



Intravenous Chemotherapy Supply Program

Alternate Funding Model

Prepared and presented by:



Community Pharmacy
Chemotherapy
Services Group

Supported and endorsed by:





This is an outline of a funding model for intravenous chemotherapy presented by the Community Pharmacy Chemotherapy Services Group and endorsed by the key stakeholder groups indicated on the cover page. This paper has been prepared for presentation to the Department of Health and Ageing at a meeting on 7 July 2009 and to serve as a basis of subsequent discussion regarding the funding of intravenous chemotherapy.

Introduction

The Commonwealth Government currently funds injectable cancer chemotherapy via three programs:

- Section 85 of the PBS.
- Specific injectable cytotoxic drugs, funded via Section 100, which is accessed by some public hospitals.
- Joint funding of hospital budgets with state government in all other public hospitals.

The current funding arrangements for intravenous cancer chemotherapy are not sustainable in the long term for a number of reasons. These include:

- Lack of compliance with current approved processes.
- On occasions the Government pays for drugs unable to be used by the patients for whom they were prescribed.
- The overall viability of chemotherapy services is dependent on the margins achieved on a very small number of drugs.
- The administrative burden of managing prescription requirements.

The Commonwealth Government has proposed a new model for funding intravenous cancer chemotherapy, called the Intravenous Chemotherapy Supply Program (ICSP). This intends to make cytotoxic drugs available only via Section 100 and remunerate pharmacy on a per mg of price, calculated solely on the amount of drug administered with minimal recognition of the unavoidable excess ('wastage') involved in the process and no payment for the wholesale supply chain. A fee of \$40 is proposed for the reconstitution of each dose (Infusion Fee) and the dispensing fee is to be withdrawn from the private sector.



Doses of chemotherapy are calculated exactly by the milligram for each individual patient. As a result, there is some genuine and unavoidable excess when the amount in the vial is greater than the dose required and no other patient requiring treatment with the same drug can safely use the remaining contents. The ICSP per mg model appears to be based on the flawed notion that all leftovers are able to be used for other patients or all doses can be purchased on a per mg basis. In effect, the ICSP per mg model is unworkable, dangerous and will result in long lasting deleterious impacts on patients, public and private hospitals, pharmacies and doctors.

Summary of concerns regarding the ICSP Model

If the ICSP is implemented unchanged on 1 September 2009, there will be a potentially devastating impact on cancer sufferers and their families. This is because the proposed ICSP will:

- Create a shortfall in funding for the supply of many chemotherapy doses, which will either lead to the unfunded cost being passed on to patients or the provision of particular drugs and whole services becoming unviable.
- Reduce patient access to effective, timely and affordable chemotherapy treatments, particularly in rural and private sectors as pharmacy services find it is no longer viable to supply drugs.
- Force a wave of privately insured cancer patients to travel further for treatment and go on waiting lists at already overwhelmed public hospitals.
- Put pressure on the supply process to use opened vials of drug beyond the TGA approved parameters, thus compromising patient safety.

In consideration of the above, the Community Pharmacy Chemotherapy Services Group believe the ICSP compromises patient safety, access and choice in its current form.



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Alternate chemotherapy funding model

The data used by the Department of Health and Ageing for modelling of the ICSP and calculating projected savings have not been made available to stakeholder groups. Therefore the Community Pharmacy Chemotherapy Services Group (CPCSG) has estimated the components of the Government’s ICSP financial modelling based on information supplied by the First Assistant Secretary Pharmaceutical Benefits Division at the Stakeholders Forum on 7 May 2009.

| ICSP Component | Annual Expenditure or (Saving) | Based on |
|-------------------------------|--------------------------------|--|
| 1. Infusion Fee | \$26.6M | Infusion fee to cost ~\$80M over 3 years. At \$40 per infusion it implies the Government expects 666,667 infusions/yr. |
| 2. Per mg Reimbursement Model | (\$34.8M) | Federal budget paper estimates |
| 3. Wholesaler Margin | (\$26.6M) | Saving to be ~\$80M over 3 years. Estimate confirmed by the wholesale margin component of annual PBS expenditure on injectable cytotoxics(~\$300M) |
| Net Saving | (\$34.8M) | |

As the current funding arrangements are not sustainable and the ICSP is not viable, an alternate funding model is required. The model must be acceptable to all parties involved with cancer chemotherapy, including the Commonwealth Government.



Five key aspects of an alternate model have been identified to enable more efficiency, including reductions associated with non-administered supply via a transparent and sustainable model that places patient safety uppermost. These were previously articulated to the Department of Health and Ageing¹ as:

1. An adequate and indexed Infusion Fee for each dose of drug supplied.
2. Compensation for pharmaceutical wholesalers to maintain integrity of supply chain.
3. An Unusable Portion Factor to ensure safety and equity of access.
4. The funding of clinical pharmacy services.
5. The treatment chart must become the record of order and basis for remuneration.

The CPCSG is pleased to present an alternate funding model based on these 5 key aspects, which is supported and endorsed by the key stakeholders groups indicated on the cover page.

Before outlining the economic case for the alternate model, the CPCSG would like to recognise the substantial positive benefit the Commonwealth Government has brought to the table following stakeholder consultation around mitigating the potential increase to medical practitioner workload and patient co-payment burdens that the original ICSP proposal could have caused. CPCSG would strongly support the inclusion of the revised arrangements in any alternate model and has constructed this proposal under that expectation.

Furthermore, the alternate model has broken the 5 key aspects into 2 core groups. This paper focuses on the first 3 aspects that make a material contribution to the existing pharmacy business case for chemotherapy supply in the public or private setting. Some general and directive statements will also be made regarding the remaining 2 aspects. These are the funding of clinical services and use of the treatment chart as the record of order and basis of remuneration. Both are significant contributors to the long term sustainability of cancer treatment in Australia, but all stakeholders identified them as beyond the scope and timing of implementation contemplated by the Commonwealth Government for the ICSP.

1. Alternative Principles of Funding Paper, Community Pharmacy Chemotherapy Services Group, March 2009.



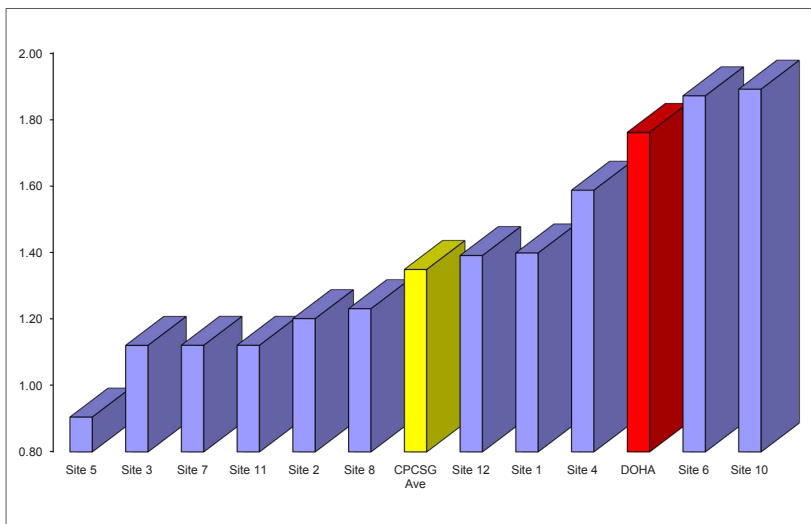
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1. Infusion Fee

The Infusion Fee is proposed as funding for the safe and accurate reconstitution of the prescribed dose of a chemotherapeutic drug from the manufacturer's vials ready for administration to the patient.

As tabled above, the ICSP \$40 infusion fee to pharmacy is 'based' on an \$80M government expenditure over 3 years, indicating an expectation of about 667,000 infusions each year. Using Medicare data of 375,000 chemotherapy prescriptions (Rx) per annum, this equates to approximately 1.8 infusions per Rx.



Infusions per script by site

undertaken extensive research in multiple cancer treatment sites, across several Australian states in both public and private settings, in an attempt to determine actual number of infusions/Rx.

As can be seen from the left-hand graph, the vast majority of sites deliver a far lower number of infusions per Rx than the ratio of 1.8 implied by the Commonwealth Government data. If the CPCSG average ratio of infusion/Rx of 1.35 is applied against the Medicare data, this would suggest that the

more likely number of Commonwealth Government funded infusions per annum will be 506,000. Consequently, CPCSG data would suggest a cost to the Government for Infusion Fees of just over \$20M rather than the \$27M (or \$80M over 3 years) indicated publicly to date. It should also be noted that this reduction in projected expenditure is calculated without removal of the existing private sector dispensing fee which CPCSG maintain should be retained - otherwise the program has the unintended consequence of delivering a greater Infusion Fee compensation to the Public Sector than Community Pharmacy. Consideration must also be given to payment of a Diluent Fee to cover the costs of the materials used in the compounding process. Based on PBS cost prices, CPCSG estimates that the Diluent Fee should be approximately \$4.75 per infusion.



2. Per Infusion Reimbursement Model

There are three models for remuneration of injectable cytotoxic drugs:

1. Per prescription based on PBS maximum quantity approved for each drug (current practice).
2. Per infusion based on the minimum PBS vials needed to prepare the dose.
3. Per dose based on the mg of drug in the dose (proposed ICSP model).

As discussed, the core aspiration of the ICSP to render chemotherapy supply more efficient, transparent and sustainable are both commendable and achievable. However, the proposed per dose based model which would use a per mg remuneration formula would compromise patient safety and the capacity of pharmacy services to maintain viable supply of chemotherapy. Introduction of a payment per infusion model delivers the Government their stated aim of a more efficient and transparent model, while also delivering substantial cost savings without compromising patient safety or pharmacy viability. In effect, a payment per infusion model equates to a payment per vial model because pharmacy will only dispense and be remunerated for the minimum vial presentations required for that infusion, as opposed to the current practice of dispensing PBS maximum quantities prescribed by the doctor on the PBS prescription.

With current practice, when a patient discontinues treatment there may be dispensed vials which are unused. This is a function of PBS prescribing and indicates a mismatch between prescribed PBS quantities and what is actually required by the patient for each episode of treatment. CPCSG has undertaken extensive research across multiple cancer treatment sites to determine the value of these unused vials and potential savings to the PBS by moving to a per infusion, vial based remuneration model. Initial modelling of a single chemotherapy site to assess the likely savings in moving to per vial based supply, indicated a saving of around 7.8% of total drug cost. Further analysis of this site indicates that the over-prescribed quantity was actually 8.8% (site 4 below). Application of this modelling program to a much wider range of clinical service settings around the country has yielded the following results among CPCSG members.



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| CPCSG Member | Estimate of quantity over-prescribed |
|--------------|--------------------------------------|
| Site 1 | 9.50 |
| Site 2 | 9.10 |
| Site 3 | 10.60 |
| Site 4 | 8.80 |
| Site 5 | 10.27 |
| Site 6 | 8.02 |
| Site 7 | 10.00 |
| Site 8 | 8.20 |
| CPCSG Ave | 9.31 |

PBS expenditure on injectable chemotherapy drugs for the 12 months up to May 2008 totalled approximately \$362M. Removal of non-ICSP drugs (e.g. interferons, BCG etc) and drugs which are already funded per infusion (trastuzumab, rituximab), results in an annual PBS expenditure of \$275M. Based on the CPCSG data above, the estimate of over-prescribed chemotherapy drugs is 9.3% and this would equate to just over \$25.5M in potential savings if the PBS funding model moved from the current prescription basis to a per infusion basis of remuneration.

3. Compensation for Wholesalers and the Supply Chain

As tabled above, the elimination of the wholesaler margin has been stated to potentially save the government \$80M over 3 years - effectively funding the ICSP Infusion Fee.

The distribution of cytotoxic drugs via existing pharmaceutical supply networks including wholesalers, should be facilitated under any new funding model in order to maintain the integrity of the supply chain. The CPCSG has listened to the Commonwealth Government’s concerns regarding the lack of transparency within the existing system and recommends moving away from the current percentage model, which is then ‘broken down’ by the industry, to a flat wholesale fee per infusion paid to pharmacy. CPCSG modelling of the existing supply chain includes manufacturer funded and unfunded channels via the wholesaler, manufacturer direct supply of some lines and supply via third party reconstitution service providers who apply a margin inclusive of wholesale costs and unusable portions.



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The modelling suggests that a flat fee of \$24 per infusion (indexed as per the Infusion Fee), would sufficiently enable pharmacy to continue funding the supply chain. While payment of this fee, based on the infusion calculations above, would result in a \$14.5M reduction in predicted annual wholesaler margin savings, the CPCSG believe this investment is fundamental for the continued certainty of access for all Australians under QUM principles. Furthermore, The CPCSG would strongly advocate continued CSO eligibility for these lines as essential medicines. As the CSO is a capped pool of funds, this inclusion would have no additional cost to government.

Consolidation of the components of the CPCSG model

The size and overall expenditure on the infusion fee, the remuneration for the drug either per mg or per vial and funding of the other contributors to the supply chain are the 3 key levers for delivery of a viable business case for supply of injectable chemotherapy. Compared with the ICSP, the CPCSG model described above presents a viable combination of these three key inputs. A sustainable delivery of chemotherapy is dependent also on addressing the additional two aspects, namely funding of clinical pharmacy services and utilisation of the treatment chart for ordering and remuneration.

The following table consolidates the three aspects of the CPCSG model described above.

| ICSP Component | Annual Expenditure or (Saving) | Alternate Infusion Based Model | Annual Expenditure or (Saving) |
|-------------------------------|--------------------------------|-------------------------------------|--------------------------------|
| 1. Infusion Fee | \$26.6M | 1. Infusion Fee | \$20.24M |
| | | Diluent Fee | \$2.4M |
| 2. Per mg Reimbursement Model | (\$34.8M) | 2. Per Infusion Remibursement Model | (\$25.5M) |
| 3. Wholesaler Margin | (\$26.6M) | 3. Supply Chain Fee | (\$14.45M) |
| Net Saving | (\$34.8M) | Net Saving | (\$17.31M) |

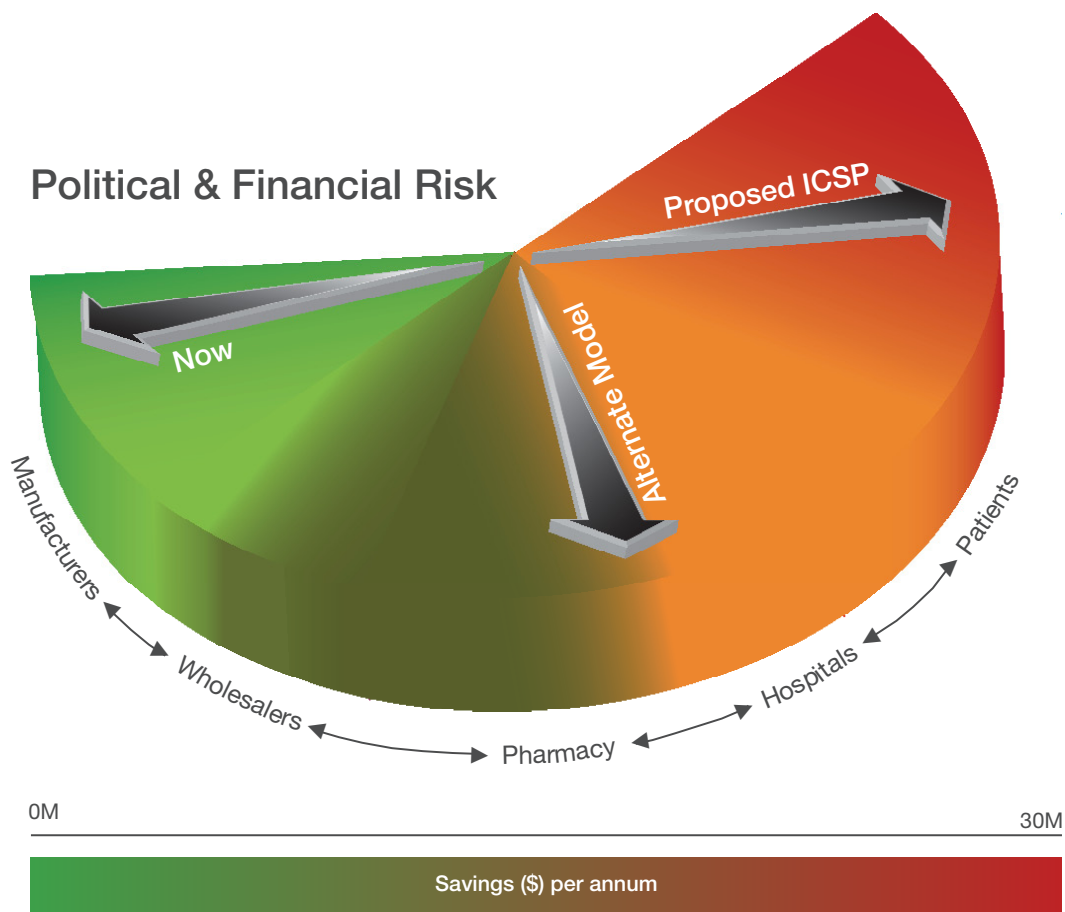


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Economic Imperative vs Clinical Risk

The graphic below illustrates the CPCSG view of the current “eco-system” and stability enjoyed via existing PBS arrangements, plus the likelihood of significant risk and suffering that will be passed on to patients depending upon the savings per annum pursued by the Commonwealth Government under any new program.





The CPCSG, with the support and endorsement of leading health professionals and health service providers, will continue to strongly argue that the ICSP in its current form, and the savings aim of approximately \$30M per annum, present an unacceptable political and financial risk to government and stakeholders. The alternate model delivers the core aspirations of the ICSP to render chemotherapy supply more efficient, transparent and sustainable, without compromising patient safety and the capacity of pharmacy services to maintain viable chemotherapy supply. This model mitigates the political and financial risk, while delivering substantial savings to government.

The savings are still substantial and certainly place additional burden at the manufacturer, wholesaler and pharmacy components of the continuum, but (as per the risk indicator above) it stops short of placing a funding shortfall on the system which would render private cancer care out of reach for many Australians and place a subsequent burden on the public setting. CPCSG believe any changes above the magnitude presented in this alternate model, will place cancer care patients in the 'danger zone' and cannot be supported.

The CPCSG and the endorsing parties to this model would strongly urge the Commonwealth Government to alter the proposed ICSP program to include the elements detailed above and pursue savings in the order of \$20M per annum, before presenting the program to the Senate for legislative approval.



Further changes required for a sustainable cancer care future:

4. Clinical Service Fee In Lieu of Price Disclosure

It must be recognised that revenue currently derived from trading terms on a small number of off-patent items plays a crucial role in the viable operation of chemotherapy services including cross-subsidising the funding of clinical pharmacy services. It is an undeniable fact that if chemotherapy items continue to fall in price due to the Price Disclosure aspects of PBS Reform then it will not be possible to cross subsidise clinical pharmacy services. It is proposed that a risk share arrangement be entered into via the 5th Pharmacy Government Agreement or some parallel negotiations, that ensure a sizeable portion of savings from Price Disclosure are re-invested in the provision of service delivery via an appropriate chemotherapy related clinical pharmacy service fee.

Payment to allied health professionals under the Enhanced Primary Care program for services provided to patients on referral by a general practitioner [items 10950-10970] could serve as an example of a model under which, on referral by oncologists, pharmacists would receive payment for providing clinical pharmacy services to patients receiving chemotherapy. Appropriate patient eligibility criteria, reporting requirements and service frequency guidelines would be developed to suite oncology practice.

5. Treatment Chart as the basis for Pharmacy Remuneration

The treatment chart must become the record of order and basis for remuneration for injectable chemotherapy. In addition to ensuring complete capture for the Commonwealth Government of the real and achievable saving of any new program, by completely eliminating payment for vials that are never accessed during the course of treatment, it would ensure some of the most valuable and precious resources in the cancer care continuum, medical practitioners and highly trained pharmacists, are not weighed down with clerical duties. This concept of utilising orders written by doctors on patients' treatment charts for authorising funding of PBS medication was strongly endorsed at every workshop attended by CPCSG members during the recent Review of the Existing Supply Arrangements of PBS Medicines in Residential Aged Care Facilities and Private Hospitals. The CPCSG strongly endorses this recommendation and urges its implementation within the Fifth Pharmacy Government Agreement and believe it should be extended to cover supply under the PBS in all Public Hospital Chemotherapy settings.



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The undersigned members of the CPCSG are pleased to present this alternate model to the Commonwealth Government and look forward to a resolution that delivers a safe and sustainable future for cancer care in Australia.



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