Report to the Minister for Health:
Review of Funding Arrangements for
Chemotherapy Services

October 2013
1 Executive Summary

Preparation and supply of chemotherapy infusions is a niche area of pharmacy practice requiring both capital investment and specialised knowledge. In Australia, fewer than sixty pharmacies (one per cent) supply 80 per cent of chemotherapy infusions funded under the Pharmaceutical Benefits Scheme (PBS). Chemotherapy infusions are administered to patients in the hospital or day clinic setting with approximately 60 per cent of infusions administered through private hospitals and day procedure centres and 40 per cent administered through public hospitals. In 2012-13, the PBS subsidised around 830,000 chemotherapy infusions at a cost to the Australian Government of $570 million.

Following recent concerns from a range of stakeholders that reductions in the ex-manufacturer price of some chemotherapy medicines would make chemotherapy services unviable, the former Government commissioned the ‘Review of Funding Arrangements for Chemotherapy Services’. This Review has been conducted by the Department of Health with the assistance of four independent experts from the fields of health administration, pharmacy, medical oncology and oncology nursing. The Review process included both formal and informal consultation with the pharmacy sector, as well as a formal consultation process with consumers, conducted by the Consumers Health Forum.

Key Findings

- Product quality, patient safety and necessary associated services are currently provided to a generally high standard.
- In the past, excessive margins available from medicine price discounts had delivered substantial profits and provided the capacity and flexibility for providers to divert PBS funds into areas outside of PBS responsibility and enabled the introduction of inefficient supply models.
- There is a high level of complexity with many different models of chemotherapy pharmaceutical service provision, each with differing commercial arrangements between the hospitals, pharmacies and oncologists involved:
  - Economies of scale and location have driven an increased use of out-sourced infusion compounding through commercial third-party compounders.
  - Some of these delivery models involve commercial or equity relationships between pharmacists, oncologists and hospitals.
  - Chemotherapy services have shifted from the public sector to the private sector over time, transferring medicine costs to the PBS.
- Existing funding arrangements do not align with these complex business models.
- Now that the price disclosure measure has removed the excessive profit margins for multi-brand medicines, remuneration available thorough PBS mark-ups and fees under the Efficient Funding of Chemotherapy arrangements may no longer be sufficient to adequately meet the costs of compounding and supply for the average pharmacy.
Data provided by a sample of pharmacies indicate that there may be a deficit in funding however there are limitations in the verifiability and representativeness of the data due to the small number of data sets and inconsistencies between reported costs.

Beyond funding, efficiency benefits could be achieved by reducing the complexity and administrative burden associated with chemotherapy reimbursement on the PBS.

## Acknowledgements

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4 Terms of Reference for the Review of Chemotherapy Funding Arrangements

1. The Review will investigate and report on:
   a. current arrangements for funding of chemotherapy services;
   b. how those arrangements have changed over time;
   c. how chemotherapy services are provided, including in relation to
      i. Different hospital and community settings
      ii. Different business models
      iii. Use of third-party compounders
      iv. Integration of hospital, pharmacy and oncology services;
   d. the involvement of public and private hospitals in providing chemotherapy services, including
      i. the extent to which each sector provides services
      ii. differences by state
      iii. how that service mix has changed over time
      iv. current trends in that service mix
      v. any implications for community pharmacy or the Pharmaceutical Benefits Scheme
      vi. any implications for private hospitals and private health insurers;
   e. cost structures associated with provision of chemotherapy services – dispensing, support, administration and clinical services.

2. The Review will provide advice on funding arrangements appropriate to the efficient supply of chemotherapy services by community pharmacy.

3. The Review will provide advice on any other relevant matters in relation to securing efficient and effective provision of chemotherapy services.

4. The Review will ensure appropriate consultation with relevant stakeholders.

5. The Review will report to the Minister for Health by October 2013.
## 5 List of acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>5CPA</td>
<td>Fifth Community Pharmacy Agreement</td>
</tr>
<tr>
<td>ABF</td>
<td>Activity based funding</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>CADD</td>
<td>Computerised Ambulatory Delivery Device</td>
</tr>
<tr>
<td>CHF</td>
<td>Consumers Health Forum</td>
</tr>
<tr>
<td>COSA</td>
<td>Clinical Oncology Society of Australia</td>
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<tr>
<td>DHS</td>
<td>Department of Human Services</td>
</tr>
<tr>
<td>EFC</td>
<td>Efficient Funding of Chemotherapy</td>
</tr>
<tr>
<td>HITH</td>
<td>Hospital in the Home</td>
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<tr>
<td>IHPA</td>
<td>Independent Hospital Pricing Authority</td>
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<td>IV</td>
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<td>Monoclonal Antibodies</td>
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<td>MBS</td>
<td>Medicare Benefits Schedule</td>
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<td>NRMC</td>
<td>National Residential Medication Chart</td>
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<td>ORPs</td>
<td>Other Referred Patients</td>
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<td>Pharmaceutical Benefits Advisory Committee</td>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>RACF</td>
<td>Residential Aged Care Facilities</td>
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<td>RPBS</td>
<td>Repatriation Pharmaceutical Benefits Scheme</td>
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<tr>
<td>RRP</td>
<td>Rights of Private Practice</td>
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<tr>
<td>s90</td>
<td>Section 90 of the <em>National Health Act 1953</em></td>
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<tr>
<td>s94</td>
<td>Section 94 of the <em>National Health Act 1953</em></td>
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<tr>
<td>SHPA</td>
<td>Society of Hospital Pharmacies of Australia</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>The Department</td>
<td>The Department of Health (previously the Department of Health and Ageing)</td>
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<tr>
<td>The Guild</td>
<td>Pharmacy Guild of Australia</td>
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<tr>
<td>The Reforms</td>
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<tr>
<td>TPC</td>
<td>Third party compounder</td>
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PART ONE: BACKGROUND

This section provides the background to the Review and this Report.

6 Background to the Review

6.1 Chemotherapy medicines on the PBS

The term ‘chemotherapy’ is used to refer to the use of medicine in the treatment of cancer. Chemotherapy includes the use of antineoplastic medicines to inhibit the reproduction of cancer cells as part of a standardised regimen. Most chemotherapy medicines are ‘cytotoxic’; that is, they act by killing cells that divide rapidly (including non-cancerous cells). These medicines are dangerous to administer and are only available at specialised medical services, usually hospitals. Newer, advanced medicines that are able to target cancer cells specifically are also emerging and being used to increase treatment options and improve outcomes for patients.

Chemotherapy medicines are supplied to patients in both private and public hospitals in Australia through the Pharmaceutical Benefits Scheme (PBS), which is ‘the primary means through which the Australian Government ensures Australians have timely and affordable access to pharmaceuticals’\(^1\).

Under the PBS the Government subsidises the cost of 753 medicines for a range of medical conditions. While some chemotherapy medicines cost nearly $24,000 per dose, the PBS subsidy ensures that patients never pay more than the patient co-payment per treatment (currently $36.10 for general patients and $5.90 for concessional patients).

When a pharmacist supplies a medicine that attracts an Australian Government benefit, the pharmacist is paid the PBS dispensed price of the medicine, less any patient contribution. Public and private hospitals and community pharmacy remuneration arrangements are set out under individual determinations. Community pharmacy remuneration is negotiated in the context of community pharmacy agreements.

The PBS dispensed price consists of the ex-manufacturer price, a retail mark-up, dispensing fees, and any other fees to which the pharmacist is entitled. Chemotherapy medicines are funded in the same way, but attract fees based on the Efficient Funding of Chemotherapy (EFC) measure.

6.2 Efficient Funding of Chemotherapy Medicines

Chemotherapy medicines present unique reimbursement challenges. The medicines are not supplied in a manner ready for patient use and must be compounded and prepared into infusion doses. Due to their risk profile and potential toxicity, chemotherapy medicines must be made up to a specific dose, based on body weight or body surface area or other dosing regimens. As each dose is made up from set vial sizes, there is almost always a level of wastage, which cannot be reused due to the short shelf-life of the medicine. This level of wastage varies depending on the vial sizes chosen to make up each infusion. Wastage adds to the cost of these expensive medicines.

\(^1\) Department of Health and Ageing, Portfolio Budget Statements 2012-13, Outcome 2.2, p. 90.
As a result, in 2011, the EFC measure was introduced, to calculate PBS reimbursement on the basis of the cheapest possible combination of vials, minimising the cost of each infusion to taxpayers and thus contributing to the sustainability of the chemotherapy program. The EFC measure, in combination with the Fifth Community Pharmacy Agreement (5CPA), was negotiated with the Pharmacy Guild of Australia (the Guild) and announced in the 2010-11 Budget. The revised arrangements were implemented on 1 December 2011 by a new ‘special arrangement’ under Section 100 of the National Health Act 1953 (the Act). Further information on the funding arrangements for EFC medicines is at section 10.2.1.

There are currently 37 medicines funded through special arrangements under EFC and the PBS. They are listed below at Table 1.

Table 1. Drugs provided through the EFC measure on the PBS

<table>
<thead>
<tr>
<th>Arsenic</th>
<th>Bevacizumab</th>
<th>Bleomycin</th>
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<tr>
<td>Bortezomib</td>
<td>Cabazitaxel</td>
<td>Carboplatin</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Cisplatin</td>
<td>Cladribine</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Cytarabine</td>
<td>Docetaxel</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Doxorubicin – pegylated</td>
<td>liposoma</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>Etoposide</td>
<td>Fludarabine</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>Fotemustine</td>
<td>Gemcitabine</td>
</tr>
<tr>
<td>Idarubicin</td>
<td>Ifosfamide</td>
<td>Ipilimumab</td>
</tr>
<tr>
<td>Irinotecan</td>
<td>Methotrexate</td>
<td>Mitoxantrone</td>
</tr>
<tr>
<td>Oxaliplatin</td>
<td>Paclitaxel</td>
<td>Paclitaxel – nanoparticle albumin-bound</td>
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<tr>
<td>Pemetrexed</td>
<td>Raltitrexed</td>
<td>Rituximab</td>
</tr>
<tr>
<td>Topotecan</td>
<td>Trastuzumab</td>
<td>Vinblastine</td>
</tr>
<tr>
<td>Vincristine</td>
<td>Vinorelbine</td>
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The amount paid by the Australian Government for chemotherapy medicines in 2012-13 was $570 million.
6.3 Price disclosure and EFC medicines

The sale and reimbursement price of a medicine is also affected when multiple brands become available. While most medicines are on patent when they are listed on the PBS (and reimbursement prices are based on the cost of supplying a single brand of medicine), many chemotherapy medicines are now off-patent and multiple brands are available on the PBS. Once brand competition is in place, manufacturers often sell their brands at prices much lower than the Government approved price, in order to compete for market share (for some brands, there are discounts in the order of 80 per cent). Pharmacists purchasing a discounted brand still receive the full PBS reimbursement because Government and consumers continue to pay the PBS-listed price.

To ensure that PBS prices are regularly adjusted to reflect the market price, the price disclosure programme was implemented in 2007\(^2\). Price disclosure uses sales, volume and incentive/discount data submitted by manufacturers for all brands of a medicine (excluding public hospital sales) to calculate an average market price, proportionally weighted by sales volume, known as the ‘weighted average disclosed price’. If the weighted average disclosed price is more than ten per cent lower than the PBS price, the weighted average disclosed price becomes the new ex-manufacturer price of the medicine (plus the relevant fees and retail mark-up) (see section 10.2). Price disclosure does not directly affect the mark-up or fees paid to pharmacies.

A full list of multi-brand EFC medicines subject to price disclosure is provided below at Table 2.

Table 2. Multi-brand EFC medicines subject to price disclosure as of 1 October 2013 and price disclosure reductions incurred to date

<table>
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<th>EFC Drug</th>
<th>Price disclosure reduction(s)</th>
<th>Quantity of Scripts(^3) (2012-13)</th>
<th>Example change in ex-manufacturer prices per vial(^4)</th>
</tr>
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<tr>
<td>Bleomycin</td>
<td>No reduction to date</td>
<td>5,969</td>
<td>N/A</td>
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<tr>
<td>Carboplatin</td>
<td>66.41% (1 Apr 2012)</td>
<td>49,031</td>
<td>$112.03 to $37.63</td>
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<td></td>
<td>22.50% (1 Aug 2013)</td>
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<td>$37.63 to $29.16</td>
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<tr>
<td>Cisplatin</td>
<td>39.02% (1 Apr 2011)</td>
<td>31,656</td>
<td>$44.25 to $26.98</td>
</tr>
<tr>
<td></td>
<td>30.37% (1 Apr 2012)</td>
<td></td>
<td>$26.98 to $18.79</td>
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<tr>
<td></td>
<td>24.02% (1 Aug 2013)</td>
<td></td>
<td>$18.79 to $14.28</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>76.20% (1 Dec 2012)</td>
<td>30,426</td>
<td>$2310.90 to $549.99</td>
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<tr>
<td>Doxorubicin</td>
<td>63.54% (1 Dec 2009)</td>
<td>32,688</td>
<td>$477.99 to $177.83</td>
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<tr>
<td></td>
<td>34.62% (1 Aug 2010)</td>
<td></td>
<td>$177.83 to $116.27</td>
</tr>
<tr>
<td></td>
<td>32.97% (1 Aug 2012)</td>
<td></td>
<td>$116.27 to $77.94</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>78.05% (1 Apr 2012)</td>
<td>16,489</td>
<td>$666.26 to $146.24</td>
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<td></td>
<td>51.35% (1 Aug 2013)</td>
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<td>$146.24 to $71.15</td>
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<tr>
<td>Etoposide</td>
<td>34.23% (1 Aug 2013)</td>
<td>32,564</td>
<td>$265.54 to $174.65</td>
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<tr>
<td>Fludarabine</td>
<td>62.40% (1 Apr 2013)</td>
<td>5,762</td>
<td>$1,371.22 to $515.58</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>21.52% (1 Apr 2013)</td>
<td>157,932</td>
<td>$34.69 to $27.22</td>
</tr>
</tbody>
</table>

\(^2\) The price disclosure program was further modified in 2011 under the Expanded and Accelerated Price Disclosure measure and the 2013 Simplified Price Disclosure measure.

\(^3\) These script totals include the scripts that are provided for under the Repatriation Pharmaceutical Benefits Scheme (RPBS).

\(^4\) Example price change is the change in ex-manufacturer price for one pharmaceutical item on the reduction day. For a complete list of pharmaceutical items referred to, see Appendix A.
### Review of Funding Arrangements for Chemotherapy Services

#### Background to the Review

By 2012, many high cost chemotherapy medicines had become subject to price disclosure, and price reductions were announced for these medicines. In some cases reductions were very high, such as the case of docetaxel, for the treatment of breast, ovarian, prostate and non-small cell lung cancer, which had a weighted average disclosed price that was 76.20 per cent below the approved price.

The price disclosure outcomes demonstrated that, in some cases, pharmacies had made a substantial profit above that allocated through PBS remuneration arrangements for these medicines over a number of years. In the case of docetaxel, pharmacies had been purchasing brands at prices up to 80 per cent below the reimbursed price, resulting in the Government paying pharmacists up to $2,800 above the market price per infusion. As a result, the price of docetaxel was reduced by 76.20 per cent on 1 December 2012.

Further information on price disclosure, Expanded and Accelerated Price Disclosure and Simplified Price Disclosure is provided at Appendix A.

### 6.4 The need for a review of chemotherapy funding arrangements

#### 6.4.1 Stakeholder concerns

In October 2012, some stakeholders informed the Department of Health, previously the Department of Health and Ageing (the Department), that the discounts received by pharmacists for off-patent chemotherapy medicines had been used for several years to fund the cost of broader services associated with the provision of chemotherapy medicines, including dispensing services, clinical pharmacy services, compounding costs and other costs (e.g. specialised infusion devices).
Stakeholders were concerned that, without additional subsidy for these medicines, there was insufficient reimbursement in the existing funding model to cover the costs of providing these services.

Initially, the Department investigated the costs associated with chemotherapy, by conducting site visits and gathering detailed information from stakeholders. During this information gathering phase, further information came to light on the complexity of chemotherapy models of service provision, whether existing reimbursement was sufficient, quality and standards issues and other issues faced by pharmacists when dispensing chemotherapy medicines.

Following initial investigations undertaken by the Department in late 2012, the key issues for stakeholders were identified as follows:

- A collective view among pharmacy stakeholders that, for some pharmacies, chemotherapy services would not be adequately covered without further funding. This was because in many cases, the additional profit from chemotherapy medicines pre-price disclosure was used to fund a range of other chemotherapy activities including clinical pharmacy services.
- Concerns that the retail mark-ups calculated using the EFC algorithm were inconsistent with the expectations of the sector.
- The significant administrative burden associated with managing chemotherapy under the PBS arrangements, and that this could be simplified.

### 6.4.2 Senate Inquiry

On 7 February 2013 the Senate referred matters pertaining to the supply of chemotherapy medicines in Australia, including the medicine docetaxel to the Senate Community Affairs Committee for inquiry. The inquiry was tasked to report on:

(a) the supply of chemotherapy medicines such as docetaxel, particularly in relation to:
   (i) patient access to treatment;
   (ii) cost to pharmacists and suppliers; and
   (iii) cost to the private and public hospital systems;
(b) any long-term sustainable funding models for the supply of chemotherapy medicines, including docetaxel; and
(c) any related matters.

The inquiry was undertaken and a report was tabled on 10 May 2013\(^5\). In its report, the committee recommended that:

“...the government and industry parties, through the review, continue the examination of issues in chemotherapy drug pricing to ensure that existing funds under the Fifth Community Pharmacy Agreement as already agreed are appropriately directed to reflect the costs and benefits of the supply of chemotherapy drugs, and to ensure the ongoing supply of these drugs across all services, particularly in rural and regional areas”.

The Senate Inquiry report is at Appendix B.

\(^5\) The Senate Community Affairs References Committee: Supply of chemotherapy drugs such as docetaxel. May 2013.
6.4.3 Interim funding while undertaking a review

On 5 May 2013, the Government announced Commonwealth funding to provide an interim amount of $60.00 per chemotherapy infusion, in addition to the existing fee ($77.66 per infusion), to ensure the ongoing viability of chemotherapy services while a comprehensive Review was conducted. This Review was to explore the issues raised by stakeholders and followed a proposal from the Guild on 4 March 2013. The Review was to report to the Minister for Health in October 2013.

7 Process undertaken to inform the Review

7.1 Aim of the Review

The aim of this 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.

The Review does not consider any matters relating to Medicare Benefits Schedule (MBS) items or arrangements for oncology services.

7.2 The Review Team

To assist with the Review process, the Department engaged four independent experts representing health administration, pharmacy, oncology and oncology nursing (Appendix C). The Department also contracted Consumers Health Forum (CHF) to provide consumer input and McGrathNicol, an independent corporate advisory, to provide independent data analysis.

7.3 The Review process

To inform the Review, stakeholders in the following sectors were consulted:

- hospital and community pharmacies;
- parties performing chemotherapy compounding services;
- representative organisations including health professionals involved with chemotherapy provision;
- health departments in states and territories; and
- consumers via the CHF.

To that end, a number of these stakeholders:

- provided Submissions in response to a Discussion Paper;
- participated in bilateral discussion meetings; and
- provided chemotherapy related cost data.

7.3.1 Stakeholder Submissions in response to the Discussion Paper

A Discussion Paper was released on 29 June 2013, seeking public comments. Stakeholders provided submissions in response to the Discussion Paper between 22 July 2013 and 31 July 2013.
The Discussion Paper was developed around the issues that the Department had identified during its preliminary investigations, and was tailored to seek further information on these issues, as well as other issues. The Discussion Paper is provided at Appendix D.

The pharmacy, hospital, medical, consumer and compounding sectors were well represented by the range of submissions received. 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 commercial compounders, one response from a private health insurer, and three responses from state governments. Those organisations and individuals who lodged a submission are listed at Appendix E and the Summary of Submissions received in response to the Discussion Paper is provided at Appendix F.

7.3.2 Bilateral discussions

Twenty seven bilateral discussions were held between July 2013 and September 2013. These were undertaken either through face-to-face meetings, or via teleconference. Some discussants also contributed a submission in response to the Discussion Paper.

Stakeholders involved comprised dispensing hospital pharmacies in regional and metropolitan areas, dispensing community pharmacies in regional areas, compounders, prescribers, private health insurers, state governments and other government agencies. A full list of stakeholders who participated in the bilateral discussions is available at Appendix G.

7.3.3 Chemotherapy Cost Data

Pharmacy and hospital respondents to the Discussion Paper and stakeholders engaged through the bilateral meetings were encouraged to substantiate their views on appropriate chemotherapy remuneration by providing costing data. The Department prepared a template so that consistent data could be captured.

Throughout the submissions and bilateral meetings, the majority of stakeholders maintained that an increase in funding was required. However, only a small number of pharmacies provided data in support of their views (20 individual sites providing an estimated 35 per cent of all chemotherapy infusions dispensed in Australia).

McGrathNicol identified a number of limitations in the data provided, including concerns that:

- the data sets were not supported by any verifiable documentation and accordingly, accuracy cannot be verified;
- there were a number of consistency issues between individual data sets provided, with some providing less detail than others and some apparent differences in interpretation of each cost component; and
- there were a number of matters which may impact whether the data can be considered representative of the industry, including the small number of data sets and that a number of the data sets appeared to be part of group submissions, which may impact the weighting of the average cost calculations.
The data were analysed by the Department and by McGrathNicol to provide an independent perspective.

7.3.4 Consumer consultation

The CHF was engaged by the Department to consult directly with consumers and consumer groups, with a particular focus on rural and regional areas. CHF hosted targeted consultation meetings, managed an online consultation platform, and undertook tele-consultations. CHF’s consultations also included a discussion paper for CHF voting members. CHF provided the Department with a report with recommendations based on the issues raised by consumers, which is provided at Appendix H.

Information obtained from submissions, bilateral meetings, data and consumer consultation is incorporated within this report.
PART TWO: CURRENT ARRANGEMENTS FOR CHEMOTHERAPY SERVICES

This section provides information on the provision of chemotherapy services in the Australian PBS context.

8 Supply of chemotherapy

Pharmacies and compounders purchase chemotherapy medicines from a combination of manufacturers, wholesalers and third-party logistics providers. Once the medicine has been received and compounded into the appropriate infusion presentation for the patient, it is then administered to the patient through a hospital or day procedure centre (Figure 1).

Figure 1. Supply chain for chemotherapy medicines

8.1 Pharmacy dispensing

Regardless of treatment location, all PBS chemotherapy medicines are dispensed by an approved pharmacy before being infused at the hospital. In practice, this means that the medicine is ordered by the hospital, dispensed by the pharmacy and then the infusion is administered at the hospital. However, all claims for PBS reimbursement are made by the pharmacy.

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6 ‘Approved pharmacy’ and ‘pharmacy’ in this report is used to refer to either a community pharmacy or a hospital pharmacy approved under the Act.
The pharmacist is responsible for arranging for the preparation of the medicine, either by compounding it themselves (if they have in-house compounding facilities) or by using the services of a third-party compounder.

There are two types of dispensing pharmacies, namely community pharmacies and hospital pharmacies.

8.1.1 Community pharmacies (s90 approved)

‘Community pharmacy’ means ‘a pharmacist approved under s90(1) of the Act to supply pharmaceutical benefits at a particular premises’. S90 community pharmacies can dispense chemotherapy for any eligible patient in any setting. Some s90 pharmacies are situated within the hospital setting (public and private) and these pharmacies may dispense chemotherapy services. Around 57 per cent of chemotherapy scripts are dispensed from s90 pharmacies.

8.1.2 Hospital pharmacies (s94 approved)

‘Hospital pharmacy’ means ‘a hospital authority approved under s94(1) of the Act for the purpose of supplying pharmaceutical benefits to patients receiving treatment in or at the hospital of which it is the governing body or proprietor’. There are two types of s94 pharmacy: a s94 in a private hospital can dispense all PBS medicines but only to hospital patients; a s94 in a public hospital can only dispense PBS medicines for out-patients, non-admitted day patients or patients on discharge.

These pharmacies are approved to supply PBS subsidised medicines to patients in or at the approved hospital only. That is, they are not allowed to supply medicines to the general public, or patients of other hospitals. Around 43 per cent of chemotherapy scripts are dispensed in s94 pharmacies.

8.2 Compounding of chemotherapy medicine

Due to the nature of chemotherapy medicines, compounding is a necessary step in the provision of these medicines in a ready-to-use form for the patient. This is a more complex process than for most other PBS medicines. As most chemotherapy medicines are cytotoxic and require a high level of precision in the preparation process, pharmacists or pharmacy technicians reconstituting the medicines require specialist skills and training. The compounding of chemotherapy medicines also requires a sterile environment which ensures the safety of both the compounder and the patient receiving the medicine is maintained.

There are three types of chemotherapy compounders:

- compounding pharmacies (with an estimated seven per cent market share)\(^7\);
- public and private hospitals that undertake in-house compounding (30 per cent market share); and
- non-pharmacy third-party commercial compounders (63 per cent of market share).

\(^7\) As reported by a stakeholder.
8.2.1 Compounding s90 pharmacies

There are pharmacies outside of the hospital setting that provide compounding services as well as PBS dispensing services. These pharmacies are able to compound and dispense chemotherapy infusions on-site. They can also prepare chemotherapy infusions on behalf of non-compounding pharmacies. Compounding pharmacies have a range of quality and safety guidelines and standards that they are guided by but not obliged to follow (see section 16 for more information).

The degree of compounding undertaken by compounding pharmacies varies. Some pharmacies purchase medicines directly from the supplier (manufacturer, third-party logistics company or wholesaler) and compound in-house; while other pharmacies primarily source their chemotherapy medicines from third-party compounders, and limit their own compounding to providing services such as short-turnaround time orders, clinical trial medicines or making adjustments to the dosages.

8.2.2 Hospital pharmacies with in-house compounding facilities (s94 public or private hospitals)

A number of hospital pharmacies, both public and private, have compounding facilities on-site. In-house compounders must meet hospital and/or state based quality standards (see section 16).

Hospitals approved under s94 of the Act with pharmacies that compound in-house are only allowed to supply PBS medications to patients in or at the hospital.

In-house compounders can compound and dispense medicines for a patient at short notice and can usually wait until the treatment order is confirmed (e.g. following blood tests, review from an oncologist, etc.) before preparing an infusion. This can reduce wastage.

8.2.3 Third-party compounders

Approved pharmacies that do not have compounding facilities are still able to dispense and claim for PBS-subsidised chemotherapy infusions. They do so by outsourcing the compounding of the infusion to a third-party (either a commercial compounding or a compounding s90 pharmacy). These are commercial arrangements between the claiming pharmacy and the compounder, attracting various fees and charges over which the Commonwealth has no control.

Third-party compounders prepare the majority of chemotherapy infusions provided in Australia. According to the Therapeutic Goods Administration (TGA) there are five third-party compounders in Australia operating from 11 sites: Fresenius Kabi Australia Pty Ltd, Slade Health Pty Ltd, McBeat Health Services, Baxter Healthcare Pty Ltd and the Wesley Pharmacy. Some also have a dual role as a s90 pharmacist which allows them to dispense PBS medicines. Baxter Healthcare Pty Ltd provides compounding services only, while others are structured to provide both compounding and, either directly or by indirect arrangements, pharmacy dispensing.

Third-party compounders may provide chemotherapy infusions direct to hospital pharmacies or to community pharmacies acting as dispensers on behalf of a hospital or day procedure clinic. Commercial third-party compounders must be licensed by the TGA to operate (see section 16.1.2).
8.3 Supplier – manufacturer or wholesaler

Compounding pharmacies or commercial third-party compounders will purchase chemotherapy medicines from the supplier, which may be the manufacturer or a wholesaler.

Manufacturers are responsible for listing the medicine on the PBS and for supplying their brand(s) of medicine in Australia. Manufacturers agree a base price for the medicine with the Minister for Health known as the ‘ex-manufacturer price’ (further described in section 10.2.1). However, manufacturers are free to sell their brand of medicine at a price below the ex-manufacturer price as an incentive to gain market share. This discounting was the trigger for the price disclosure measure.

Wholesalers usually purchase stock from multiple manufacturers, concentrate these items at local distribution centres, then distribute from that range of brands at the customer’s request. When supplying non-EFC medicines listed on the general schedule (under s85 of the Act), wholesalers are bound by the Community Services Obligation (CSO), which requires wholesalers to provide such medicines within 24 hours. This requirement does not apply to chemotherapy medicines.

Some manufacturers do not allow their medicines to be purchased by wholesalers; instead they deliver them through third-party logistics providers. Other manufacturers prefer to distribute their high cost and s100 medicines directly to hospitals.

8.4 Vertically integrated providers

In addition to the providers listed above there are vertically integrated business models for chemotherapy provision. In one model, vertically integrated organisations provide multiple levels of service (day hospital services, medical oncology and haematology services, chemotherapy compounding services and chemotherapy-related clinical pharmacy services) via equity relationships with subsidiary companies. Similarly another model provides manufacturing, compounding, clinical services, dispensing and claiming all under the umbrella of single ownership.

9 Model of service for chemotherapy provision

The model of service for chemotherapy provision in Australia is highly complex and depends on:

- preparation and dispensing arrangements, discussed in section 8 above, such as whether the medicine is dispensed by a community pharmacy or a hospital pharmacist; and whether the pharmacist compounds the medicine or uses the services of a separate compounder; and
- The patient pathway, including patient type (how they are classified by the state/territory they reside in) and their treatment location.

9.1 The patient pathway

There is no single patient pathway or treatment protocol for cancer(s). Decisions taken by treating oncologists are patient specific and can be subjective, depending upon a series of factors that include but are not limited to the patient’s diagnosis, staging of cancer and prognosis, the patient’s proximity to treatment, their treatment preferences, and the range of treatment options available.
Each patient journey is individual however, in general the journey of the patient can be described as follows:

- discussion with their general practitioner;
- referral to a specialist;
- diagnostic tests;
- treatment decisions being taken; and
- treatment provided at an appropriate facility based on these treatment decisions.

### 9.1.1 Patient type

Most patients will receive chemotherapy in the hospital setting. Intravenous infusions are administered in these settings by a nurse. The services provided by the dispensing pharmacist will vary (see section 14.1).

States and territories classify and treat chemotherapy patients differently. Patients receiving chemotherapy may be treated as:

- inpatients (public/private);
- outpatients (public/private);
- day patients (public/private);
- privately referred non-admitted patients;
- other referred patients;
- rights of private practice; or
- self-funded.

They can be treated in hospitals, day procedure centres or in their home.

### 9.1.2 Treatment locations

Chemotherapy services are provided by both the public and the private sector. Patients may be treated:

- in public hospitals (as an admitted day patient, inpatient or outpatient);
- in private hospitals (admitted day patient or inpatient);
- in private day procedure centres/clinics; or
- within patients’ own homes under Hospital in the Home (HITH) programs.

Nationally, Australian Institute of Health and Welfare (AIHW) data indicate that the private sector (private hospitals and private day procedure centres/clinics) accounts for approximately 60 per cent of chemotherapy services provided – made up of 16.5 per cent of patients who attended private freestanding day facilities and 45 per cent who attended other private hospitals (see Table 3) in 2011-12.
The service mix between the public and private sector has changed over time, with a gradual shift of chemotherapy services and patients from the public sector to the private sector (see Table 4).

Table 4. Same-day acute separations for chemotherapy AR-DRG (R63Z), public and private hospitals 2008-09 to 2011-12

<table>
<thead>
<tr>
<th></th>
<th>Public hospitals</th>
<th>Private freestanding day facilities</th>
<th>Other private hospitals</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-12</td>
<td>141,876 (38.5%)</td>
<td>60,797 (16.5%)</td>
<td>166,136 (45%)</td>
<td>368,809</td>
</tr>
<tr>
<td>2010-11</td>
<td>143,492 (40.7%)</td>
<td>57,831 (16.4%)</td>
<td>151,073 (42.9%)</td>
<td>352,396</td>
</tr>
<tr>
<td>2009-10</td>
<td>138,477 (41.3%)</td>
<td>54,917 (16.4%)</td>
<td>141,959 (42.3%)</td>
<td>335,353</td>
</tr>
<tr>
<td>2008-09</td>
<td>126,859 (40.5%)</td>
<td>48,506 (15.5%)</td>
<td>138,054 (44%)</td>
<td>313,419</td>
</tr>
</tbody>
</table>

Source: AIHW, Australian hospital statistics, various years.

Hospital admission for public patients, whether they are admitted to a public or a private hospital, is funded via hospital funding. Admissions for private patients are funded by the private health insurer or the patient if they are not privately insured.

### 9.1.3 National distribution of services

According to AIHW data, chemotherapy infusions are most commonly provided in New South Wales, Victoria and Queensland (Table 5 refers).

Table 5. Separations for chemotherapy for same-day acute separations (public hospitals and private hospitals) and outpatient care individual occasions of service (by outpatient clinic type) in selected public hospitals by states and territories 2011-12

<table>
<thead>
<tr>
<th></th>
<th>NSW</th>
<th>Vic</th>
<th>Qld</th>
<th>WA</th>
<th>SA</th>
<th>Tas</th>
<th>ACT</th>
<th>NT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public</td>
<td>2,943</td>
<td>83,239</td>
<td>23,040</td>
<td>29,378</td>
<td>77</td>
<td>2,091</td>
<td>657</td>
<td>451</td>
<td>141,876</td>
</tr>
<tr>
<td>Outpatients</td>
<td>85,268</td>
<td>1,394</td>
<td>9,718</td>
<td>640</td>
<td>26,653</td>
<td>1,029</td>
<td>0</td>
<td>3,975</td>
<td>128,677</td>
</tr>
</tbody>
</table>


(a) There were variations among jurisdictions in the reporting of occasions of service because of differences in admission practices and in the types of facilities offering these services.

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8 Separation is the process by which an episode of care for an admitted patient ceases.

[Australian Institute of Health and Welfare](https://www.aihw.gov.au)
There is insufficient data to break down the distribution of chemotherapy services any further (e.g. by region). This is because:

- the AIHW published data does not identify the specific location of each separation; and
- departmental data relates to prescriptions dispensed, not separations. In many cases, infusions may be dispensed in one location while being administered in another, which may be some distance from the pharmacy (even in another state).

### 9.2 Summary of models of service provision for chemotherapy

Based on the various patient types, treatment locations, compounding and dispensing arrangements, there are at least 25 variations to chemotherapy delivery in Australia (see Table 6).

<table>
<thead>
<tr>
<th>#</th>
<th>Setting</th>
<th>Patient type</th>
<th>Treatment location</th>
<th>Compounder</th>
<th>Dispenser</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>2.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>3.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>4.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>5.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>6.</td>
<td>Public</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>7.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>8.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>In-house</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>9.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>10.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>11.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>12.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>13.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>14.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Private day procedure centre</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>15.</td>
<td>Private</td>
<td>Admitted day patient</td>
<td>Private day procedure centre</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>16.</td>
<td>Public</td>
<td>Outpatient</td>
<td>Public hospital**</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>17.</td>
<td>Public</td>
<td>Outpatient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>18.</td>
<td>Public</td>
<td>Outpatient</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>19.</td>
<td>Private</td>
<td>Outpatient</td>
<td>Private home care</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>20.</td>
<td>Private</td>
<td>Inpatient/overnight</td>
<td>Private hospital</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>21.</td>
<td>Private</td>
<td>Inpatient/overnight</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>22.</td>
<td>Private</td>
<td>Inpatient/overnight</td>
<td>Private hospital</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
</tbody>
</table>
### Table of Funding Arrangements for Chemotherapy Services

<table>
<thead>
<tr>
<th>#</th>
<th>Setting</th>
<th>Patient type</th>
<th>Treatment location</th>
<th>Compounder</th>
<th>Dispenser</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>Public</td>
<td>Inpatient/overnight</td>
<td>Public hospital**</td>
<td>In-house</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>24</td>
<td>Public</td>
<td>Inpatient/overnight</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Hospital pharmacist</td>
</tr>
<tr>
<td>25</td>
<td>Public</td>
<td>Inpatient/overnight</td>
<td>Public hospital**</td>
<td>Third-party</td>
<td>Community Pharmacist</td>
</tr>
</tbody>
</table>

*This table may not represent all models of service provision in chemotherapy delivery*

*Includes privately referred, non-admitted patients, Other Referred Patients (ORPs), Rights of Private Practice (RPPs), and self-funded.

**Includes HITH

*** Depending on state/Pharmacy Reform Agreement participation

While these variations are generally not apparent to the patient, the different pathways lead to significant complexity in the chemotherapy service model and can lead to markedly different costs for each infusion across the PBS.

## 10 Remuneration

### 10.1 Eligibility for PBS remuneration

To be eligible for PBS remuneration, chemotherapy prescriptions must be dispensed and claimed by an approved s90 community or s94 hospital pharmacy.

The cost of chemotherapy medicine treatment is funded by the PBS for patients in community pharmacies, private hospitals and public hospitals participating in Public Hospital Pharmaceutical Reforms (the Reforms) only. Under the Reforms, eligible hospitals can receive access to PBS funding for day-admitted or non-admitted chemotherapy patients only. Of all states and territories, only NSW and ACT have declined to participate in the Reforms. Chemotherapy services in non-participating public hospitals are funded by states/territories. As such, public hospitals in NSW and the ACT are not eligible to claim for chemotherapy medicines under the PBS. Further information on the Reforms is available at Appendix I.

### 10.2 Reimbursement amounts

PBS funding paid to pharmacies is intended to cover costs associated with all stages in the supply chain, including suppliers, wholesalers, compounders and dispensers. The pharmacy receives all components of the PBS reimbursement, using this total amount to cover costs associated with procuring and compounding the medicine from suppliers and compounders.

#### 10.2.1 EFC reimbursement

Following the introduction of the EFC measure, there were changes in the calculation of the reimbursed amount for pharmacists. The measure requires prescribers to write dose specific prescriptions using milligrams (in most situations) without specific reference to forms and strengths. Payment is made to approved pharmacies for the combination of vials that most cost-efficiently makes up the required patient dose.

PBS payment is made to the pharmacy submitting the claim to the Department of Human Services (DHS). The reimbursement received by the pharmacist comprises the ex-manufacturer price of the
cheapest combination of vials for the amount to be dispensed, as well as a retail mark-up and a suite of fees in recognition of the more complex nature of chemotherapy medicines (Table 7), minus any co-payment paid by the patient. More detail on the calculation of the reimbursement amount via the EFC algorithm, and an example medicine price calculation, is available at Appendix J.

Table 7. Components of PBS reimbursement to pharmacies.

<table>
<thead>
<tr>
<th>Drug ex-manufacturer price (agreed between manufacturer and Minister for Health) for the required number of vials (most efficient combination)</th>
<th>EFC fees (see table below)</th>
<th>Interim additional fee</th>
</tr>
</thead>
</table>

The fees paid to pharmacists depend on the type of pharmacy making the claim, as indicated in Table 8.

Table 8. Current fees for dispensing chemotherapy medicines (to 31 December 2013)

<table>
<thead>
<tr>
<th>Component of PBS reimbursement</th>
<th>Community Pharmacy</th>
<th>Public Hospital</th>
<th>Private Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug ex-manufacturer price</td>
<td>Agreed between manufacturer and Health Minister</td>
<td>Agreed between manufacturer and Health Minister</td>
<td>Agreed between manufacturer and Health Minister</td>
</tr>
<tr>
<td>Retail Mark-up</td>
<td>Tiered based on medicine cost</td>
<td>Nil</td>
<td>1.4% of medicine cost</td>
</tr>
<tr>
<td>Wholesale/distribution fee</td>
<td>$24.79</td>
<td>Nil</td>
<td>$24.79</td>
</tr>
<tr>
<td>Diluent fee</td>
<td>$4.91</td>
<td>Nil</td>
<td>$4.91</td>
</tr>
<tr>
<td>Preparation fee</td>
<td>$41.33</td>
<td>$41.33</td>
<td>$41.33</td>
</tr>
<tr>
<td>Dispensing Fee</td>
<td>$6.63</td>
<td>Nil</td>
<td>$6.63</td>
</tr>
<tr>
<td>All fees</td>
<td>$77.66</td>
<td>$41.33</td>
<td>$77.66</td>
</tr>
<tr>
<td>Interim additional fee</td>
<td>$60.00</td>
<td>$60.00</td>
<td>$60.00</td>
</tr>
<tr>
<td>Total fee</td>
<td>$137.66</td>
<td>$101.33</td>
<td>$137.66</td>
</tr>
</tbody>
</table>

From 1 July 2013 to 31 December 2013, all eligible pharmacies dispensing PBS chemotherapy medicines are also receiving an additional interim fee of $60.00 per infusion, bringing the total fees to $137.66 for community and private hospital pharmacies and $101.33 for public hospital pharmacies.

An explanation of the intention behind each element of the PBS reimbursed price is as follows.

Ex-manufacturer price
The ‘base’ price that the Commonwealth will pay for the medicine is known as the ‘approved ex-manufacturer price’, which is based on the price recommended by the Pharmaceutical Benefits Advisory Committee (PBAC).

Generally, the medicine is purchased from the manufacturer at the ex-manufacturer price. As noted in section 8.3, manufacturers are free to sell their brand of medicine at a price below the ex-manufacturer price as an incentive to gain market share. Any discount off the approved ex-manufacturer price is kept by the pharmacist (further detailed at section 13.1). It is this
Review of Funding Arrangements for Chemotherapy Services

discounting that is captured by price disclosure, which adjusts the ex-manufacturer price based on the average sales price disclosed by manufacturers (weighted by sales volume).

The ex-manufacturer price is also subject to change over time as a result of price reviews or statutory price reductions.

Retail mark-up
This mark-up is applied to recognise the business costs associated with storing and handling the medicines, including refrigeration of certain medicines.

The retail mark-up for medicines dispensed in community pharmacies is tiered based on the ex-manufacturer price as follows (Table 9 refers):

Table 9. Retail mark-ups for medicines dispensed in community pharmacies

<table>
<thead>
<tr>
<th>Drug cost (ex-manufacturer)</th>
<th>Retail mark-up on medicine cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than or equal to $30.00</td>
<td>15.00%</td>
</tr>
<tr>
<td>$30.00-$45.00</td>
<td>$4.50</td>
</tr>
<tr>
<td>$45.01-$180.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>$180.01-$450.00</td>
<td>$18.00</td>
</tr>
<tr>
<td>$450.01-$1750.00</td>
<td>4.00%</td>
</tr>
<tr>
<td>Over $1750.00</td>
<td>$70.00</td>
</tr>
</tbody>
</table>

S94 private hospitals receive a flat 1.4 per cent retail mark-up on the medicine cost and s94 public hospitals do not receive a retail mark-up.

In the case of EFC medicines, the average retail mark-up paid to eligible pharmacies is around $15.00 per infusion⁹.

Distribution fee
The chemotherapy remuneration received by pharmacies includes a distribution fee of $24.79 per infusion. This fee is intended to cover the cost (generally charged to the pharmacy) of the logistics and transport of the vials to the community pharmacy or third-party compounder.

Dispensing fee
Pharmacies receive the same $6.63 dispensing fee as the fee paid for dispensing of non-chemotherapy items by an approved pharmacy.

Preparation fee
The preparation process for chemotherapy medicines is a vital and necessary element of infusion treatment which is more complex than for the majority of other PBS medicines. The $41.33 preparation fee is intended to cover the cost of taking the medicine from the vial and preparing the

⁹ Derived from the average retail mark-up paid for the most commonly prescribed dose for all EFC medicines during 2012-13 (excluding trastuzumab) and the average retail mark-up paid for all prescribed dose of the top 10 most commonly prescribed EFC medicines in 2012-13.
infusion (a process that is also referred to as reconstitution or compounding) so that the medicine can then be dispensed and administered to the patient in the hospital or clinic.

*Diluent fee*
This fee of $4.91 is intended to cover the cost of the diluting agent used in the reconstitution process.

**10.3 Patient co-payment**
Under the EFC arrangements, patients pay only one PBS co-payment ($5.90 concessional or $36.10 general) for each original prescription dispensed but not for repeat prescriptions. Patients accessing non-PBS medicines (for example, through public hospitals that do not participate in Pharmaceutical Reforms) may be required to pay different co-payments (see Appendix I).

**11 Changes to the delivery of chemotherapy over time**
The current chemotherapy arrangements exist in a complex, shifting environment. There have been changes to a variety of the elements of chemotherapy services over time.

**11.1 Location**
As previously noted, there has been a shift of chemotherapy services from the public to the private setting over time, with AIHW data indicating that 60 per cent of chemotherapy services are provided in a private setting where chemotherapy was traditionally a service provided in public hospitals. Day procedure centres have been established, with some facilities specialising in cancer care. In some circumstances patients may have chemotherapy infused in their home, under HITH programs or through ambulatory infusion pumps.

**11.2 Medicine options**
Treatment choices for patients have grown, with the increased range of medicines available. New targeted and immunotherapy medicines are emerging (referred to as personalised medicine), increasing patient access to new therapies.

There has been growth in the use of chemotherapy agents in early and advanced stages of cancer care. There has also been an increase in the use of new medicines, which have a higher purchase price and subsequent financial risk. With the availability of new, more complex medicines, there is more pressure on providers and pharmacists to review each patient’s complete medication regimen to check for potential interactions and unwanted side effects with their chemotherapy.

The number of complex chemotherapy regimens has increased in recent years with an impact on the resources required to both clinically verify prescriptions and to compound infusions. This increasing complexity has a flow on effect for those involved in chemotherapy provision, including compounders and pharmacists. In some cases the role of the pharmacist goes beyond dispensing to include patient support and physician interaction. The services provided by pharmacies are discussed later in this report (section 14.1.3 refers).
11.3 Compounding requirements
There is a trend towards more rigorous regulation and standards for commercial compounders, which has increased compliance costs. Quality and standards are discussed later in this report (section 16 refers).

11.4 Technology
There is now greater sophistication in technological and patient management practices for chemotherapy management, using systems such as the CHARM\textsuperscript{10} platform (an oncology information management solution for cancer care clinical coordination and management). Because chemotherapy medicines are carcinogenic for non-cancer patients, there is also a growing trend towards the use of closed system transfer devices for the safety of patients and staff handling chemotherapy infusions, to reduce risk of contamination or exposure to staff (see section 19).

11.5 Growth in cancer incidence and EFC expenditure
The growing number of cancer diagnoses and the costs of emerging new technologies will be a challenge for PBS funding in the future.

Treatment of cancer will continue to be a major health priority as cancer incidence is projected to grow significantly over the next twenty years in Australia. The AIHW\textsuperscript{11} estimated that more than 120,700 Australians were diagnosed with cancer in 2012. The AIHW also reported that, in 2010, cancer accounted for about three in ten deaths in Australia, making it the second most common cause of death, exceeded only by cardiovascular diseases. For all cancers combined, the age-standardised mortality rate decreased by 17 per cent from 210 per 100,000 in 1991 to 174 per 100,000 in 2010. Despite this decline and an increase in survival over time the AIHW concludes that one in two Australians will develop cancer and one in five will die from it before the age of 85.

Emerging technologies have contributed to the improved outcomes for people diagnosed with cancer. A recent report by the Medicines Australia Oncology Industry Taskforce\textsuperscript{12} (the Oncology Taskforce) noted that recent advances in molecular biology and the development of targeted cancer therapies has greatly expanded cancer treatment options and improved outcomes for patients. These new cancer therapies are often very expensive. For example, in August 2013 three new medicines for terminal cancer, including ipilimumab for end-stage melanoma, were listed on the PBS at a cost of $430 million over four years.

Drugs used for the treatment of cancer are key contributors to PBS growth. According to PBS data, Expenditure on cancer medicines has grown by more 60 per cent in the five years to 2012-13. In

\textsuperscript{10}Charmhealth
the five years to 2011 chemotherapy expenditure was grew faster than for any other group of medicines on the PBS.

The Oncology Taskforce reported that there are 981 cancer medicines and vaccines currently in all phases of clinical development, which will bring new treatment options as well as new costs for consideration.
PART THREE: FINDINGS OF THE REVIEW

This section identifies the key issues raised by stakeholders and examines the appropriateness of the existing funding arrangements.

12 Complexity of service and funding

12.1 Previous funding arrangements

Pharmacies rely on PBS reimbursement to deliver services for the preparation and dispensing of chemotherapy infusions. PBS reimbursement consists of fees, retail mark-ups and margins on medicines.

Prior to the introduction of the price disclosure programme, pharmacies were benefiting from significant discounts available from suppliers of off-patent medicines which provided substantial margins through the PBS reimbursement (see section 13.1). These excessive profits provided the opportunity and capacity for pharmacists to direct funding towards activities outside of the normal scope of PBS arrangements (see section 13.2).

The increased margins and re-allocation of costs provided the capacity for pharmacists to develop and sustain a variety of complex business models with varying levels of efficiency. This included the opportunity to package a number of PBS and non-PBS services together, at a discounted rate, in order to win business. Without incentives to create efficiencies, redirection of PBS funds has become accepted practice.

Some providers implemented business models which rely on this funding to cover the costs of some related elements of the provision of chemotherapy services and other elements of their business, which is a fundamentally flawed approach in that it is not sustainable in the longer term. Some may also have taken advantage of these arrangements to provide some services to hospitals/facilities at a discount rate or loss in order to secure a greater market share, in what is a limited market. In some cases pharmacies were able to provide services to hospitals and other chemotherapy facilities at no charge, or at a discounted rate, because of this redirected funding.

12.2 Shift from public to private systems

There has been a shift over time of the provision of chemotherapy services from the public sector to the private sector, which offers greater flexibility to structure the delivery of services in the most cost-effective package between the hospital and the provider (see section 9.1.2).

However, these arrangements have often led to greater or maximised access to PBS funding at the expense of other sources. Within the various delivery and business models, all stakeholders involved in the provision of chemotherapy services, including oncologists, pharmacists, hospitals and other facilities, for different reasons, have incentives to maximise access to PBS fees paid for each infusion. This shifts costs from public hospital sector to the PBS.
12.3 Variety of business models

There is a high level of complexity associated with the models of service and business models used to deliver chemotherapy services in Australia. This has arisen from the multitude of supplier categories and sources of funding.

There are a variety of models of service provision for the delivery of chemotherapy services in terms of the whether the patient is treated in the public or private health sectors, in a hospital, day procedure centre, outpatient clinic or at home or as a day patient, overnight admitted patient or non-admitted outpatient. During the Review, stakeholders identified at least 25 variations to chemotherapy delivery (section 9.2 refers).

There is also significant variance between business models for the preparation, dispensing and delivery of chemotherapy services, depending on whether chemotherapy is delivered in a public or private setting, the compounding is done in-house or by a third-party, or the medicines are dispensed by a s94 hospital pharmacy or a s90 community pharmacy. Generally, the more steps/parties involved in the preparation, dispensing and delivery process, the higher the overall costs and greater the complexity of issues. Some vertically integrated companies provide most or all services under one umbrella and can therefore deliver services according to a business model designed to maximise efficiencies and profits.

The different business models result in different remuneration and claiming pathways. Fees paid by the Government for dispensing chemotherapy medicines are different for different pharmacies (community pharmacy, private hospital, public hospital). In addition, different preparation pathways can impact on the overall costs involved in the delivery of chemotherapy.

One stakeholder noted “The arrangements for providing pharmacy services, including chemotherapy, vary from hospital to hospital - with some pharmacies being owned by the hospital and others being operated by outside third parties. Similarly, some hospital pharmacies outsource the compounding process, whilst others undertake this in-house. The mix of cancer treatments and chemotherapy medication that is supplied to patients also varies between hospitals. This results in different hospitals experiencing different financial outcomes between hospitals from their supply of chemotherapy services.”

The excessive margins available from the discounts on the cost of the medicines have allowed for multiple business models and claiming pathways. Each model may have differing commercial arrangements between the hospitals, pharmacies and oncologists involved, some of which are inefficient.

12.4 Complex nature of chemotherapy in Australia

The chemotherapy space is a complicated environment for providers. Providers must make business decisions in this context. Elements of the complex service environment relate to:
Review of Funding Arrangements for Chemotherapy Services

- technical and specialised nature of chemotherapy services;
- compounding, which is expensive and cannot be performed by all providers, creating a new link in the supply chain (third-party compounders) who also require funding; and
- widely dispersed consumer need.

12.4.1 Technical and specialised nature of chemotherapy services

The technical and specialised nature of the compounding and dispensing of chemotherapy services has also contributed to the complexity of the arrangements. The need for appropriate sterile compounding facilities means that a significant capital investment is required to enter into the market. In addition, there is a need for specialised staff with specific skills and training to both compound and dispense chemotherapy medicines. This has resulted in a relatively small number of providers in the chemotherapy field, which is demonstrated by the fact that one per cent of all community pharmacies provide approximately 80 per cent of all PBS funded chemotherapy infusions (according to PBS data). In all cases, the viability and sustainability of these services is dependent upon sufficient numbers of services to realise economies of scale.

12.4.2 Third-party compounders

There has been a trend for some hospitals that previously compounded chemotherapy medicines in-house to outsource this function to third-party compounders. This appears to be due to issues like changing economies of scale in individual circumstances but also a number of factors including the availability of specialised staff, the costs of maintaining compounding facilities, costs of training and maintaining staff to appropriate standards, and competing internal priorities for resource allocation, including floor space.

The PBS chemotherapy reimbursement model does not explicitly recognise the emerging dependence on third-party compounders in the chemotherapy supply chain, however, preparation fees paid to pharmacists are intended to cover the costs of compounding.

12.4.3 Widely dispersed consumer need

While there are no data available to detail where patients receive their infusions (AIHW data breaks down to the level of state and hospital type only), the nature of the population distribution in Australia is that some regional patients may live some distance from the nearest available service.

The provision of chemotherapy services in regional areas can be more complex due to the need to co-ordinate the attendance of patients with the delivery of the chemotherapy medicine. Patients who have travelled on the day may require same day weight and blood tests before the dose for the chemotherapy medicine can be confirmed. This may require an adjustment to the infusion in the pharmacy before the medicine is administered to the patient. This process can be further complicated for regional areas by the logistics and freight issues involved, especially for those chemotherapy medicines with a short shelf-life (see section 20.2).
Findings:
- The excessive margins available on the cost of chemotherapy medicines has provided the capacity for pharmacists to develop and sustain a variety of complex business models, with varying levels of efficiency.

13 Non-PBS activities

13.1 Excess PBS reimbursement

Prior to the Review, pharmacy stakeholders informed the Department that excess PBS reimbursement from chemotherapy medicines was being reallocated to a range of activities. These profits have reduced over time as a result of price disclosure.

For example, stakeholders reference docetaxel in their submissions. This medicine came off-patent in March 2010 and from then was subject to brand competition. Based on sales information disclosed to the Department by manufacturers, the weighted average disclosed price was 76.20 per cent below the approved ex-manufacturer price and, in accordance with price disclosure legislation, incurred an equivalent price reduction on 1 December 2012. The example below summarises the estimated impact on pharmacy per infusion, based on a brand discounting at the 76.20 per cent level.

Example: Docetaxel

Without the price reduction for docetaxel on 1 December 2012, PBS reimbursement for docetaxel would be approximately $3,886.25 per infusion, comprising:
- medicine cost of $3,745.32\(^{13}\) (based on the ex-manufacturer prices of the required vials);
- around $63.27 retail mark-up\(^{14}\) and
- $77.66 EFC fee (without interim fee)

However, the discounts offered by manufacturers meant that the ‘market price’, or the weighted average disclosed price, was 76.20 per cent below the approved ex-manufacturer price, meaning that the pharmacy was only paying the manufacturer, on average $891.39 for the same volume (plus any amount paid to the wholesaler or the compounder).

On average, the pharmacy would receive around $2994.86 in excess PBS reimbursement for dispensing the maximum amount of docetaxel (while also potentially paying fees to wholesalers and/or compounders) if there was no price change. The price disclosure reduction on 1 December 2012 reduced the amount paid to pharmacists to align with the market price.

\(^{13}\) PBS reimbursement for docetaxel in this example is calculated for a maximum amount of 250mg. The most efficient combination of vials available is chosen to make up that amount. Most patients will receive less than the maximum amount.

\(^{14}\) Based on the application of the EFC algorithm and retail mark-up calculation – see Appendix J.
13.2 Reallocation of excess PBS reimbursement

Stakeholders reported using the excess PBS reimbursement collected to ‘cover costs’ and fund a range of services. Many stakeholders claimed that this was necessary due to lack of funding from other sources or because their costs exceeded the current funding amount.

One stakeholder noted “...The PBS reimbursement amounts are intended to cover the cost of the medicine. Use of the margin between purchase price and reimbursement to fund a clinical pharmacy service has largely occurred from necessity due to the importance to provide this valuable service, with no other funding mechanism being available.”

Another noted “Our business model has been reliant on the PBS-based EFC funding mechanism. Historically we (as has the sector) have been utilising the revenue generated from a small number of non-patented drugs such as, but not limited to Docetaxel, to cross-subsidise or absorb the losses of other loss-making activities associated with the complex and costly compounding and supply of other chemotherapy-related medicines and clinical pharmacy services to patients.”

Another noted “…public hospitals providing chemotherapy services are also impacted by the price reductions as public hospitals also used trading terms to cross-subsidise the cost of preparing and dispensing other chemotherapy drugs. With price reductions, public hospitals would be required to prepare these items at an additional unbudgeted cost.”

Many activities described by stakeholders were outside the realm of services intended to be covered by the PBS, such as payment for non-PBS medicines and clinical trials of chemotherapy medicines. These developments have occurred because the funding arrangements meant they could be resourced in this manner, rather than a more appropriate funding arrangement. While both of these activities are valuable and have a role to enable better understanding, and potentially future funding, of contemporary medicines, the PBS does not fund these activities (this issue is discussed further in section 14.1).

Some stakeholders acknowledged that they were aware that this level of profitability was time limited and was not a sustainable business model. They were also aware that, once the medicine came off-patent, any discount received would be taken into account when the first price disclosure reduction was triggered – giving pharmacies around 18 months to prepare for the price change. All price reductions were announced at least three months before the reduction day, giving time for pharmacies to manage their inventory. Pharmacists could also estimate the expected reduction on a medicine, based on the level of discount they received during the period of data collection, and prepare for the new price.

Even while price disclosure continues to align reimbursement to market price, the claim made by one stakeholder that docetaxel was the ‘last molecule that covered other loss making medicines’ is challenged by the evidence of continued discounting across already reduced medicines. Many have taken multiple price disclosure price reductions over the last few years, demonstrating that significant discounting continues after price reductions. For example, epirubicin has seen two price
disclosure price reductions (78.05 per cent on 1 April 2012, 34.23 per cent on 1 April 2013). Similarly, paclitaxel has also seen two price reductions (52.58 per cent on 1 April 2011 and 86.94 per cent on 1 April 2013) (Table 2 in section 6.3 refers).

The CHF report recommended that the PBS subsidy for chemotherapy medicines should reflect the market price of the medicine, and Government should not pay inflated costs for chemotherapy medicines in order to fund other elements of the delivery of these medicines.

Findings:
- Reimbursement amounts received for discounted brands of chemotherapy medicines have been used to fund other non-PBS, non-dispensing activities, including clinical pharmaceutical services, clinical trials and devices.
- Like all PBS medicines, the reimbursement paid for EFC medicines is intended to cover the cost of dispensing the medicine itself. PBS funds are not intended to fund other activities, and any business model that relies on redirecting PBS funds to maintain viability is inherently unsustainable.

14 Funding arrangements for chemotherapy services

Following the introduction of price disclosure, pharmacists are no longer able to rely on discounts to fund non-dispensing and non-PBS related services. Therefore, pharmacists will be more reliant on the EFC fees to ensure that services can be maintained, whilst also needing to fund other services from appropriate sources.

The Review has:
- investigated the components of chemotherapy services;
- obtained cost data to quantify the costs of each component; and
- examined whether the existing fee structure is sufficient to cover the costs associated with providing chemotherapy services.

14.1 Components of chemotherapy service

The Review was tasked with identifying the cost structures associated with provision of chemotherapy services – including dispensing, compounding, administration and clinical services. Stakeholders identified three key components to the provision of chemotherapy infusions to patients with cancer:

a. Compounding of chemotherapy (including the preparation of a ready-to-administer products);
b. Dispensing, administration and related processes; and
c. Clinical pharmacy services and patient support.
The roles of pharmacists, pharmacy technicians, oncology nurses and other professionals in the provision of chemotherapy services vary between settings and facilities.

### 14.1.1 Compounding

The compounding process is an essential element of the provision of chemotherapy medicines, which involves a greater complexity than the preparation of the majority of other PBS medicines.

Compounding involves the preparation of a therapeutic product, which is intended for use by a specific patient, which requires or involves special competencies, equipment, processes or facilities. Compounding can be done by pharmacies themselves in-house, if they have the facilities. Alternatively, pharmacies can purchase prepared infusions from third-party compounders with facilities licensed by the TGA (see section 16.1.2).

It was identified that:

- In general, in-house compounding is the most efficient model (in terms of cost effectiveness and logistics). However in many circumstances, for a variety of reasons (such as significant start-up costs, hospital or pharmacy size) the in-house model may not be available or viable.
- The cost for a pharmacy purchasing infusions from a third-party compounder is usually higher overall than if the product was compounded in-house. Pharmacies engaging third-party compounders will pay additional fees generally incorporating the medicine cost, a compounding fee, general freight costs, container fees and a margin for business return. Additional fees may be added on an ad-hoc basis, e.g. urgent freight.
- While third-party compounders are entitled to charge mark-ups and fees (as private businesses), these costs flow on to the pharmacies that purchase from them.
- There are some instances where wholesalers or manufacturers charge above the ex-manufacturer price. There is no mechanism to prevent this from occurring for EFC medicines.

Several stakeholders recognised that chemotherapy infusions take significantly longer to compound than other medicines, and some are more expensive. This is reflected in the additional diluent and preparation fees provided to pharmacies for each infusion.

There was a question around whether newer chemotherapy medicines with lower levels of toxicity were treated in the same way as cytotoxic chemotherapy medicines. For example, monoclonal antibodies (MABs), such as the newly subsidised ipilimumab, are targeted to cancer cells and are therefore considered to be less toxic. These medicines therefore would not, as a class, be expected to be dangerous to the patient themselves or to the staff handling the medicines. These medicines are prominent among the new types of therapeutic agents currently in clinical practice and are predominantly used for non-cancer related medical conditions. Many of these agents are ‘dual listed’, meaning they are also provided on the general schedule and handled by community pharmacies in the same way as other non-EFC medicines.
Stakeholders reported that, in the absence of Australian guidelines on the safe handling of these medicines, they are erring on the side of caution and treating these medicines in the same way as conventional cytotoxic agents, incurring higher costs. South Australia is the only state that currently has guidelines on the treatment of these medicines and the South Australian Department of Health is in the process of updating their guidelines on treatment of MABs. If safety data support a change in treatment, associated handling costs could be decreased.

14.1.2 Dispensing and related processes

The dispensing process for chemotherapy medicines is a vital and necessary element of the infusion process which is more complex than for the majority of other PBS medicines. Stakeholders provided detailed information on the dispensing activities performed on their premises.

Generally dispensing activities are considered to be any activity designed to ensure the right patient gets the right medicine at the right time with the right dose. While a chemotherapy infusion is administered in a hospital by a nurse, the pharmacist plays a key role in delivering dispensing services and this is reflected in the dispensing fee paid to pharmacies.

The pharmacist’s dispensing role usually includes the steps identified in Figure 2:.
In 2005, the Australian Pharmaceutical Advisory Council of the Department also published ‘Guiding Principles to achieve continuity in medication management’. These guiding principles included a description of the ‘Medication Management Cycle’ (Figure 3 below) which outlines the components of medication management undertaken by the pharmacist when dispensing a medicine.
Dispensing services will vary across different settings. In public or private hospitals that undertake in-house compounding, a clinical pharmacist usually reviews orders before forwarding these to the pharmacist responsible for chemotherapy compounding who undertakes dispensing activities such as checking orders for appropriateness of dose, and potential interactions.

Some stakeholders noted that additional dispensing activities include extra checking and reconciliation between product and prescription and extra care in ensuring that all components of the order are supplied. Stakeholders also noted that chemotherapy-specific dispensing activities also require:

- additional level of skill/competence/experience required for verification and dispensing of chemotherapy;
- increased level of coordination between suppliers (incoming) and hospitals (outgoing) to synchronise to patient appointment;
- managing storage to expiry dates and temperate conditions, which includes additional/separate storage facilities, and higher refrigeration expenses;
- additional safety procedures for handling chemotherapy medicines;
- increased time/administration in following up prescriptions and aligning with charts;
- additional requirements for labeling, including cytotoxic warning labels;
- separate delivery of chemotherapy medicines in hard walled containers; and
extra administration associated with disposal of unused chemotherapy medicines.

The dispensing pharmacist may either be the hospital’s pharmacist or a community pharmacist. In each of these scenarios, the dispensing pharmacist is responsible for ensuring the medicine is appropriate for the patient. Home-based nursing providers will also source the chemotherapy medicine from a pharmacy on prescription by the oncologist. The nursing service may provide the pharmacist with blood test results prior to compounding. The dispensing pharmacist is responsible for dispensing the medicine, and the nurse administers the infusion.

While models of service provision differ, the dispensing pharmacist is a constant, and is the party who makes a claim under PBS arrangements. However, there may be situations where the pharmacist does not consult with the patient directly and makes their judgements based on the information provided. There is no mechanism for collecting this information.

The quality management framework for dispensing services is well-established. There are a range of professional standards that set out the requirements for pharmacies, as part of their normal dispensing activities, including:

- the Pharmacy Board of Australia’s Pharmacy Guidelines for Dispensing of Medicines\(^\text{17}\); and
- the Pharmaceutical Society of Australia, which has a profession-wide National Competency Standards Framework for Pharmacists in Australia\(^\text{18}\).

Consumers were aware that much of a pharmacist’s role in the provision of chemotherapy occurred ‘behind the scenes’, and that they may not be aware of the specific tasks they undertake. They stressed that consumers’ main concern was for the high quality provision of chemotherapy, and it was not the role of consumers to assess the performance of individual pharmacists. Consumers did consider it important that there were standards for the provision of chemotherapy services and medicines by pharmacists, and that these needed to be monitored by an appropriate authority.

### 14.1.3 Clinical pharmacy services and patient support

The clinical pharmacy services involved in the delivery of chemotherapy infusions are also a necessary component of a best practice chemotherapy treatment model. The collective view of the stakeholders was that chemotherapy infusions attract greater need for clinical pharmacy services than other PBS medicines because they require:

- a more complex medication regime and additional related treatments (such as antiemetics) and medications for any pre-existing conditions;
- higher levels of safety management as most chemotherapy medicines are potentially toxic for the patient and/or handler;
- consideration of the seriousness of condition being treated and the potential for adverse events; and
- a high level of monitoring required to ensure patient safety.

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\(^{17}\) [Pharmacyboard Website. Pharmacy Guidelines for dispensing of medicines.pdf](#)

\(^{18}\) [Pharmaceutical Society of Australia - Competency Standards](#)
Clinical pharmacy services are beyond that which is required to dispense the medicine and can be delivered by a number of health professionals depending on the facility and/or setting. For example, the Society of Hospital Pharmacists of Australia (SHPA) standards\textsuperscript{19} consider the following activities to be clinical pharmacy services:

- medication reconciliation;
- assessment of current medication management;
- clinical review, therapeutic medicine monitoring and adverse medicine reaction management;
- contributing to the Medication Management Plan;
- providing medicines information;
- facilitating continuity of medication management on discharge or transfer;
- participating in interdisciplinary ward rounds and meetings;
- training and education;
- participating in research; and
- quality improvement activities and peer review.

Another stakeholder also identified that their clinical service offering included:

- providing advice to clinicians on availability of chemotherapy medicines through clinical trials; and
- coordinating medicines for individual patients through special access schemes with manufacturers.

Pharmacies emphasised that clinical pharmacy services are an integral component of patient care, however, consumer groups suggested that the variety in services delivered across locations means that many patients do not receive what they considered to be ‘direct assistance’. However, most respondents acknowledged that specialised oncology pharmacists are vital to the safe and timely administration of chemotherapy, performing a complex series of functions to prepare medicines for individual patient needs, providing expert input and safety checks.

Clinical pharmacy services provided by pharmacists are a standard part of good pharmacy practice, and stakeholder views are that pharmacists have always provided these clinical pharmacy services for medicines they dispense, including chemotherapy. It is clear that the pharmacist provides valuable clinical pharmacy services that contribute to a patient’s safe chemotherapy infusion.

CHF also asked consumers about the role pharmacists play in the delivery of their chemotherapy medicines. Most reported minimal face-to-face contact with pharmacists, although some reported that their pharmacist played a key role in the provision and coordination of services, particularly in the hospital setting. In general, consumers valued the expertise and advice of pharmacists in relation to chemotherapy and most felt that they would prefer to receive advice on medicine interactions from their pharmacist than from their doctor, due to their belief that pharmacists had greater knowledge of this area.

\textsuperscript{19} SHPA Standards of Practice for Clinical Pharmacy Services, 2013
Clinical pharmacy services are funded via hospital funding directed to the states and territories. State governments are provided with Commonwealth funding to fund public hospitals, using the agreed activity-based funding (ABF) model, administered by the Independent Hospital Pricing Authority (IHPA). The ABF model currently includes funding for oncology, where hospitals provide oncology services. While some public hospitals have privatised elements of their business, e.g. pathology or pharmacy services, they are still funded to provide these services, and purchase them. Under this model, it is also recognised that rural hospitals incur higher costs and sometimes have to purchase services that they do not have on-site. As such, they receive a rural loading under ABF arrangements. Private hospitals also employ salaried staff responsible for providing patient care and support services (including theatre and accommodation). Where services are required for particular types or categories of admissions, the specific elements for that admission are considered and negotiated with private health insurers as episodic or case payments.

Accordingly, funding of these services is considered to be outside of the remit of the PBS under the Act. Hospitals/facilities providing chemotherapy services are therefore responsible for meeting the cost of providing clinical pharmacy services.

There is some disagreement in the sector around which activities are classified as clinical pharmacy services versus dispensing services. There is a range of views as to where dispensing and compounding activities start and stop, and where clinical pharmacy services start and stop. When asked to describe the clinical pharmacy services performed, many stakeholders identified several dispensing processes and vice versa. This has implications both for this Review and beyond. Some state health departments also indicated that historically public hospitals have been very poor at identifying all elements of inputs for chemotherapy services, and they have not until recently identified pharmacy inputs, in order to collect adequate data. Data provided for ABF calculation purposes have evolved and become more comprehensive over time. Given the complexity of the chemotherapy arrangements, it is not surprising that different understandings exist; however, clarity in terminology is important for discussions around adequacy of PBS funding.

**14.2 Costs associated with delivering chemotherapy services**

A key focus of the Review was to investigate the existing funding arrangements for chemotherapy services. This includes determining whether the existing fees are sufficient to cover the reasonable costs of providing chemotherapy services. This was approached in two ways:

- seeking comments from stakeholders on the current funding arrangements; and
- analysing the reported costs of providing an infusion compared to the existing funding arrangements.

**14.2.1 Stakeholder concerns**

Some pharmacy stakeholders have continued to report that funding for chemotherapy services is now considered inadequate and that chemotherapy services could become unviable for some pharmacies without additional funding. The views on the exact level of additional funding required differed across providers.
One stakeholder noted “The current funding arrangement does not fully provide for the clinical role of pharmacists in the delivery of chemotherapy, nor does it adequately support the critical, highly specialised training required for the safe and sustainable provision of chemotherapy.”

Stakeholders noted that costs varied across different locations and provider types. Nine stakeholders identified differences in the costs or processes for providing chemotherapy services in rural and regional areas. Stakeholders noted that there are likely to be higher fixed costs for hospital dispensers/compounders as well as pharmacy dispensers/compounders in regional areas, due to a range of reasons including lower production volumes and scarcity of labour. In these cases, providers may need to pay higher salaries to attract staff (although they can capitalise on a number of government incentives) or incur higher costs to send staff to training courses and manage inventory levels. One pharmacy compounding provided a comparison between their regional and metropolitan compounding pharmacies (both of which are s90 approved pharmacies), noting that the regional facility costs are more expensive by $10 per infusion. This claim seems reasonable.

Some state health departments also referred to the higher costs for provision of chemotherapy in regional areas.

IHPA determines adjustments to the national efficient price (on which Commonwealth funding for public hospitals is based) where there are legitimate and unavoidable variations in wage costs and other inputs which affect the costs of service delivery including: a) hospital type and size; b) hospital location, including regional and remote status; and c) patient complexity, including Indigenous status. IHPA has determined that in 2013-14\(^{20}\), there will be adjustments including:

- an adjustment of +8 per cent for all admitted public hospital services provided to patients from outer regional locations, payable wherever these patients are treated;
- an adjustment of +15 per cent for all admitted public hospital services provided to patients from remote locations, payable wherever these patients are treated; and
- an adjustment of +24 per cent for all admitted public hospital services provided to patients from very remote locations, payable wherever these patients are treated.

In addition to the costs discussed above, regional stakeholders reported that they incurred a higher rate of chemotherapy medicines which needed to be discarded because of last minute dose or treatment changes, although no data or evidence was provided to support these assertions.

### 14.2.2 Cost data

Dispensing pharmacies were invited to provide cost data substantiating their views. Eleven pharmacy/chemotherapy compounding sites submitted individual cost data sets according to a prescribed template. These data were combined with nine data sets previously provided to the Department by the Guild. In total, twenty individual sites undertaking chemotherapy related activities provided data; however, only nineteen data sets were received within a sufficient

\(^{20}\) [IHPA - Public Hospital pricing framework](http://www.iha.gov.au) accessed 29 August 2013
timeframe to be considered in the analysis. The data received represent around 35 per cent of PBS infusions dispensed. Pharmacies were free to provide de-identified data if they desired.

Pharmacies were asked to provide information on all costs associated with the provision of chemotherapy services, including clinical pharmacy services (e.g. patient counselling and multidisciplinary liaison) which are outside the remit of the PBS, and business on-costs.

The data were analysed by both the Department and McGrathNicol (Appendix K). There were some significant limitations to the data. McGrathNicol note that the accuracy of the data could not be verified and that the small number of data sets received may impact the generalisability of any findings. That said, the data provide insight into the estimated average cost of chemotherapy provision and the considerable variance in the sector.

### 14.2.3 Adequacy of existing funding

Costing information was provided for each of the three components identified in section 14.1 (compounding/preparation, dispensing/processing and clinical services) as well as other business costs (e.g. rent and capital costs).

Table 10 below provides a breakdown of the average cost per infusion (counting each data set equally in the average), and the weighted average cost per infusion (proportionally weighted based on the number of infusions per annum), for each cost component.

**Table 10. Average cost per infusion and weighted average cost per infusion for each cost category**

<table>
<thead>
<tr>
<th>Component</th>
<th>Average cost per infusion (range*) ($</th>
<th>Average cost per infusion – weighted by number of infusions ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBS-related costs (funded by EFC fees)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation (including diluent)</td>
<td>92.61 (49.07-137.38)</td>
<td>78.27</td>
</tr>
<tr>
<td>Dispensing/processing</td>
<td>18.79 (1.46-46.71)</td>
<td>11.99</td>
</tr>
<tr>
<td>PBS funded costs - Total</td>
<td>111.40 (56.68-163.49)</td>
<td>90.26</td>
</tr>
<tr>
<td>Related business costs (covered by retail mark-up)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other business costs (deliver, rent, overheads etc.)</td>
<td>22.33 (5.40-92.66)</td>
<td>21.25</td>
</tr>
<tr>
<td>Non-PBS related costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical services</td>
<td>11.16 (2.79-39.40)</td>
<td>11.59</td>
</tr>
<tr>
<td>Total reported costs</td>
<td>144.90 (89.22-199.68)</td>
<td>123.10</td>
</tr>
</tbody>
</table>

Source: McGrathNicol analysis  
*Includes figures derived by the Department of Health from the McGrathNicol analysis
The average cost of providing PBS-related services (preparation and dispensing) was $111.40, with reported values ranging from $56.68 to $163.49 (Table 10 refers). When adjusted to account for sales volume (by weighting by number of infusions), the average cost drops to $90.26. These figures are supported by the Department’s analysis.

When all reported cost components are taken into account (including business on-costs and non-PBS costs such as clinical pharmacy services), the average cost per infusion of providing chemotherapy services is $144.90 (weighted average $123.10). This is consistent with earlier reports from stakeholders. However this figure includes non-PBS components such as clinical pharmacy services which are not PBS-funded, and business on-costs, which are intended to be covered by the retail mark-up.

Costs were compared to existing funding to determine whether funding is currently adequate. Table 11 below compares the costs reported by pharmacies to the relevant remuneration amounts:

- the cost of PBS-related components ($111.40) to the EFC fee ($77.66);
- the cost of PBS-related components and business on-costs ($133.73) to the EFC fee and average retail mark-up ($92.66); and
- the total reported cost of all PBS and non-PBS elements of chemotherapy services ($144.90) to the EFC fee and average retail mark-up ($92.66).

Table 11 also includes a comparison of these costs compared to the existing remuneration plus the interim additional fee of $60.00.

**Table 11. Difference between current fees and the average cost per infusion**

<table>
<thead>
<tr>
<th>Related components</th>
<th>Average cost per infusion</th>
<th>Related remuneration (excl. $60.00 interim fee)</th>
<th>Difference A (excl. $60.00 interim fee)</th>
<th>Related remuneration (incl. $60.00 interim fee)</th>
<th>Difference B (incl. $60.00 interim fee)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBS components only</td>
<td>$111.40</td>
<td>$77.66</td>
<td>-$33.74</td>
<td>$137.66</td>
<td>$26.26</td>
</tr>
<tr>
<td>PBS components + business on-costs</td>
<td>$133.73</td>
<td>$92.66*</td>
<td>-$41.07</td>
<td>$152.66*</td>
<td>$18.93</td>
</tr>
<tr>
<td>PBS components + business on costs + clinical services</td>
<td>$144.90</td>
<td>$92.66*</td>
<td>-$52.24</td>
<td>$152.66*</td>
<td>$7.76</td>
</tr>
</tbody>
</table>

Source: McGrathNicol analysis

*($77.66 plus $15.00 average retail mark-up to cover business on-costs)

Based on the available data, it is apparent that the funding available per infusion (without the interim $60.00 fee) is less than the average cost of production and supply. When the interim additional fee of $60.00 is excluded, the ‘Difference A’ column shows that there is a deficit in funding that ranges from $33.74 (when only PBS components are considered) to $52.24 (when all costs, included those outside of the PBS, are considered).
When the interim $60.00 fee is included, the ‘Difference B’ column shows that total remuneration is more than sufficient to cover these costs, including non-PBS clinical services.

It must be stressed that this calculation is based on a self-reported average cost and as such, it will conceal the specific arrangements of individual pharmacies. As noted above in Table 10 earlier, the range of costs for individual pharmacies is wide. If revised funding arrangements were based on the average difference, some pharmacies would receive funding in excess to their costs, and others would continue to incur costs beyond what is funded.

In particular, the data show that costs differ according to the business model used by the pharmacy – that is, whether they compound in-house or purchase prepared infusions from a third-party compounding site (Table 12 refers).

<table>
<thead>
<tr>
<th>Included components*</th>
<th>Average cost per infusion (range across providers)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacies compounding in-house ($), Pharmacies purchasing from a third-party compounder ($), Third-party compounders (TGA-licensed) ($)</td>
</tr>
<tr>
<td>PBS components only (preparation/compounding and dispensing/processing)</td>
<td>83.96 (56.68 - 135.67), 136.00 (58.84 - 163.49), 80.75 (61.27 - 115.03)</td>
</tr>
<tr>
<td>PBS components + clinical pharmacy services + business on-costs</td>
<td>118.69 (89.22 - 171.58), 168.42 (104.80 - 199.68), 150.11 (120.93 - 165.21)</td>
</tr>
</tbody>
</table>

Source: McGrathNicol analysis. Includes figures derived by the Department of Health from the McGrathNicol analysis

* Four third-party compounding sites provided data to the Review; however, one site provided costs preparation/compounding only. This site was excluded from this analysis.

As data were provided by a range of chemotherapy providers (pharmacies compounding in-house, pharmacies purchasing from a third-party compounding site, and third-party compounders) it was possible to examine the full range of costs reported by stakeholders with different business models; however, it is important to note that all data sets are small, affecting accuracy and reliability.

Table 12 above indicates that the average cost per infusion for a pharmacy, grouped by pharmacy type, ranges from $80.75 to $136.00 for PBS components. If non-PBS components and business on-costs are included, the average cost rises to between $118.69 and $168.42.

It is noted that the current fee structure does not align with the actual costs incurred in the compounding and dispensing of chemotherapy medicines and the existing arrangements for the delivery of chemotherapy services. However, the pressing issue is the total quantum of the funding in relation to the average total cost.
14.2.4 Variance and uncertainty in quantifying appropriate funding amount

It is clear that there is considerable variance in costs across the sector. When costs are weighted by number of infusions, the average cost per infusion (for PBS components only) is reduced to $90.26 (table 10 refers), indicating either that there are a small number of pharmacies with higher costs that skew the average cost higher or there may be confounding factors.

Differences in costs can arise for a number of reasons. For example, the data indicate that costs differ across pharmacies that compound in-house compared to those who must engage third-party compounders (table 12 refers). Stakeholders reported that third-party compounders generally have higher compliance and capital costs than in-house compounders, while pharmacies that outsource chemotherapy compounding face a range of fees associated with purchasing medicines.

Table 12 shows that pharmacies purchasing from third party compounders have the highest costs per infusion; however, as previously indicated, it is important to note that there are a number of limitations to the data. These include:

- the small number of data sets provided, affecting accuracy and reliability;
- the lack of verification of the accuracy of the data; and
- consistency issues between individual data sets provided, with some providing less detail than others and some apparent differences in interpretation of each cost component, including what costs are incorporated into the third party compounder fee.

A total of 70 per cent of the data sets for pharmacies that purchase from third party compounders were provided by members of the same commercial entity. In general, these pharmacies had higher costs than the remaining pharmacies that purchase from third party compounders. This may also skew the findings in the direction of this commercial entity.

Some stakeholders indicated that they were able to negotiate lower prices from third-party compounders when purchasing significant volumes. The data provided did not enable the Review to determine the extent of any discounting in this area.

For these reasons, and the variety of business models involved, there is a wide range in the costs reported. As a result, the figures at either end of the range should be treated with some caution.

Another likely source of variance is location (some stakeholders reported varying costs based on whether an infusion was provided in a rural area or a metropolitan area). Unfortunately the data cannot be stratified reliably by location as many data sets were de-identified and, for those providers who deliver services nationwide, were not broken down by location. However, as an indicator of potential variance, data provided by three identified regional providers shows that the average cost per infusion was varied for those pharmacies (Table 13). Additional factors influencing costs may include lower production volumes and scarcity of staff.

Table 13. De-identified average costs per infusion reported by regional providers
Components of reported costs | Average reported cost | Site 1 | Site 2 | Site 3
--- | --- | --- | --- | ---
PBS components only (preparation/compounding and dispensing/processing) | $111.40 | $75.70 | $135.67 | $163.49

Source: McGrathNicol analysis. Includes figures derived by the Department of Health from the McGrathNicol analysis

**Findings:**
- Data provided by a small number of dispensing pharmacies (dispensing 35 per cent of all chemotherapy infusions) indicate that the current remuneration for PBS costs (without the interim $60.00 fee) associated with chemotherapy dispensing may be inadequate for some providers (while being sufficient for others). Additionally, the remuneration available under EFC arrangements does not align with the source of costs for chemotherapy infusions.
- However, the limited reliability and generalisability of the data means that the quantum of any required additional fee is uncertain.

**15 Issues affecting the consumer**

The Review found that the key issues for consumers with regard to chemotherapy medicines were:

- safety and quality;
- equity of access and quality across different locations;
- cost to the consumer; and
- transparency and consumer focus of chemotherapy arrangements.

The CHF also emphasised consumer support for price disclosure, noting that ‘the PBS subsidy for chemotherapy medicines should reflect the market price of the medicine, and Government should not pay inflated costs for chemotherapy medicines in order to fund other elements of the delivery of these medicines’.

**15.1 Safety and Quality**

The CHF report emphasised the importance of ensuring that chemotherapy funding arrangements support high standards of safety and quality. Chemotherapy dispensing in Australia is considered to be world-class and of high quality and safety. However the CHF report noted that while there are many guidelines and standards relating to chemotherapy medicines, there is no current agreement on which standards are the most appropriate. Consumers also expressed concern over whether there was consistent quality and safety across all locations and providers.

Quality and standards are further discussed in section 16 of this Report.

**15.2 Equity of access and quality across different locations**

Consumers told CHF that funding mechanisms are important insofar as they impact on the nature, availability and location of services. These factors all influence the conditions under which...
consumers can access chemotherapy. There are additional issues for patients living in regional and rural areas, with increased time and costs for travel, accommodation, and higher risk of not receiving the chemotherapy treatment as expected.

The CHF report noted that supplying chemotherapy medicines to consumers in rural and regional areas creates a range of additional challenges, due to the distances involved, the time taken to reach these areas, lower levels of health infrastructure and the smaller and more dispersed population. CHF reported that there is little available data on whether these challenges have created cost or other barriers to the delivery of high quality chemotherapy treatment or on the specific costs involved.

However, CHF identified some additional expenses incurred by patients living in regional areas including costs associated with treatment, travel, accommodation and leaving work for an extended period of time. In addition, some patients reported delaying treatment due to the difficulties involved in being away from their homes and families for extended periods.

Other potential issues identified by CHF include lower levels of competition and higher supply costs, plus extra costs for allied health professionals associated with treatment, such as radiation, General Practitioners and other professionals, although CHF has not provided clarity as to why these costs would be higher and there is no evidence supporting this claim.

Consumers participating in the consultations agreed that those seeking treatment in rural and regional areas deserved the same level of access to quality care as those in cities, although they recognised that in some cases a trade-off may need to be made between convenience and quality. In these cases, it was important that consumers were able to make informed decisions.

In addition to the information provided through CHF consultations, seven submissions by stakeholders also identified that travel costs can be higher for consumers, with three of these also noting that accommodation costs and additional time away from paid employment impact consumers.

It was identified that doctor/hospital choices are more limited in regional areas, but patient costs are equitable regardless of location. One submission noted that rural consumers are generally shielded from extra costs by the pharmacy and/or hospital absorbing some charges.

Several consumers also raised questions about the relative quality of chemotherapy services provided in rural and regional areas. The CHF report noted that there was anecdotal evidence that the outcomes for patients in metropolitan areas are higher, although there would likely be many causal factors underlying such a correlation. Consumers suggested that developing consistent standards for chemotherapy services could assist in driving improvements in quality across rural and regional areas. However, there is no evidence to date that the quality of chemotherapy infusions provided in regional areas is any different to those provided elsewhere.
The issues related to the provision of cancer services in regional Australia have been recognised through the funding of Regional Cancer Centres through the Health and Hospitals Fund, which has enhanced the delivery of services in regional areas. The impact of this initiative was acknowledged by a number of stakeholders.

One stakeholder noted “The recent expansion of chemotherapy services in rural and regional cancer centres has been warmly welcomed by consumers”

Stakeholders were asked to comment on whether there was a different level of quality of service between rural and regional areas. Three providers stated that there is no difference in quality of services across locations, with another provider noting that no change to quality is intended, but there are additional logistical challenges in providing a quality service in regional areas. One provider noted current resource constraints put pressure on staff involved. Two responses referred to AIHW findings that regional and rural areas experience significantly higher mortality rates from cancer, but did not specifically relate this to the quality of chemotherapy infusions. During discussions, a state government indicated that there is some concern about whether patients receiving their chemotherapy in the private sector have their chemotherapy medicines appropriately checked by the dispensing pharmacist prior to delivery to the hospital. Other submissions shared this concern, noting that public hospitals provide this service to all patients, irrespective of whether the patient is public or private.

Some providers also made reference to consumer issues, indicating concerns for patient access if private hospitals were to 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.

15.3 Cost to the consumer

15.3.1 Out-of-pocket costs relating to chemotherapy treatment

A Stakeholder noted “Before their treatment begins, cancer patients should be provided with full financial information as to its cost [...] Many are surprised and distressed about the costs they find they are incurring, especially those not covered by their private health insurance, or government subsidies of drugs via the PBS. Even multiple co-payments incurred through a course of chemotherapy can mount to a considerable out of pocket expense.”

There can be significant costs associated with undergoing cancer treatment. Research in the CHF report, commissioned by the Cancer Council NSW, found that the estimated average lifetime out-of-pocket cost for a person with cancer and their family is $47,200. This includes $38,300 in productivity costs such as lost income, $3,900 in non-health costs and $5,000 for health care.

The CHF reported that consumers stressed the importance of understanding all costs associated with chemotherapy when assessing the overall costs of treatment, not just the applicable PBS costs. These costs include ancillary medicines (for example, anti-nausea medication), radiation treatment,
Review of Funding Arrangements for Chemotherapy Services

doctor visits, allied health services and transport and accommodation, particularly for consumers who need to travel for treatment.

The CHF note that these non-PBS and out-of-pocket costs are outside the terms of reference for this Review.

15.3.2 Patient Co-payment

According to CHF some consumers reported that they have been charged co-payments for their repeat prescriptions by some providers. No further information was provided to support this claim. It is likely that this is a function of the different arrangements for public and private hospitals. PBS arrangements are only available to patients in a private setting, through a community pharmacy or through a public hospital participating in Public Hospital Pharmaceutical Reforms (further information on these Reforms is available at Appendix I). NSW and ACT are not signatories to this Agreement, so there is no requirement in the Act to apply PBS co-payment policies in hospitals in these settings.

While NSW operates outside of PBS arrangements, recent advice from the NSW Ministry of Health indicates that their co-payment arrangements for chemotherapy arrangements are now consistent with PBS co-payments (as of 21 December 2012)\(^2^1\). However stakeholders reported that actual levels of chemotherapy dispensed via public hospitals in NSW is negligible, as there is a practice in NSW practice to shift public chemotherapy patients to the private setting and therefore these patients should be paying co-pays under normal PBS arrangements. If any instances of inappropriate charging of co-payments under PBS arrangements are occurring, these should be reported to the Department.

Consumers also reported to the CHF that there was a lag in time between the introduction of the EFC measure, which ruled that patients could no longer be charged co-payments for repeat prescription, and its implementation. No evidence of such charging for repeat prescriptions has been provided.

15.4 Transparency and consumer focus of chemotherapy arrangements

According to CHF consultations, consumers are generally dissatisfied with the current chemotherapy funding arrangements. CHF reported that current funding arrangements for chemotherapy did not meet consumers’ needs for reliable and high quality supply of chemotherapy, and that they questioned whether current arrangements delivered value to them as taxpayers. Consumers told CHF that they want chemotherapy funding arrangements that are transparent, equitable and good value for money. Many consumers reported feeling disempowered by the current arrangements, with little scope for them to provide input of feedback.

The CHF report also noted that consumers find the current funding arrangements complex and difficult to understand. The role of each of the various funding sources in the provision of

\(^2^1\) NSW Health Information Bulletin “Pharmaceutical charges for hospital outpatients and safety net thresholds for 2013”, available at New South Wales Health Website
chemotherapy services was not always clear to them and this complexity was itself considered a barrier to accountability.

**Findings:**
- Key issues for consumers are safety and quality, equity of access and cost to the consumer.
- Consumers consider that the funding arrangements could be made more transparent and less complex, with scope for improving accountability and cost-effectiveness.

### 16 Quality and Standards

The Review investigated the quality and standards surrounding the preparation and dispensing of chemotherapy infusions in Australia. Compounding quality in Australia is of a high standard and there have been no major adverse events due to compounding errors in Australia in recent times. The Review received responses relating to:
- standards and compliance;
- training; and
- adverse events.

#### 16.1 Standards and compliance

##### 16.1.1 Need for consistent guidelines

The quality of the compounding and dispensing of chemotherapy medicines in Australia is generally of a high standard due to strong adherence to appropriate standards and guidelines that apply to the compounding process, facility conditions and to the dispensing process for chemotherapy medicines.

Providers of chemotherapy infusions often apply different standards and guidelines to the provision of services. Fifteen respondents to the Discussion Paper commented on the extensive range of relevant guidelines and standards that apply to chemotherapy services and how these standards are enforced. For example, pharmacies involved in the dispensing and compounding of chemotherapy medicines are guided by a multitude of guidelines and professional standards including the:

- SHPA Standards of Practice for Clinical Pharmacy Services;
- Pharmacy Guild’s Quality Care Pharmacy Program;
- Pharmaceutical Society of Australia Professional Practice Standards;
- Board of Australia’s Pharmacy Guidelines for Dispensing of Medicines;
- Clinical Oncology Society of Australia (COSA) Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy; and
- Australian Council on Safety and Quality in Health Care standards.
The Pharmaceutical Society of Australia also has a profession-wide National Competency Standards Framework for Pharmacists in Australia. There are also a range of state-based regulations relating to workplace health and safety, and handling and storing medicines and poisons.

Pharmacies that compound are also guided by, but not obliged to follow:

- TGA Good Manufacturing Practice Standards;
- International standards for medical devices and cleanrooms;
- Australian standards for cleanrooms, pharmaceutical isolators and methods of tests;
- South Australian Safe Handling of Cytotoxic Drugs and Related Wastes Guidelines; and
- Pharmaceutical Inspection Convention and Co-operation Scheme.

Submissions noted that currently there are no enforced regulations for compounding pharmacies. However, stakeholders identified that compliance was generally high. Many providers self-audited or used tools such as the Institute for Safe Medication Practices International Medication Safety Self-Assessment for Oncology, peer benchmarking. State-based pharmacy authorities may also conduct reviews of facilities.

Stakeholders themselves had a range of different views on the multiple sets of standards.

One submission noted “All providers of chemotherapy services should comply with a level of minimum standards to manage the risks associated with poor practices in the preparation of chemotherapy.”

Another submission noted “All private hospitals are required to meet the requirements of The National Standards for Safety and Quality in Health Facilities together with State private hospitals [sic] licensing requirements and legislation regarding workplace health and safety, poisons regulation, waste disposal and building.”

The same submission went on further to say “Noting that the requirements of The National Standards for Safety and Quality in Health Facilities include detailed requirements across ten areas including requirements for clinical governance (Standard 1), engagement with consumers (Standard 2) and medication safety (Standard 4) [we do] not regard it necessary for additional standards to be framed in respect of chemotherapy in accredited private hospitals and day clinics.”

Consumers were concerned that there was no consistent standard applied to chemotherapy preparation/infusion (see section 15). Consumers were aware that much of a pharmacist’s role in providing chemotherapy services occurred ‘behind the scenes’ and that they may not be aware of the specific tasks they undertake. They stressed that consumers’ main concern was for the high quality of chemotherapy infusions and it was not the role of consumers to assess the performance of individual pharmacists. Consumers did consider it important that there were standards for chemotherapy and medicines by pharmacists and that these needed to be monitored by an appropriate authority.
While current practice standards and guidelines were acknowledged as valuable, relevant and practical, it was noted that there is likely to be variance in compliance to these standards across both public and private hospitals, third-party providers and community pharmacies. Stakeholders consider that consistent standards could be implemented. Some suggested that these could be included in the existing National Safety and Quality Health Service Standards, or enforced by the Australian Pharmacy Board or state pharmacy authorities. A national accreditation scheme would also be welcomed by some stakeholders.

16.1.2 TGA licensed compounders

At present only third-party compounders, providing around 63 per cent of PBS chemotherapy infusions, are externally licensed by the TGA. These compounders are highly regulated, and ongoing compliance is expensive, however these controls and audits minimise the risk to product quality and patient safety.

There is a significant cost associated with maintaining a commercial manufacturing facility to appropriate levels to protect patient safety and ensure product quality to TGA standards. Licensing costs range between $5,000 and $10,000 per annum, with annual auditing costs of $500 per hour for an average of five days each audit. Additional compliance costs include equipment validation, monitoring systems and documentation.

In addition to the set-up costs, the TGA has stringent requirements around sophisticated air handling, multiple daily bacterial cultures, product stability testing and auditing that lead to significant ongoing costs.

16.1.3 Non-TGA licensed compounders

In-house hospital compounding units (providing 30 per cent of PBS chemotherapy infusions) have a variety of standards they work to and an element of self-regulation. Adherence to quality and safety processes is audited through the hospital accreditation process. Compliance costs for these compounders are substantially less than for TGA-licensed facilities.

Pharmacies with in-house compounding facilities (providing seven per cent of PBS chemotherapy infusions) are not subject to any formal accreditation, enforcement or monitoring of standards. However there is no evidence to suggest that these facilities are not adhering to acceptable quality and safety standards. Pharmacy compounders reported that they were providing compounding services at the same level as the current TGA standard.

The TGA is currently undertaking a separate review to determine options for reform of the regulatory framework for pharmacy compounding. Options in this review include the requirement for all compounders of chemotherapy medicines to be TGA-licensed. Hospital pharmacies are not currently covered by TGA requirements and would be exempt from the TGA findings at this point.
There was strong stakeholder support for mandatory licensing although it was acknowledged that the costs of adhering to these standards may be prohibitive for some providers. One non-TGA licensed compounder noted that should TGA approval be required for all compounding, this could eliminate small compounders that are not able to generate sufficient volumes to incur the cost of TGA compliance and still stay viable. They also note that there is little or no evidence of non-compliance with standards by pharmacies and third-party compounders. Another compounder who claims their facility meets TGA standards has indicated that they would not seek to become TGA licensed, as the ongoing costs of maintaining the standards would be prohibitive.

Some stakeholders suggested that Commonwealth funding could be linked to standards following a transition period. One compounder suggested that additional costs associated with meeting the quality and safety standards of TGA licensing could be recognised by a corresponding higher level of infusion fee.

### 16.2 Training

There are a number of comprehensive but informal training programs for pharmacists and compounding technicians who either compound or dispense chemotherapy medicines. However there is no formal accreditation, enforcement or monitoring of these programs for non-TGA licensed compounders.

Discussions with state government departments indicated that significant on-the-job and off-site training is provided to staff prior to dispensing chemotherapy medicines; however, the adequacy and consistency of this training is uncertain. For example, the Review was informed of one case where a pharmacist only had two hours training before working unaided as the sole oncology clinical pharmacist in a hospital.

There is scope for professional bodies and/or universities to consider introducing formal training and credentialing for all staff involved in compounding activities and pharmacists providing specialised clinical oncology pharmacist services. The responsibility for mandating quality standards is the role of the sector.

### 16.3 Adverse events

Due to the toxicity profile of chemotherapy medicines, these medicines have the potential to initiate unexpected reactions in patients.

These risks are highlighted by recent overseas events. Late in 2012, a nationwide fungal meningitis outbreak in the USA sickened 741 and killed 55 patients, due to tainted medicines mixed by a Massachusetts compounding pharmacy, with more than 17,000 vials of contaminated medicine potentially shipped to providers across the country. As a result, the US Senate has been considering adopting legislation aimed at regulating large-scale compounding manufacturers. Since that meningitis outbreak, at least 48 large-scale compounders in the USA have been found to have

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USA Compounding Deaths article [article of 10 May 2013](#)
produced medicines that were contaminated or created in unsafe conditions, with at least three pharmacies with visible contamination spotted in widely distributed compounded injectable medicines, intended to be sterile. These examples highlight that adverse incidents still occur, regardless of our contemporary understanding of the risks of chemotherapy medicines.

However, submissions noted that adverse medicine events are monitored and reported to the Advisory Committee of the Safety of Medicines or TGA. As noted above, there is a strong adherence to the appropriate standards and guidelines as a result of the work by the various organisations involved in safety and quality of medicines in Australia.

Further, the Review was not presented with any evidence or feedback to suggest there were any significant adverse events due to quality concerns in Australia. There have been no major adverse events due to compounding errors reported in Australia in recent times.

**Findings:**

- There is an extensive range of guidelines and standards that apply to chemotherapy services, but no existing agreement on a consistent set of standards.
- Third-party compounders are licensed by the TGA however pharmacies that compound in-house are not monitored to the same extent.
- Training opportunities vary and there is a recognised need among stakeholders for formal accreditation.
- Any changes to the existing standards, training requirements or licensing requirements could improve the quality and safety of preparation and dispensing in Australia but would also be very costly for the sector. For some providers, particularly smaller ones, these costs may be prohibitive to continued provision of chemotherapy services.
- There is a greater role for the sector to play in establishing and enforcing common standards.

**17 Administrative burden**

Some pharmacies reported that they consider managing chemotherapy under the PBS is a significant administrative burden, and they would appreciate efforts to create efficiencies in the dispensing and claiming systems.

A stakeholder noted “*We would welcome any improvements in the administrative tasks associated with supplying chemotherapy through the PBS. We support the increased use of streamlined authorities as well as the use of paperless claiming.*”
17.1 Reducing claim documentation through paperless claiming

One area that was identified for improvement was in reducing the duplication of paperwork associated with processing a prescription. At present, hospital medication charts prepared by an authorised oncology prescriber are not acceptable as a PBS prescription and a second document (the formal prescription) needs to be generated specifically to accommodate PBS billing requirements.

Stakeholders expressed interest in the medication chart prescribing model being trialled in Residential Aged Care Facilities (RACF). Under the ‘Supply and Claiming from a Medication Chart in RACFs’ initiative, since 3 April 2013 medical practitioners in selected RACFs have been able to use a standard national residential medication chart (NRMC) to prescribe most PBS medicines to patients in RACFs, without the need to write a traditional PBS prescription. Pharmacists have been able to use a copy of the NRMC to supply and claim most PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS) medicines. The trial concludes at the end of this year and an evaluation report is expected in early 2014.

One stakeholder stated: “The administrative burden of supplying chemotherapy agents through the PBS is substantial. The introduction of paperless claim as per Residential Home paperless system would significantly streamline this process.”

Similarly another stakeholder noted: “The administrative burden associated with the collection of all paper prescriptions (Authority and standard) should be removed by allowing the chemotherapy drug chart to be accepted as the prescription.”

It may be appropriate to extend this model to the chemotherapy setting and all PBS medicines in hospitals, once the RACF trial and the subsequent evaluation has been completed. The design of the NRMC has specifically enabled its incorporation into electronic prescribing and dispensing systems. A chemotherapy medication chart could also be integrated with existing electronic prescriptions and the Personally Controlled Electronic Health Record. This ‘paperless claiming’ would reduce the administrative burden for both oncologists and dispensing pharmacists.

The photo below is from the SHPA submission to the Senate Inquiry into chemotherapy funding early in 2013.
17.2 Streamlined authorities

Another source of identified inefficiency related to those chemotherapy medicines that require authorisation prior to prescribing.

There are currently 21 ‘Authority required’ chemotherapy medicines listed on the EFC schedule. These medicines can only be prescribed if prior approval is obtained from DHS. This creates an administrative burden for the prescribing oncologist.

Since the phased introduction of streamlined authorities into hospitals from 2010, the need for prior authority has been removed for most EFC medicines in the public hospital setting (for hospitals participating in the Reforms).

The additional administrative burden is particularly noticeable to those doctors who practice in both the public and private settings, but require an authority to prescribe in the private setting. It was proposed that private hospitals should also be able to utilise streamlined authority processes to reduce the administrative burden for oncologists.

One stakeholder noted “PBS requirements for drug authorities and paper based prescriptions and claiming contribute significantly to the administrative workload associated with the provision of chemotherapy services.”

According to stakeholders, prescribing doctors, as well as pharmacists and hospitals, are keen to reduce the burden of authorities, noting that they are never refused an authority on request. However, they acknowledge that these medicines are expensive and it is possible that they could be used for conditions other than for those indications approved under PBS arrangements. This is an issue for consideration by the PBAC.
There has been a shift towards streamlining authority required medicines across the PBS; however revising EFC listings will require PBAC approval.

**Findings:**
- There is the capacity to reduce administrative burden, including through the expansion of the paperless claiming model and changes to streamlined authorities.

18 **EFC Reimbursement algorithm and retail mark-ups**

The EFC measure was introduced to calculate PBS reimbursement on the basis of the most efficient possible combination of vials to minimise wastage and reduce costs. The notable changes arising from the measure were:

- An algorithm now determines the most cost-efficient set of vials to make up the prescribed amount of the chemotherapy medicine; and
- The retail mark-up paid to pharmacy for chemotherapy medicines listed under s100 of the Act is now calculated in the same manner as non-EFC medicines.

The reimbursement algorithm calculates the appropriate PBS reimbursement, including the retail mark-up and applicable preparation and dispensing fees. The method of calculating the PBS reimbursement is at Appendix J.

Two key issues were identified:

- retail mark-ups calculated using the algorithm are considered by many stakeholders to be unfair, and
- the algorithm is built on the assumption that an infusion can be made up of multiple brands of a medicine, which is not the case in clinical practice.

18.1 **Retail mark-ups**

Many stakeholders raised concerns with the way the EFC mark-up for pharmacies is calculated via the algorithm. They consider that an unintended consequence of the EFC measure was that it resulted in a retail mark-up that was lower than expected in some cases. Some stakeholders claimed that the algorithm is ‘illogical’.

A submission noted “The PBS algorithm for the calculation of the payment for high cost medications pharmacists [sic] must be corrected.”

There is a disconnect between the expectations of stakeholders and the algorithm itself at the point where the retail mark-up is paid. The Review sought to unpack the algorithm calculation and to determine whether the calculation is appropriate.
The retail mark-up paid to pharmacy for chemotherapy medicines is based on the maximum amount of the medicine that can be dispensed and for some amounts can result in only a proportion of the full mark-up being paid.

Retail mark-ups for infusions dispensed by a community pharmacy are set out in the 5CPA for community pharmacy (Table 9 in section 10.2.1 refers). S94 private hospitals receive a flat 1.4 per cent mark-up on the medicine cost and s94 public hospitals do not receive a mark-up on the medicine cost consistent with the Reforms.

The issue lies in the stage of the process that the retail mark-up is calculated. Retail mark-ups are calculated for EFC medicines in the same way as they are calculated for other PBS medicines – that is, the mark-up is first calculated for each vial of the medicine. The PBS reimbursement is then based on the sum of the ‘marked up prices’ for the vials used, plus the dispensing fee, for the ‘maximum amount’ that can be dispensed. This can result in an unexpected mark-up when the combination of single vial mark-ups attracts a lower retail mark-up than if the mark-up was determined on the value of the dispensed amount.

An example of this is summarised below:

<table>
<thead>
<tr>
<th>Example – Bevacizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab is available as a 100mg vial and an 400mg vial only.</td>
</tr>
<tr>
<td>• 100mg vial and</td>
</tr>
<tr>
<td>• 400mg vial</td>
</tr>
<tr>
<td>The maximum amount for Bevacizumab in the EFC supplement to the Schedule of Pharmaceutical Benefits is 900mg. If 900mg is prescribed, the cheapest and most efficient way to pay for the medicine, given the current ex-manufacturer prices for each vial, is</td>
</tr>
<tr>
<td>• 2x 400mg vial and</td>
</tr>
<tr>
<td>1x 100 mg vial.</td>
</tr>
<tr>
<td>The retail mark-up for each strength of the medicine is calculated according to the total medicine price ex-manufacturer for the maximum amount (determined by the PBAC and set out in the EFC Schedule), equal to $3,870. As the medicine cost is over $1,750, it could reasonably be expected to attract a $70 retail mark-up.</td>
</tr>
<tr>
<td>However, the actual retail mark-up, calculated in accordance with standard PBS processes, is based on a single vial. The maximum amount would require three 400mg vials or nine 100mg vial.</td>
</tr>
<tr>
<td>• The retail mark-up for each 400mg vial is equal to $70 / 3 = $23.33.</td>
</tr>
<tr>
<td>• The retail mark-up for the 100mg vial is equal to $70/9 = $7.78.</td>
</tr>
<tr>
<td>• The total retail mark-up would be (2 × $23.33) + (1 × $7.78) = $54.44.</td>
</tr>
</tbody>
</table>

This seems counterintuitive because, if a 900mg vial was available, the retail mark-up on this vial would be $70.00. As it is not available, the mark-up for a cost-efficient set of vials making up 900 mg of this medicine is $54.44, representing a difference of $15.56.
Example – Bevacizumab

Bevacizumab is available as a 100mg vial and an 400mg vial only.

- 100mg vial
- 400mg vial

The maximum amount for Bevacizumab in the EFC supplement to the Schedule of Pharmaceutical Benefits is 900mg. If 900mg is prescribed, the cheapest and most efficient way to pay for the medicine, given the current ex-manufacturer prices for each vial, is

- 2x 400mg vial and
- 1x 100 mg vial.

Further, most patients do not require the maximum amount. If the prescribed amount was 500mg, and the cheapest and most efficient combination of vials was 1x 400mg vial and 1x 100mg vial, the retail mark-ups are still calculated based on the maximum amount and would be:

- The retail mark-up for each 400mg vial is equal to $70 / 3 = $23.33 (as 3 vials are required to dispense the maximum amount).
- The retail mark-up for the 100mg vial is equal to $70/9 = $7.78.

The total retail mark-up would be (1 × $23.33) + (1 × $7.78) = $31.11.

The discrepancy between the expected and actual retail mark-up for EFC medicines has been cited by many stakeholders as a notable financial loss to pharmacy. Many stakeholders noted that the calculated mark-ups were unexpected, and some believed that they were inconsistent with the remainder of the PBS, or that the retail mark-up was intended to cover the costs associated with dispensing an infusion:

A stakeholder noted “the Department of Health and Ageing’s unreasonable manipulation of the PBS pricing algorithm seems to be a cynical attempt to further reduce margin [sic] available to pharmacies involved in the cancer care sector. This should be altered to reflect the mark-ups as agreed in 2010. Full fees should apply regardless of the dose. The current position is illogical because the cost to serve is not a factor of actual dose prepared.”

In fact, the calculation is consistent both with the way that retail mark-ups are calculated across the PBS for other medicines, and with the original EFC agreement.

The retail mark-up for general schedule (non-EFC) medicines is also first calculated per pack, before the ‘marked-up prices’ per pack are added together with the dispensing fee to give the PBS reimbursement price – the dispensed price for the maximum quantity (that can be dispensed). In general listings as well as EFC medicines, the sum of the mark-ups for each pack or vials used to work out the price for maximum amount or maximum quantity can be different from the mark-up that would apply if a single vial could be used to achieve the maximum amount/quantity.

The effect is not always unfavourable to the pharmacy. There are eight $100 (non-EFC) medicines where calculating the retail mark-up based on the above method results in a mark-up that is higher than the amount to which the pharmacist would otherwise be entitled. The loss in mark-up for EFC
Review of Funding Arrangements for Chemotherapy Services

medicines is equivalent to the additional mark-up for the s100 (non-EFC) medicines, and the majority of these would be dispensed by the same pharmacies. EFC retail mark-up concerns should be examined in the context of total PBS funding.

18.2 Brand substitution

Some pharmacists identified situations where the combination of vials recommended by the algorithm may be inconsistent with the vial sizes offered by a manufacturer.

The algorithm by which the cheapest combination of vials is calculated assumes that any infusion may involve vial sizes of different brands. Hypothetically, if one manufacturer supplies a 400mg vial, and another supplies a 100mg vial, the algorithm may calculate reimbursement based on a combination of 400mg and 100mg vials from different brands.

Outside of the chemotherapy space, the use of different branded medicines which are considered suitable for brand substitution is acceptable. However, best clinical practice recommends against mixing different brands for dispensing chemotherapy doses. The practice of mixing two different brands of chemotherapy medicines is seen as a "modification" of the product/brand. There are concerns regarding the safety of such practice in relation to chemotherapy medicines, and it would be difficult to determine where liability or responsibility rests if an adverse event occurred. The extent of the occurrence and impact of the brand substitution issue is unclear.

Findings:
- Many stakeholders have raised concerns with the way the retail mark-up for pharmacies is calculated for EFC reimbursement, although it is consistent with the remainder of the PBS.
- The issue is the difference between the expected retail mark-up and the mark-ups calculated using the PBS method.
  - Pharmacies expect that the retail mark-up will be calculated based on the amount dispensed.
  - However, actual retail mark-ups across the PBS are derived using the maximum amount/quantity of the medicine (on a per vial/pack basis), then applied according to the specific vials/packs that are required for the prescription (which can be less than the maximum amount/quantity).

19 Infusion Devices

Many stakeholders discussed the costs associated with using innovative infusion devices during chemotherapy. The Review examined whether it is appropriate for these devices to attract additional PBS funding.
19.1 Costs and benefits associated with infusion devices

While the standard device for delivery of chemotherapy infusions is the intravenous (IV) bag, there are also a number of new devices which can be used to dispense some medicines. The use of such devices can free up hospital beds/chairs and/or allow a patient to be discharged earlier, which can result in savings or efficiencies for the facility and/or patient. There is also a growing in the trend use of ‘closed system transfer devices’ while preparing and supplying infusions, to reduce the risk of exposing hospital personnel to cytotoxic medicines.

The decision to use these devices is largely a choice of the oncologist, in consultation with patients and staff, either for particular patient outcomes or for occupational health and safety reasons for staff. These optional devices are not funded under the PBS and would represent a significant PBS cost increase if they were. For example, although most chemotherapy is delivered diluted in an IV solution bag (with 1000mL bags costing approximately $1.30) some chemotherapy is delivered with the assistance of a computerised ambulatory medicine delivery (CADD) pump which can cost up to $4,950\(^{24}\) per pump.

A number of stakeholders concurred that the issue with infusion devices is a growing area. Stakeholders noted that some patients benefit as infusion devices allow them to remain ambulatory and can remove the need to travel or attend a hospital in some cases. Patients and their families now have a greater awareness of what is available. There are particularly more opportunities for home infusions for palliative patients; this is expected to be a growing market.

19.2 Funding of infusion devices

The PBS does not fund infusion devices for chemotherapy; instead, costs of these devices are covered by the hospital, the insurer or the patient. Where a particular device is essential for the delivery of the medicine, this is taken into account by the PBAC in assessing the cost-effectiveness of medicines submitted for listing but the cost of the device itself is not funded by the PBS. There is currently only one example of a chemotherapy medicine where an infusion device is essential for the dispensing of the medicine: fluorouracil (5-FU) which requires a specialist device for each infusion.

Twelve submissions listed the cost of devices and containers as needing to be addressed and included in any funding changes stemming from the Review. However, another stakeholder submitted that they “do not believe that the PBS should be extended to cover the cost of such items where those costs relate to and are incurred in the hospital setting.”

Some patients have these costs covered by their private health insurers but otherwise the provider absorbs the costs without transferring them onto the patients. A private health insurer confirmed that the cost of containers and devices are provided for in the hospital or extras tables of many insurers for private patients, and insurers are required to cover the costs of any devices that are listed on the Commonwealth’s Prostheses List, which does include CADD cassettes and infusors.

\(^{24}\) [Department of Health - Prostheses list](http://www.health.gov.au) (Prostheses List – August 2013, page 441) accessed 3 September 2013
A stakeholder also noted that costs associated with closed system transfer devices may be offset by a reduction in hospital workcover expenses, as they reduce the Occupational Health and Safety risk to their employees.

The costs of infusion devices are outside of the remit of the PBS, which is to provide timely, reliable and affordable access to necessary medicines, but must be limited to essential medicine costs. New device technologies will deliver benefits to patients and reduce costs to hospitals and insurance providers; the costs of funding such devices will be an emerging issue for hospitals and private health insurers.

**Findings:**

- While the standard device for delivery of chemotherapy infusions is the IV bag, there are also a number of devices which can be used in various situations of the oncologist and patient prefers.
- Where a particular device is essential for the delivery of the medicine, this is taken into account by the PBAC in assessing the cost-effectiveness of medicines submitted for listing. However, the cost of these devices is not included in the ex-manufacturer price as the PBS is not responsible for funding such choices.
- As new devices are developed, funding for devices will become more of an issue for hospitals and private health insurers.

### 20 Freight costs to the pharmacy

The current distribution fee is in part intended to cover the cost of transport of chemotherapy medicines. However, stakeholders identified certain exceptional circumstances where the costs of freight exceeded the remuneration.

#### 20.1 Standard Freight costs

Currently, EFC fees plus discounts from the cost of the medicine are combined to accommodate all costs borne by the pharmacy in order to provide a compounded medicine to the patient. In practice, however, there are specific instances where these fees do not cover all the costs for individual patients, and these costs are then passed onto hospitals.

With regard to payment for freight, the distribution fee is provided under EFC arrangements specifically to cover the cost of the logistics and transport of the vials to the community pharmacy or third-party compounder. Third-party compounders charge their clients a fee (either an apportioned fee included as part of their broader fees, or an explicit freight fee, depending on the compounder and the situation) to cover their costs, and market forces determine the degree to which compounders absorb these costs in order to secure higher market share. This is the usual case in metropolitan and regional areas. Many instances reported their regular freight costs for rural delivery were charged to, and absorbed by, the pharmacy.
While freight costs are generally included in the infusion purchase price, additional costs can be incurred in urgent or emergency cases, shown as follows (Table 15).

### Table 14. Freight costs

<table>
<thead>
<tr>
<th>Location</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metropolitan</td>
<td>Freight costs are generally included in the infusion purchase price from third-party compounders. * #</td>
</tr>
<tr>
<td>Regional</td>
<td>Freight costs are generally included in the infusion purchase price from third-party compounders. * # These costs may be higher than for metropolitan areas.</td>
</tr>
<tr>
<td>Exceptional freight</td>
<td>In exceptional circumstances, when chemotherapy is required urgently, or a medication with a short shelf life (four to six hours) is required in a regional/rural area, freight costs can be substantial. These instances are rare.</td>
</tr>
</tbody>
</table>

* Freight costs were not divulged by individual third-party compounders

# Compounding pharmacies may also wear freight costs for deliveries to hospitals

#### 20.2 Exceptional freight costs

Exceptional freight costs can be an issue for facilities providing chemotherapy services in regional centres. This is particularly an issue when short shelf-life medicines such as azacitadine, which must be infused into the patient within four to six hours of being compounded. Orders from third-party compounders are usually received 24-48 hours in advance of the scheduled administration time to allow adequate time for compounding and delivery but medicines with a short shelf-life require immediate delivery which incurs higher costs.

Stakeholders’ key concerns include the costs of delivery, particularly for these time-sensitive or urgent requests, as well as delivery to rural and regional areas.

One submission noted “Regional hospitals/clinics are under more financial pressure than their urban counterparts because they need to pay more for staff and sometimes receive a lower DRG [Diagnostic Related Group] payment for the same service due to less bargaining power when negotiating health fund contracts. The freight costs for each clinic would be around $500 per week. For items with 8 hour expiry, significant effort is required to schedule the patient and prepare the dose to link with a flight or courier to ensure that the dose is available for the patient. 8 hour expiry drugs cost us around $100 per patient per day in additional freight. If there is insufficient margin for the pharmacy to absorb these costs, some of the hospitals that we service have indicated that they would be unable to continue these treatments.”

Stakeholders reported that costs for freight to regional/rural areas met by compounders or pharmacies. Some third-party compounders explicitly chose not to charge extra for freight to regional areas, factoring freight costs into their broader billing, while others adopt a ‘user pays’ approach.

A compounding stated that they absorb around $500 per week in delivery costs to regional locations and $100 per infusion for short shelf life items where the time of compounding needed to be linked
with a flight or courier to ensure its availability for the patient. Another submission noted that a third-party compounding pharmacy has increased charges per infusion by $85 to some regional areas in the last 12 months, although this was not specifically attributed to increased freight costs. One provider indicated that they expected increased freight costs for a new Regional Cancer Centre of between $280 and $455 for some infusions.

There are instances, however, where there are exceptional circumstances that generate substantial costs that are not absorbed by compounders. These usually relate to complex freight for time-sensitive medicines or urgent requests. An example was provided where the cost of transporting a seven day cycle of emergency/short shelf-life medicines to Orange was $650 per day (or $3,250 per cycle). While these instances appear to be quite rare, when they do occur, it is likely that the cost is absorbed by the pharmacy or passed on to the hospital. A private health insurer reported that when hospitals requested funding for freight costs for chemotherapy medicines, the insurer rejected the request.

One compounding pharmacy’s submission raised the issue of temperature sensitive products requiring special packaging during transport, which is particularly critical when transporting infusions over long distances to rural and regional areas. Overly hot or cold days or incorrect storage conditions can affect the stability of the product, resulting in it being unusable for patients once it arrives at the facility. Special temperature-controlled packaging is used to insulate the product and guarantees a particular temperature range over a defined time period. The use of this packaging costs $25-$96 per box, depending on the size.

20.3 Funding for freight costs

Regional hospitals are most likely to be impacted due to their geographical distance from compounders, and in theory, are provided with a rural loading through IHPA funding, or accommodated under private health insurance negotiations. In practice, however, funding for instances of $3,250 for an individual patient to receive chemotherapy medicines is likely to be outside these considerations.

Similarly, costs for private hospitals are covered by private health insurers, who also take account of each hospital’s individual throughput, case-mix, size, location etc. There are opportunities for both sectors to renegotiate for exceptional cases, via ex gratia payments in the private sector, or through submissions to state government funding authorities in the public sector. With regard to private hospitals, discussions with private health insurers indicated that they regularly receive requests from private hospitals for ex-gratia payments to cover high-cost freight items. Under their hospital funding arrangements, some regional hospitals might receive a slightly higher bundled (episode of care) case payment fee, or a bigger ex-gratia pool.
Findings:
- Exceptional freight costs can be an issue for facilities providing chemotherapy services in regional centres. This is particularly an issue when short shelf-life medicines require immediate delivery.
- Regional public hospitals are provided with additional funding to cover different costs in the IHPA costing models. Private health insurers also consider regionality in determining funding for private hospitals.

21 Other issues raised

A number of other issues were raised during the Review. These included:

- the high costs associated with storing and preparing new high cost chemotherapy medicines; and
- confusion around several PBS reimbursement business rules.

21.1 High costs associated with new medicines

When a new medicine is listed on the PBS that is also very expensive, the capital outlay and risk related to this medicine is higher than for other chemotherapy medicines.

Stakeholders reported that the resulting increased value of stockholdings has flow-on effects to the operation of the business, although little evidence was provided. Stakeholders reported that insurance premiums may increase for compounders who need to hold stock of very expensive new items. Other stakeholders have indicated that they have needed to purchase higher specification refrigerators in order to appropriately store these medicines. One compounding reported that their supplier required them to provide detailed financial statements to declare their going concern, in order to increase their line of credit to allow them to purchase very high cost chemotherapy medicines.

While some pharmacies indicated they required more upfront capital to purchase these medicines, it is understood that in most cases pharmacists are reimbursed by the PBS before they have to pay a wholesaler or manufacturer’s invoice.

One stakeholder suggested that Centres of Excellence could be established to exclusively compound newer expensive medicines. This would mean that fewer facilities have the burden of the additional costs associated with these medicines, such as higher insurance premiums, capital, stock and refrigeration costs. However concentrating services could impact timely access for patients in other areas.
21.2 Clarification of PBS business rules

Some stakeholders raised a range of issues and concerns that have been grouped together principally because they relate to business rules. These include:

- a lack of a consistent understanding about whether a pharmacy can claim PBS reimbursement (in good faith) in circumstances where the infusion has been compounded for an individual patient but cannot be administered for patient specific reasons and the infusion is not used;
- a lack of consistent understanding about whether the ‘in good faith’ rules apply to infusions prepared for deceased patients; and
- the administrative burden associated with the DHS practice of not automatically paying a claim which is above $5,000, in the case of (some) chemotherapy medicines.

In circumstances where the infusion has been compounded for an individual patient but cannot be administered for patient-specific reasons, the pharmacy can claim PBS reimbursement for the infusion (in good faith) even if it is not used. Similarly, there is a two-week window for claims relating to a deceased patient to be lodged and the claim will be paid.

Stakeholders reported that there are sometimes instances where the recommended vial sizes are unavailable due to short-term (one-two days) stock shortages.

Some stakeholders identified that claims for payment of $5,000 or more are not automatically processed by DHS. They indicated that many chemotherapy medicines are affected by this due to their expense, and this administrative process has potential to delay cash flow to pharmacies, should payment delays result. While there are only a small percentage of prescriptions affected (3,500 out of 832,000 prescriptions in 2012-13 or 0.42 per cent) this administrative change should be considered.

Findings:

- Some stakeholders would find value in clarification from DHS on the PBS business rules and in changes to the DHS automatic payment threshold.
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