Australian Government

Department of Health and Ageing

Review of funding arrangements for chemotherapy services

Discussion paper and call for submissions

June 2013

Introduction and background to the review of arrangements for funding chemotherapy services

As part of the 2008-09 Budget, the Government announced a proposal to implement the Intravenous Chemotherapy Supply Program (ICSP) to reform funding arrangements for chemotherapy infusions. The aim of the program was reduce wastage across both the public and private sectors.

The Government subsequently agreed on 10 September 2009 to delay implementation of the ICSP. This was to enable the remuneration component of the ICSP to be negotiated within the context of all relevant policy measures for the remuneration of pharmacy, particularly the then upcoming Agreement, which provides for the fees associated with chemotherapy remuneration, as distinct from payments for the cost of chemotherapy drugs.

In parallel with the Fifth Agreement negotiations, the Pharmacy Guild of Australia submitted an "Alternative Funding Model for Chemotherapy". During the agreement negotiations the Commonwealth and the Guild agreed on this alternative funding model, and it formed the basis for the new EFC funding model. Details of the new EFC funding were announced in the 2010-11 Federal Budget as part of the Fifth Community Pharmacy Agreement Budget announcement.

The revised arrangements for the Efficient Funding of Chemotherapy Drugs (EFC) commenced on 1 December 2011. The aim of these revised arrangements was to achieve greater efficiency in the use of injectable and infusible chemotherapy medicines used in the treatment of cancer. Medicines used in cancer therapy dispensed via vials are expensive, with some drugs costing thousands of dollars per script. Specifically the revised arrangements:

- Require prescribers of chemotherapy medicines to write dose specific prescriptions measured in milligrams, without specific reference in the prescription to forms or strength of medications. That is, prescriptions must specify the individual patient dose expressed in the appropriate unit of measure, rather than in vials, and the quantity and number of repeats on the prescription will be clinically appropriate for a single treatment cycle as set out by the Pharmaceutical Benefits Advisory Committee (PBAC); and
- Pay approved chemotherapy suppliers/pharmacies for the combination of vials of medicines that most cost efficiently makes up the required patient dose of chemotherapy medicine.

The revised EFC arrangements were implemented through a new 'special arrangement' under Section 100 of the *National Health Act 1953*. All relevant forms and strengths of drugs chemotherapy medicines, including trastuzumab for treatment of early stage breast cancer, are covered by the revised arrangements. Prescribers are no longer able to write prescriptions ordering particular forms or strengths of a drug, nor may they order enough drug for a course of treatment in a single prescription; they can only order enough for one infusion.

As a result of concerns about the impact of the price reduction of Docetaxel raised by a number of stakeholders in 2012, the Minister for Health, the Hon Tanya Plibersek MP requested that staff from the Department of Health and Ageing (the Department) visit key organisations to gain a first-hand understanding of the possible impact of the Docetaxel price reduction on the provision of chemotherapy medicines. In late 2012, senior staff from the Department visited a number of chemotherapy suppliers, third party chemotherapy compounders, and private hospitals with chemotherapy services, across Australia to understand this issue.

The Department sought information from a range of stakeholders including hospitals and pharmacies, the Australian Private Hospitals Association (APHA), the Society of Hospital Pharmacists of Australia (SHPA) and from the Pharmacy Guild of Australia (the Guild).

Subsequent to this, it was announced on 7 February 2013 that matters pertaining to the supply of chemotherapy drugs in Australia including the drug docetaxel would be referred to the Senate Community Affairs Committee for inquiry. The inquiry was to report on:

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

The Inquiry's report, tabled on 10 May 2013, made a single recommendation:

> *3.41 The committee recommends 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.*

On 5 May 2013, the Commonwealth Government announced the '*Increased Funding for Chemotherapy Services*' initiative. Under this initiative, the Government is providing an additional amount of $60 for each chemotherapy infusion prepared between 1 July 2013 and 1 December 2013, while a review of chemotherapy funding arrangements is undertaken. This interim funding is being provided while the Government examines how much it should be paying to support the ongoing viability of the provision of chemotherapy medicines. The review of chemotherapy arrangements will report to the Minister by October 2013.

Aim of the review

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

Scope of the review

REVIEW OF ARRANGEMENTS FOR FUNDING CHEMOTHERAPY SERVICES

TERMS OF REFERENCE

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.

Review Overview

The provision of Pharmaceutical Benefits Scheme (PBS) chemotherapy medicines to Australians with cancer occurs through a range of complex funding arrangements and business models. This takes place across the interface of private hospital arrangements, community pharmacies, and third party compounders. Chemotherapy infusion funding also intersects across a range of current Commonwealth programs such as: the PBS and MBS, Expanded and Accelerated Price Disclosure, Private Health Insurance and the Fifth Community Pharmacy Agreement.

The review will address areas in which the Government requires further information to determine the most appropriate approach to funding chemotherapy infusion services in the longer term.

This will broadly involve:

1. Oversight of the review by selected experts, who will provide an independent perspective on the review and technical support to assist in understanding the complexities of chemotherapy in Australia; and

2. A consumer consultation process with the aim to engage health consumers and other community members to raise community awareness of the inquiry and establish an evidence base to identify community issues related to the review.

3. A consultation process to further the information gathered to date, with the aim of addressing gaps in information and to provide the opportunity for stakeholders to provide information directly or through this call for submissions; and

4. The opportunity for stakeholders to engage directly with the Department through site visits and bilateral meetings, prior to the finalisation of a report with recommendations to Government on a longer-term approach to funding.

The following questions have been designed to address the Terms of Reference for the review, having regard to particular issues that have been raised in previous consultations and by the Senate Inquiry. Stakeholders and peak organisations are also welcome to comment on matters that may not be specifically mentioned in this call for submissions.

Questions for stakeholder input

The following background information and questions have been provided to assist in your consideration of the Terms of Reference. You may wish to respond to all or some of these questions as they apply to your involvement in the preparation and use of chemotherapy medicines. You may wish to use the costing template available on the Department's Chemotherapy Review Website .

The following questions are technical in nature, but respondents are encouraged to consider the down-stream effects on both providers of chemotherapy infusions and consumers of any suggested changes to arrangements. The Government is seeking to ensure, through this

review process, that the funding arrangements for chemotherapy services reflect a transparent, accountable and efficient use of taxpayer dollars and secure the viability and sustainability of chemotherapy services for consumers in the long term.

Question for consumers:

In addition to any other feedback you may provide, as an Australian with cancer or knowing someone with cancer, have there been any issues that have impacted on access to or the quality of chemotherapy infusion medicines?

Terms of Reference 1 and 2: How chemotherapy medicine infusions are provided, the role of each sector, and how services and funding roles have changed over time

This review seeks to establish how chemotherapy medicine infusions are provided, how that has changed over time in relation to the public and private sectors and the effect of recent changes, such as the introduction of the Efficient Funding of Chemotherapy (EFC) measure, on these matters, particularly in terms of costs and accessibility of services for consumers.

The Department has received a range of evidence and information relating to these matters, but this has largely been based upon private health sector businesses and providers. The Department now seeks to explore the differences in these services by sector, across the public and private health systems - including the impact on costs of providing the service based on recent price disclosure changes - and the implications for any funding model developed as a result.

Chemotherapy funding arrangements are complex, intersecting across public and private sectors and flowing through to a range of business arrangements, from:

- small pharmacies which compound chemotherapy drugs irregularly; to
- hospitals that may compound chemotherapy drugs in-house or purchase infusions from a third party; to
- national third party compounders which sell chemotherapy infusions to pharmacies and hospitals; to
- vertically integrated businesses that provide specialist oncology, haematology chemotherapy and potentially other related services.

Current arrangements for chemotherapy infusion preparations involve a range of fees which reflect the complexity of preparing and dispensing chemotherapy medicines. These include:

- The ex-manufacturer price of the least-cost combination of vials;
- Retail mark-up on the ex-manufacturer price;
- $40.64 infusion preparation fee (as at June 2013);
- $24.38 distribution fee (replacing what was the wholesale mark-up);
- $4.83 diluent fee; and
- $6.52 dispensing fee.

The Department has requested and received a range of detailed information from some private providers indicating the expected effect of medicine price reductions on provider costs. This information now needs to be updated and expanded to take into account the effect

of the recently announced interim funding and incorporate further consideration of public hospital arrangements and cost structures.

Chemotherapy services have been notionally described by providers during consultations as comprised of:

- The process of preparation of an infusion, which is currently funded through a set of fees provided by the Commonwealth;
- Administrative costs relating to the dispensing of the drug, including for cold storage and compliance with regulatory requirements; and
- Clinical costs for advanced care pharmacists or oncology pharmacists to interview the patient, check body measurements, dosing and the drug/s for infusion.

Some suggestions have been made by stakeholders, including to the Senate Inquiry, that the costs of containers and devices should be funded under the PBS. It should be noted that PBS drug prices do not generally fund the cost of delivery devices or specific containers, although additional fees may cover some of the costs of containers. For example, the infusion fee covers reasonable costs towards the provision of a chemotherapy infusion, including containers such as viaflex bags where appropriate. The infusion fee does not currently provide for any specialised or high-cost drug delivery system. Private health insurers may also extend coverage under ancillary tables for such devices.

One of the key issues to address is the role, moving forward, of each funder in supporting the provision of chemotherapy services and the appropriate mechanism for providing funding.

Some organisations and providers have asserted that clinical services associated with the provision of chemotherapy by an advanced care or oncology pharmacist should be recognised with explicit funding. The Department's submission to the senate inquiry noted that in the private health system, the provision of such funding would generally be through private health insurers, and this may be the case currently with some clinical services associated with chemotherapy infusion preparation.

It should be noted that the clinical interventions associated with warfarin, another complex drug, are not funded through specific fees (the exception being International Normalised Ratio (INR) testing by pathology providers), but may be funded by the hospital concerned or through private health insurance.

Questions:

1. Describe the model of care for the provision of chemotherapy medicine infusions that apply in your healthcare sector or the institution in which you practice. Please consider all components from the clinical decision to order an infusion to follow-up after the course or cycle has been completed.

2. Describe the professional and administrative practices for the provision of chemotherapy medicine infusions within the healthcare sector/s in which you participate and the business model/s which support them.

3. Can you identify and describe any changes to the provision of chemotherapy medicine infusion services over recent years? Have these changes (if relevant) affected consumer access to services and, if so, how?

4. If third party compounders of chemotherapy medicines are used within your sector or institution, please describe where and how they are incorporated within the practice and business model. Also discuss the reasoning for the decision to involve a third party compounder in preparing the chemotherapy infusions.

5. Preparation and provision of chemotherapy medicine infusions undertaken by individual pharmacy businesses or business units within a larger institution. Describe the contractual or business arrangements in place with other upstream and/or downstream parts of the same healthcare sector.

6. Please describe the components of dispensing and clinical services provided in relation to infusible chemotherapy medicines? It may be useful to provide a comparison with dispensing practice for non-infusible medicines, such as tablets. Please consider the differences in relation to costs, time involved, skills required, outcomes achieved and activities undertaken?

7. Describe in detail one or more possible options for:
   - the model of care for your institution (described in response to Q1);
   - the professional practices for the provision of chemotherapy medicine infusions (described in response to Q2);
   - possible funding models for the preparation and supply of chemotherapy medicine infusions;
   - the appropriate level and source of funding for each component of practice (described in response to Q6).

Please note that the Department will endeavour to keep any commercial information provided by you confidential. To assist in doing so, please ensure that any such information provided by you or your organisation is given as an attachment to your submission rather than in the main body of the text, and clearly marked as confidential.

Term of Reference 1e: costs and complexities involved in the provision of chemotherapy drugs

The Department has received information throughout the process of examining the evidence relating to chemotherapy services that there are some differences in the processes and costs for compounding certain chemotherapy drugs.

For example, the submission to the Senate Inquiry by the Australian Private Hospitals Association (APHA) highlighted certain drugs that the APHA asserted were incurring a loss per infusion. It has also been suggested that the processes involved in preparing infusions for certain drugs, such as monoclonal antibodies or proteasome inhibitors, may differ from that of preparing other drug infusions and incur different costs. Some suggestions have also been made that the relatively higher cost of some chemotherapy drugs for providers may be due to the charging practices of manufacturers or third party compounders of drugs.

Questions:

1. Are there significant differences in the processes or costs of compounding certain infusible chemotherapy medicines? If so, please identify those medicines; describe the different practices or processes and evidence to support your position.

2. If you described a different practice for certain infusible chemotherapy medicines (in response to Q1) should these be managed or funded differently to other chemotherapy medicines? If so, please describe a possible alternative funding model for these medicines.

Term of Reference 3: Rural and regional chemotherapy provision

The Government is committed to ensuring that consumers, particularly those living in rural and regional areas, continue to have access to chemotherapy services. The Government is seeking to understand the extent to which current arrangements help to facilitate access to chemotherapy services, and whether any additional change to funding arrangements can help to further facilitate access for consumers.

Some stakeholders have raised concerns about the effect of price disclosure changes on regional and remote consumers. This prompted the Senate Inquiry to examine issues relating to these consumers more closely. In particular, some respondents to the inquiry noted that different chemotherapy infusion preparation arrangements operate in rural and regional areas, sometimes necessarily due to the distances involved.

One submission suggested that rural and remote providers bear the cost of infusions that are prepared in good faith but not dispensed. Supplies under the Revised Arrangements continue to be claimable where an infusion has been reconstituted in good faith but is not able to be administered for reasons beyond the control of the approved supplier. In these cases, the Department of Human Services will calculate the amount payable under the PBS as if the infusion has been dispensed and if the prescription is an original or deferred, a patient co-payment will be applied.

The additional interim funding of $60 per chemotherapy infusion provided by the Commonwealth has been made available to all providers of chemotherapy services, including those that provide services to regional and remote consumers. Moving forward, the Government is seeking to ensure that the long-term approach to funding takes into account any particular modifications that may need to be made to secure the ongoing viability of chemotherapy services.

Questions:

1. Are there significant differences in the costs or processes for providing chemotherapy services in rural and regional areas? How do arrangements vary between public and private sectors, and what is the effect on accessibility of services? Please provide any data or evidence you have to support your position.

2. Do consumers or providers have extra additional costs or other factors that limit access to services in these areas? Please provide any data or evidence to indicate the difference in costs or other factors for consumers.

3. Does the quality of services vary in rural and regional and remote areas compared to more urban areas? What, if anything, should be changed about current funding arrangements to address?

4. Do the current funding arrangements help to support consumer access to chemotherapy services? What changes, if any, need to be made to current pharmacy funding arrangements to address rural and regional access issues? What is the most appropriate mechanism for making any changes and/or how should the funding be managed under any such change?

Term of Reference 3: Quality of infusion preparations

It is recognised that the provision of chemotherapy drugs is a different to, and has different risks to the provision of some other, more basic drugs – for example, some Section 85 drugs.

The Department notes that there are quality standards in relation to the manufacturing and management processes for drugs through the Therapeutic Goods of Australia's Good Manufacturing Practice, as well the international Pharmaceutical Inspection Co-operation Scheme (PICS) guide for Good Manufacturing Practice for medicines and PICS guide for good preparation in healthcare establishments. The Department also notes that there are quality standards for these matters and the preparation of infusions that have been developed by the Society of Hospital Pharmacists of Australia.

The Department is seeking information on whether and how quality standards might be linked to funding arrangements and whether this will help to ensure that consumers receive quality services. The Department is seeking to understand any limitations that should be considered in linking funding to the quality of chemotherapy infusion services.

Questions:

1. What are the range of relevant guidelines and standards that apply to chemotherapy services across States and Territories? How are these standards enforced – i.e. regulations, on-site audits? Which if any of these standards should apply where drugs are being compounded on-site, or purchased from a third party, or prepared days before the infusion is delivered? How are adverse events monitored and reported?

2. Is further development of current standards required? If so, in which area is work needed? Is there other work, such as the development of quality programs, required? How can consumers be involved in the development of standards and programs to ensure quality services?

3. Should meeting any of these standards be a mandatory requirement for Commonwealth funding? If so, which? How would this be managed or enforced? Are there different standards that should be met depending on the circumstances under which the infusion is prepared? What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?

Term of Reference 3: other matters pertinent to funding for chemotherapy infusion preparation

Lastly, the Department notes that there are a range of other matters that may be considered pertinent to the funding arrangements for chemotherapy infusion preparation. For example, several responses to the Senate Inquiry raised concerns about the differing public and private

systems, and the impact of these differences on the ability to seamlessly manage dispensing and claiming of PBS medicines.

The Department is keen to streamline and improve processes wherever possible to ensure the efficient use of taxpayer money to fund services.

Questions:

1. Are there any concerns in relation to current administrative processes surrounding the provision and claiming of PBS chemotherapy medicines and infusions?

2. What if anything should be addressed in relation to these matters?

3. Are there other matters not mentioned in other areas of the paper that should be considered in developing a sustainable, transparent funding model for chemotherapy infusion services? Are there consumer issues that may not have been considered that should be taken into account in developing a sustainable funding model for chemotherapy infusion services?

Process for providing a submission

Stakeholders are invited to answer the questions raised in this discussion paper. While these questions reflect the areas of focus for the Department in preparing recommendations for the Commonwealth Government about longer-term arrangements for funding, stakeholders may address other matters if they wish.

Stakeholders and groups interested in providing a submission should prepare the submission by no later than close of business, **29 July 2013** and forward the submission to:

Department of Health and Ageing
Chemotherapy Review
MDP 901
GPO Box 9848
Canberra ACT 2601

Or via email to:
chemoreview@health.gov.au

If you wish your submission or part of your submission to be kept confidential, you must notify the Department. Any submission not identified to the Department as confidential will be placed on the Department's web site, and may also be mentioned or quoted in a summary of submissions.

For any questions relating to submissions, contact the submissions officer on (02) 6289 1374.