts; compiling treatments; ensuring timely delivery; validation of patient, dose, drug; updating files; and dispensing.

One submission also noted that their single clinic can have a combination of public and private patients at any time, which creates administrative complexity. However, the Review Team note that this issue is the choice of that particular provider, and is not one that can be addressed through this Review.

Of note was one comment that clinicians have concerns for patient safety where supply of chemotherapy to private clinics is outsourced, as the hospital has no control over the quality of the product and clinical pharmacy input is not provided. To address this, where hospitals do in-house compounding, the clinical pharmacy service is provided to public and private patients, at the expense of the public sector.

6.4.3 Changes Over Time

In response to whether there have been any changes to the provision of chemotherapy medicine infusion services over recent years, sixteen respondents (53.3%) collectively noted that there have been a range of changes over time, including:

- A significant shift of chemotherapy services from the public to the private setting. Day procedure centres have been established. Hospital in the Home is used, where appropriate;
- Growth in the use of chemotherapy agents in early and advanced stages of cancer care;
- New targeted and immunotherapy drugs are emerging (referred to as personalised medicine), increasing patient access to new therapies;
- Increased use of patented drugs, which have a higher purchase price and subsequent risk;
- The number of complex chemotherapy regimens has increased significantly over the last few years with an impact on the resources required to both clinically verify prescriptions and to compound infusions;
- With the availability of new, more expensive, more complex drugs, there is more pressure on pharmacists to double check that everything is right;
- A significant shift in the role of the pharmacist, which now spans reconstitution and dispensing, along with patient support and physician interaction;
- A trend towards more rigorous regulation and standards for compounders, which has increased compliance costs;
- Greater sophistication in technological and administrative practices for chemotherapy management, such as the CHARM platform (which is an oncology information management solution for cancer care clinical coordination and management²);
- A growing trend towards closed system transfer devices for staff safety; and
- The introduction of price disclosure.

6.4.4 Third-Party Compounding

Fourteen submissions (46.7%) provided information in relation to how third-party compounders are incorporated within business models, and/or reasons for the decision to involve a third-party compounder.

With regard to hospital business models, private hospitals have three categories: 1. undertake their own in-house compounding; 2. use third-party compounders to supplement their own services; or 3. purchase all of their compounding services externally. Public hospitals have

² Charmhealth accessed 15 August 2013

the same three categories, but some purchase compounding through state-wide contracts with third-party compounders.

The stated reasons to undertake in-house compounding include: to minimise the risk of supply interruptions in regional areas; short shelf-life drugs; urgent requests (including for clinical trials); and compounding drugs that cannot withstand transport.

Reasons not to undertake in-house compounding include: geographic location; upfront investment of capital; ongoing investment and running costs; infrastructure; cost of quality assurance processes, compliance and regulation; the need for specialised staff, extended training needed, and recruitment and retention issues; patient volumes and case mix; lack of space. Third-party compounders can assign longer expiry dates to products due to rigours of stability testing, maximise efficiencies of scale; and produce large batches with longer shelf-life.

Identified outsourcing challenges include: extensive coordination for last minute dose amendment; additional fees for preparation of and delivery of infusions on weekends (\$750); vulnerability to price change, with one respondent noting that their third-party compounder has not reduced prices to match reduced remuneration, and another noting that some pharmacists are reverting to supply from non-TGA licensed compounders to reduce costs.

Responses from third-party compounders note that they provide sterile, quality compounded products and manage orders placed daily, or sometimes multiple times a day. These compounders purchase and store medication; prepare infusions; provide information to dispensing pharmacists on product stability, ingredient compatibility and shelf-life; and arrange delivery. Their view is that economies of scale make more extensive establishment of compounding facilities unviable. They recognise that their services are used because the investment to establish an in-house compounding facility is significant, and recurrent costs are onerous.

6.4.5 Upstream and Downstream Relationships

Twelve respondents (40%) provided information on contractual or business arrangements in place with other upstream and/or downstream parts of the same healthcare sector. A range of relationships were identified:

Third-party compounders

Compounders have contractual relationships with hospital/pharmacy customers, including state-wide contracts in some states for all public hospitals. Contracts can be for the provision of manufactured chemotherapy infusions and dispensing, or just for the manufactured chemotherapy infusions. Contracts are negotiated with varying pricing, ordering and delivery arrangements.

Pharmacies

Section 90 community pharmacies negotiate contracts with hospitals. One respondent indicated that this is typically for a period of 3-5 years, and financial contribution is variable depending on the case-mix and occupancy of the hospital.

Private health insurers

Hospitals have funding agreements with private health insurers. However, it was noted that these do not recognise administrative or clinical pharmacy services so hospitals are required to absorb additional costs.

Vertical integration

A vertically integrated business entity owns pharmacy services, cancer care services that provide oncology and haematology services, and day hospitals, and has contractual relationships with compounders and private health insurers.

Home-based care

One home-based care provider has contractual arrangements with private health insurers for providing the infusion to the patient.

6.4.6 Clinical Services

Fifteen submissions (50%) described the components of dispensing and clinical services provided by pharmacists in relation to infusible chemotherapy medicines.

Variously, clinical services are described as including: collation of orders; checking doses and protocols against patient parameters; documentation; patient support, information and counselling; ordering infusions; managing stock expiry and clinical trials. These services are undertaken by specialised staff. One submission noted that components of dispensing and clinical services are well established and documented in SHPA standards and COSA guidelines.

There was support for clinical services to be separately identified and funded by the Commonwealth under a new chemotherapy funding model. However, one private health insurer noted that health insurance funding covers many aspects of chemotherapy care beyond drugs: accommodation; nursing; other staff; and devices as per the Protheses List (such as CADD).

Three submissions stated that specialised clinical services are undertaken by the pharmacist. One stated the functions include: medication action plan for each patient, for each cycle; documentation of complex dose calculations; stability checks; drug interactions; drug-disease interactions; drug toxicity assessments; patient counselling and the provision of supportive care drugs. Another provided information demonstrating the complexities of delivering infusion chemotherapy and the highly specialised clinical role of pharmacists, which includes: patient engagement and education; and confirmation of dosing and protocol. The third noted that clinical pharmacy services is an integral component of patient care, with pharmacists responsible for oversight of the clinical assessment of chemotherapy protocols with a focus on patient safety, and ordering preparation and distribution of chemotherapy medicines. They also noted that the Independent Hospital Pricing Authority (IHPA) has recently introduced a clinical pharmacy attendance payment of \$233 under Activity Based Funding (ABF) for public hospitals. However, the Review Team note, through further investigations, that this fee is for non-admitted medication review services³.

On the other hand, one consumer group suggested that patients are not aware of direct assistance from pharmacists, in any setting, and indicated their concern that there is no

³ [SHPA Website](#) accessed 21 August 2013

guarantee of these services being provided even if they are funded. They also indicated their concern that these services may vary considerably between institutions.

An alternative view was that the clinical services described above are undertaken by the oncology nurse in public hospitals (for both public and private patients) following the oncology pharmacist's double check of the order against the patient history, treatment plan and available pathology.

More generally, views were provided on the value of clinical services include:

- Advanced care pharmacists are intrinsic to safe delivery of drugs. They perform a complex series of functions to prepare drugs for individual patient needs, providing expert input and safety checks.
- It is widely acknowledged that specialised oncology pharmacists are vital to the safe and timely administration of chemotherapy.

6.4.7 Possible Funding Model Options

Twenty two submissions (73.3%) provided suggestions in relation to possible options for the professional services for the provision of chemotherapy medicine infusions or possible funding models.

With regard to possible funding models, there was a general view that the future funding model must include recognition of the costs of safely preparing and dispensing, using specialist staff, equipment and consumables. Alternatively, one private health insurer does not believe PBS should be extended to cover costs of containers provided in hospitals, as some insurers already cover these in different ways. Most submissions provided their view on elements that should be included in a preferred funding model.

Two respondents identified their preference for explicit funding for four elements of:

- 1) cost of chemotherapy medicine;
- 2) cost of the preparation for infusions (including consumables, devices, diluents);
- 3) direct and indirect costs (labour, safety processes, toxic waste, etc); and
- 4) pharmacists clinical review cost.

One of these respondents noted that public hospitals should be eligible for elements 1, 2 and 3 (as these hospitals are already funded for provision of clinical services), where community pharmacy providers and private hospitals should be eligible for all four elements.

Alternatively, one submission recommends fees at \$100 per infusion based on funding for five elements (in addition to drug cost) of: 1. infusion fee; 2. wholesaler fee; 3. unusable portion factor; 4. clinical services fee; 5. treatment chart as script.

Three other submissions identified an additional fee of \$100, seeking \$40 in addition to existing increase of \$60. One of these suggested a flat fee is not appropriate and preferred a fixed \$60 plus variables, noting that \$15 should be for preparation in a licensed facility and 7% distribution fee should replace \$24 per infusion. Another of these submissions suggested the additional \$40 should be disbursed as \$25 for core service provision and addressing the perceived mark-up anomaly, and \$15 for clinical services. Their view was that public hospitals should not get the clinical services fee, as they provided this service in-house.

Another submission suggested a clinical services/dispensing fee of \$52.36, and licensed manufacturer fee of \$86.42. They also proposed an additional \$40 for complex compounding (MABS), and complex freight (time-sensitive).

Another submission offered an alternative model comprising of four broad categories of compounding complexity, with remuneration scaled depending on the complexity of the process involved, and includes fees for specialised containers or rate limiting devices. Their view is that Prostheses List funding options should be considered for devices.

Four respondents suggested that the payment model should be consistent across community, public and private hospitals.

With regard to explicit payment for clinical services provided by pharmacists, three submissions (in addition to those described already) were of the opinion that a clinical service component is needed in a future funding model. Submissions also noted:

- Payment for pharmacy clinical intervention has recently been recognised and funded per Home Medicine Reviews (HMR).
- Pharmacists that provide services to specialised cancer units are not general pharmacists, but specialists, and are remunerated at a higher rate accordingly.
- Clinical services could be connected with standards and compliance.
- An MBS-type item, or HMR/MedsCheck-type item could be developed.
- IHPA could include a clinical services loading to acknowledge increased costs.
- Clinical payment per infusion would be more efficient than per cycle.

With regards to current costs, one submission identified the cost of preparing an in-house infusion is \$102.12, or \$137.82 if using a third-party compounder, with another stating current dispensing costs average \$70, but the fee is \$26.52 (dispensing and distribution fee).

Two submissions recommend a fee paid direct to the manufacturer and subject to regulation.

One submission also suggested that every dose for every patient should be checked by a chemo competent pharmacist to ensure safety.

With regard to professional services, there was support for development of national standards of care, which is expanded on later in this report. There were also views on simplification of administration, which is also addressed later in this report.

Finally, one state government provided their view about a discrepancy in the Pharmaceutical Reform Agreement that means private (overnight) admitted patients in public hospitals cannot have chemotherapy drugs supplied by onsite public pharmacy under PBS funding, which they believe should be amended. However, the Review Team notes that this is not a discrepancy, but the intention of the agreement.

6.5 Costs and Complexities

6.5.1 Differences in Costs and Complexities

Eight respondents (26.7%) identified differences in the processes or costs of compounding certain infusible chemotherapy medicines.

Two respondents indicated that chemotherapy is more complex to compound than other drugs (toxic, sterile, temperature, insulated packaging for transport, special equipment, training, protective clothing, etc.) to ensure safety of the patient and the compounder. It was suggested that the average time taken to reconstitute a chemotherapy infusion is between 15-30 minutes. Another respondent indicated that costs vary from hospital to hospital depending on their respective practice and the equipment used.

Four respondents noted that some specific medicines involve significantly different methods and take much more time to dispense than others, due to stability, chemical or biological composition, and require special and different handling. Examples provided include: paclitaxel; cyclophosphamide; gemcitabine; trastuzumab; azacitidine; bortezomib; and CADD cassettes. One respondent identified that variation in complex cytotoxic preparation can also relate to the method of dissolution or container type, noting that vial breakage or bung coring adds to the cost and that drugs with short expiry times pose logistical challenges.

6.5.2 Possible Options

Six (20%) submissions describe a possible alternative funding model for these medicines, with two respondents suggesting differential fees taking into account additional time, difficulty and consumables. One of these suggested four broad categories of compounding complexity:

- 1) One step manipulation
- 2) Two step manipulation (no reconstitution/dilution or reconstitution/no dilution)
- 3) Three step manipulation (reconstitution, draw up syringe, dilution)
- 4) Complex manipulations, e.g. infusors which require a complex dispensing process to fill.

Another respondent indicated that a single source provider for complex compounding (centre of excellence) could reduce costs. Other suggestions sought additional fees for temperature-controlled packaging, for complex compounding (\$40), and to compensate for commercial risks involved in handling higher cost medicines.

6.6 Rural and Regional

6.6.1 Differences in Costs and/or Access

Nine submissions (30%) identified differences in the costs or processes for providing chemotherapy services in rural and regional areas and the effect on accessibility of services.

Three respondents noted the increased fixed costs per item in regional and rural areas due to issues such as: lower production; higher costs for recruiting, training, scarcity of labour, quality assurance, waste disposal, delivery, and maintenance costs; and the need to maintain higher inventory levels to ensure timely services in regional areas. One of these respondents provided a comparison between their similar regional and metropolitan facilities, quantifying that the regional facility costs are more expensive by \$10 per infusion.

Additional costs for freight were identified by other respondents, with one compounder stating that they absorb around \$500 per week in costs for delivery to regional locations and \$100 per infusion for short shelf life items that require the dose to link with a flight or courier to ensure it is available for the patient.

Other respondents indicated that there is an additional administrative burden associated with synchronising patient appointments with third-party compounder chemotherapy delivery schedules, synchronising flights and couriers, and logistics associated with advance orders.

Some responses noted concerns for patient access if private hospitals cease providing chemotherapy services in regional areas, as metropolitan hospitals would struggle to cope with flow-on patient increases, and the possible threat to Regional Cancer Centres.

One submission suggested that the existing funding model encourages consolidation to major regional and metropolitan areas.

6.6.2 Differences in Consumer/Provider Costs and/or Access

Eleven submissions (36.7%) discussed extra additional costs to consumers or providers or other factors that limit access to services in these areas.

Seven respondents identified that travel costs are higher for consumers, with three of these respondents also noting that accommodation costs and additional time away from paid employment would impact consumers. It was identified that doctor/hospital choices are more limited in regional areas, but patient costs are equitable regardless of location. One respondent noted that country consumers are generally shielded from extra costs by the pharmacy and/or hospital absorbing some charges, with another noting that a third-party compounder has increased charges per infusion by \$85 to some regional areas in last 12 months.

One submission noted that ‘there are potential additional costs to the consumer/patient for chemotherapy and supportive medicines arising from different interpretation of the PBS business rules between pharmacy services (e.g. definition of a ‘small supply’) especially if some of these medications are supplied from the private/retail sector’. This issue was not clear to the Review Team, and was clarified during a bilateral discussion as referring to different co-payments charged by different state hospitals. This is not an issue for the Review.

One submission referred to the COSA analysis that shows that the further away from large regional or metropolitan areas a patient is, the poorer their access is to chemotherapy.

Additional costs for providers were identified as higher costs for recruitment and salaries, training and assessment, travel expenses for specialist staff, reduced purchasing power, and increased administration to support consistent service delivery, noting that patients in rural centres require proportionately higher allocation of clinical service costs than those in urban centres. One respondent noted that ABF funding doesn't meet the costs of increases in nursing and ancillary staff provision.

Two compounders noted that additional costs for temperature validated transport are not passed on to clinics, with one noting that costs of freight to rural and regional areas can be as high as \$3,250 for a 7 day chemotherapy cycle.

6.6.3 Differences in Quality

Seven submissions (23.3%) commented on whether quality of services vary in rural and regional areas compared to more urban areas.

Three providers stated that there is no difference in quality of their services across locations, with another provider noting that no change to quality is intended, but this can be challenging. One further provider noted current resource constraints can mean that meeting standards can be challenging.

Two responses referred to Australian Institute of Health and Welfare (AIHW) evidence that regional and rural areas experience significantly higher mortality rates from cancer.

6.6.4 Possible Options

Nine submissions (30%) identified changes that could be made to current pharmacy funding arrangements to address rural and regional access issues. Suggestions included:

- A subsidy payment or rural loading similar to IHPA's existing loading to acknowledge increased costs.
- Continue paying for wasted (unused) chemotherapy in good faith.
- Explore options to enable self-administration of subcutaneous doses for regional patients, where appropriate.
- A fee to cover freight, a freight allowance for suppliers, or a freight allocation to regional hospitals.

6.7 Quality

6.7.1 Available Guidelines

Fifteen submissions (50%) commented on the extensive range of relevant guidelines and standards that apply to chemotherapy services across States and Territories, how these standards are enforced and how adverse events are reported. Guidelines and standards identified included:

- Society of Hospital Pharmacies of Australia standards of practice and guidelines
- Clinical Oncology Society of Australia guidelines
- Pharmaceutical Inspection Convention and Co-operation Scheme (PICS)
- Therapeutic Goods Administration Good Manufacturing Practice Standards
- Pharmacy Board of Australia's licensing requirements, and guidelines for dispensing of medicines
- Pharmacy Guild's Quality Care Pharmacy Program (QCPP)
- Pharmaceutical Society of Australia (PSA) Professional Practice Standards
- Peter Mac standard operating procedures
- Worksafe protocols
- State and territory hospital licensing requirements and standards
- Hospital accreditation processes and requirements; including poisons regulation; waste disposal and building requirements
- SA Health Safe Handling Guidelines
- Australian Council on Safety and Quality in Health Care (ACSQHC) standards
- Internal policies and procedures
- International standards (ISO) for medical devices and cleanrooms

With regard to compliance, audit activities identified for providers include: self-audit using tools such as ISMP International Medication Safety Self-Assessment for Oncology, and peer benchmarking; and internal audits. It was noted that TGA enforces PICS guides and

Summary of Submissions – Discussion Paper

undertakes audits for compounders who are accredited manufacturers under the Therapeutic

Goods Act. DHS-Medicare and state pharmacy boards also undertake audits. It was noted in some submissions that broader regulation for compounding pharmacies is currently being considered by TGA.

Submissions also noted that adverse drug events are also monitored and reported to the Advisory Committee of the Safety of Medicines (ACSOM).

6.7.2 Further Development Suggested

Twelve submissions (40%) provided views as to whether further development of current standards is required.

Five respondents recommend the establishment of a national set of guidelines for standards of care for all chemotherapy providers to be measured and accredited against. It was also suggested that the development of a Pharmacy Board/Pharmacy Authority audit framework would be needed to ensure compliance with standards. Further development was suggested in relation to: guidance for preparation of MABS; evidence for closed system devices to inform practice; formalised cytotoxic manufacture competency-based training or credentialing; and a national competency-based training program. It was suggested that the Pharmacy Guild Quality Care Program (QCPP) could be expanded to involve audit of sterile and cytotoxic compounding, and noted that SHPA are currently developing tools to assess competency for oncology pharmacists.

Four submissions commented on regulation of compounders, with one suggesting there should be better regulatory oversight of non-TGA licensed compounders, and two respondents of the view that standards applied to third-party compounders should also apply to in-house compounders. One response provided support for mandatory regulation of compounding pharmacies by a professional body (e.g. Pharmacy Board). It was also recommended that the outcomes of this review should align with the TGA review outcomes.

One submission provided the view that further safety and accreditation requirements are not needed for hospitals.

6.7.3 Mandatory Standards

Seven submissions (23.3%) commented on whether meeting standards should be a mandatory requirement for Commonwealth funding, with four respondents of the view that standards should be mandatory, and five of the view that standards should be linked to Commonwealth funding, one submission provided a further view that TGA licensing should provide access to a higher level of Commonwealth funding.

In relation to how standards could be enforced, suggestions were to include them within existing ACSQHC national standards; and enforced through the existing TGA, Pharmacy Board/Authority audit framework.

It was noted that the requirements to meet Australian Pharmaceutical Advisory Council Guidelines are already in the Pharmaceutical Reform Agreement between States and the Commonwealth.

An alternate view was that extending TGA compounding requirements to all compounders would unnecessarily eliminate small compounders, when there is no evidence of non-compliance with standards.

6.8 Other Matters

6.8.1 Administrative Concerns

Ten respondents (33.3%) identified concerns in relation to current administrative processes surrounding the provision and claiming of PBS chemotherapy medicines and infusions.

Seven of these submissions referred to the administrative paper burden relating to paper scripts, with one also suggesting that the online prescribing trial should be evaluated, and another noting that a dedicated technician is employed to undertake billing and dispensing activities, such as chasing PBS scripts. Submissions also noted that chemotherapy drugs not being available on streamlined authorities creates a burden.

6.8.2 Suggested Improvements

Seventeen respondents (56.7%) made suggestions to address administrative concerns.

The majority of these recommended removing paper scripts and use drug charts, as well as eleven recommending that all oncology items should be streamlined authorities. Two submissions suggested that e-prescribing should be implemented.

Two submissions noted that requesting Herceptin under the late-stage metastatic breast cancer program should be simplified, as processes are different, time consuming and convoluted. However the Review Team note that this is not a PBS issue and non-PBS issues cannot be addressed in this Review.

One respondent suggested that wastage where treatment is cancelled or changed at the last minute should be paid for under the PBS.

Five submissions are seeking the Section 90 pharmacies mark-up algorithm to be corrected and two of these are also seeking an amended mark-up for Section 94 pharmacies

One respondent suggested that where efficient vials are unavailable from the manufacturer, the algorithm should be adjusted to nearest vial, so not to penalise suppliers. The Review Team will raise this issue internally to confirm the correct approach.

6.9 Additional Issues Raised

Views on a range of other matters not mentioned in other areas of the paper that should be considered in developing a sustainable, transparent funding model for chemotherapy infusion services were provided. Topics included:

- Source of funding
- Patient payments
- Cost, accessibility and safety
- Medical Specialist fees
- State government funding
- Efficiencies for CADD devices
- Pharmaceutical Reform Agreement
- Changes to software functionality
- Inadequacy of interim funding
- Drug prices above ex-manufacturer price

Specific comments provided are at **Attachment A**.

6.10 Feedback Methodology

In compiling this summary information, each submission was read and the themes and key points were extracted and collated. Some points of similarity have been grouped, for ease of reporting. Other points that have been made infrequently have not been included, as the number of individually worded views would prohibit a concise conclusion.

7 Summary/Conclusions

There were a range of different models of care provided, and a host of different professional and administrative activities described to support these models.

Submissions also identified that there has been noteworthy change in chemotherapy arrangements over the last decade or so, with the majority enabling greater access for patients, and higher standards of safety.

While the majority of those that had a view about the fees currently paid for chemotherapy services consider them to be too low, there was limited data provided to support this. Key issues that will need to be explicitly addressed by the Review Team include:

- Compounding costs;
- Dispensing and administrative costs
- Clinical services;
- Consumables and devices; and
- Freight.

With regard to rural and regional differences, it is reassuring that providers are of the view that the quality of services does not differ generally between urban and regional areas, and that additional costs in relation to freight do not get passed on to regional cancer patients.

The range of standards and guidelines identified through these submissions was substantial, and it is clear that the pharmacy sector is active in this space, with further development underway.

There was support for mandatory standards to be linked to payment, and suggestions that this review take account the parallel review of the reform of the regulatory framework for pharmacy compounders underway by the TGA.

It is clear that any attempts by the Government to simplify administration would be well received by the sector. This could include: consideration of paperless claiming; consideration of extending streamlined authorities; clarifying business rules, such as ‘in good faith payments’ and unavailability of most efficient vials; and following up where drugs cannot be purchased at ex-manufacturer price.

Chemotherapy Review Team
August 2013

Attachment A – Alternative Suggestions and Comments Raised Within Responses

Source of funding

- Seeking transparency of funding covered under Community Pharmacy Agreements.
- Funding should not come from 5CPA.
- Funding should be sourced from EAPD savings.
- Savings from price disclosure should fund sustainable chemo funding model.

Patient payments

- Information on the full costs of chemo treatment should be provided before treatment occurs.
- Where infusions are cancelled, a patient co-payment should not be applied.
- Attempts to shift costs to insurers will ultimately impact consumers.
- Concerns about the inequity of public patients in NSW public hospitals (and one hospital in QLD) charging patient co-payments while other states are not. Some NSW women are paying up to 5 co-payments for their breast cancer treatment, while other states are paying none.

Cost, accessibility and safety

- The Federal Government must ensure that there is no disadvantage to any cancer patient in Australia in respect to cost, accessibility or safety.

Medical Specialist fees

- Moderately reduce MBS items to doctors (13915, 13918, 13921 and 13924) as care is delegated to nursing staff.

State government funding

- Concerns that reduction in PBS funding impacts public hospital budgets and service delivery.
- Activity Based Funding (ABF) funding recently introduced clinical pharmacy attendance payment of \$233 for public hospitals.

Efficiencies for CADD devices

- Other areas for efficiencies could be considered, for example a mechanism to re-use re-usable CADD devices.

Pharmacy Reform Agreement

- Pharmacy Reform agreement should be amended to enable PBS to be claimed by public hospitals regardless of public/private patient status.

Vertical integration

- DHS Medicare should audit potential conflict of interest for medical oncologist ownership of Section 94 (hospital) pharmacies supplying chemotherapy that may result in more expensive/overprescribing and/or overservicing.

Changes to software functionality

- Any changes that require software amendment must have reasonable lead time.

Inadequacy of interim funding

- Interim \$60 has not addressed all of the losses being carried, which continue with goodwill anticipating a solution.
- Fees, including interim \$60, has not covered costs of obtaining and supplying expensive medicines.

Drug prices above ex-manufacturer price

- If PBS drug sponsor chooses to charge above agreed manufacture prices, there is not method for manufacturer to be held to account, eg. paclitaxel ex-manufacturer price is \$401, and the product sponsor charges \$431.
- Inability to purchase drugs at ex- manufacturer prices, so drugs are already running at a loss.
- Price of medicine is higher than PBS reimbursement price.

Other

- Determining funding for clinical pharmacy services must include representation from public and private sectors.
- Process of dealing with changes mid cycle when a prescription contains repeats.