Department of Health and Human Services
SYSTEM PURCHASING AND PERFORMANCE - Service Quality and Improvement - Medication Strategy Reform

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Submission to the Senate Community Affairs Committee – Supply of Chemotherapy Drugs such as Docetaxel

The Department of Health and Human Services (DHHS) Tasmania, welcomes the opportunity to provide a submission to the Senate Community Affairs Committee regarding the 'Supply of Chemotherapy Drugs such as Docetaxel'.

A response to items within the Terms of Reference is provided.

A(i). Patient Access to Treatment

Australians have access to chemotherapy medicines listed on the Pharmaceutical Benefits Scheme (PBS). Chemotherapy is provided in public and private hospital settings.

Approximately 60% of all chemotherapy in Australia is delivered through private hospitals, the remainder is provided through public hospitals.

The preparation and supply of chemotherapy for private patients is performed by a limited number of specialised community pharmacies and private hospital based pharmacy services.

Contemporary cancer treatment protocols are highly complex. They generally include multiple agents which must be administered within set cycles in accordance with the patients' clinical response.

Cancer services are provided by highly specialised medical, nursing and pharmacy staff. Chemotherapy medicines are recognised globally as 'high risk medications' due to the highly toxic effect of the agents and the complexity of treatment protocols. As such the supply and administration of chemotherapy medicines is significantly more costly than other medicines.

A(ii). Costs to Pharmacists and Suppliers

Chemotherapy medicines are funded by the Australian Government via the Pharmaceutical Benefits Scheme (PBS) and are subject to the Efficient Funding of Chemotherapy Drugs Initiative (EFCDI), which came into effect in December 2011.

The EFCDI has been widely criticised as inadequate, as it does not sufficiently recognise the cost in safely preparing and supplying chemotherapy infusions.

Chemotherapy is expensive to prepare, more so than almost any other kind of medication, including other intravenous drugs. Preparation costs include;

- Specialised labour (specialist cleaners, pharmacy technicians, and oncology pharmacists).
- Installation and maintenance of specialised equipment – such as pharmaceutical isolators or cytotoxic cabinets together with pressure differential ante-rooms and (where required) clean-rooms.
- Sterile, single use, head-to-toe protective outerwear for staff handing the drugs and cleaners cleaning the sterile rooms and preparation machinery.
- Use of single use sterile protective devices on syringes, vials and bags to prevent staff and environmental exposure to the drugs.
- Consumable items, including containers and devices such as syringes, bags, cassettes, and additives such as fluids for dilution.
- Cytotoxic drug disposal, items potentially contaminated by cytotoxic drugs must be packaged and handled separately to other toxic waste and then be incinerated at 1000 degrees centigrade to ensure safe destruction.
- Constant microbial monitoring by pathology services as part of a quality control program to ensure the medicine is free of microbial contaminants.

As part of the EFCI hospital pharmacies receive a preparation fee of $40.64 per infusion prepared, private pharmacies preparing the chemotherapy infusions receive $76.37 for each item prepared (the fee consists of $6.52 dispensing fee, $40.64 preparation fee, $24.38 distribution fee, $4.83 diluent fee).

The preparation fee is grossly insufficient. A comparison of public hospital costs in preparing chemotherapy infusions in Tasmanian Hospitals supports a higher infusion fee, and even more so in a private setting. It is difficult to conceive how a range of chemotherapy infusions can be prepared safely by appropriately trained and protected staff, in facilities meeting national standards for $40.64.

Until 1 December 2012 the cost of preparing and dispensing a range of chemotherapy medicines was partially met by PBS payments but also required significant cross subsidisation from trading term discounts provided by generic suppliers for a small number of items.

Trading term discounts applicable to some generic chemotherapy drugs are subject to price disclosure – price disclosure is a Department of Health and Ageing cost saving measure. It involves monitoring the purchase price of a defined set of medications and reducing PBS payments in line with reduced market purchase prices.

Discounted purchase prices normally occur when a medicine comes off patent and less expensive generic products enter the market. Price disclosure has been in operation since 2007.

On 1 December 2012 docetaxel, a frequently used chemotherapy drug received a price reduction of 76.2%.

The trading terms on this medication had effectively been subsidising the provision of a range of chemotherapy medicines.

When the price reduction for docetaxel occurred on 1 December 2012, private provision of all chemotherapy medicines became 'at risk' and private providers indicated that they would be required to restrict and or even close their cancer treatment services unless the Department of Health and Ageing repeal the discount or provide additional funding of $100 per infusion to cover costs of manufacture.

Failure by the Department of Health and Ageing, to address the remuneration model for private provision of chemotherapy medicines before 1 December 2012 has resulted in a commercially unviable model for the private provision of chemotherapy infusions.

A(iii). Cost to Private and Public Hospital Systems

The commercially unviable model that has resulted since 1 December 2012, will inevitably lead to decreased private hospital cancer services and a shift of private patients to the public sector.

A shift of even a modest percentage of those patients to the public system would require increased public infrastructure (increased oncology beds and day chairs) increased public workforce (oncologists, nursing, medical, pharmacy staff) and increased public pathology and radiology services.

In Tasmania, we recognised that public hospitals would be unable to meet the increased demand, in the short term. To ensure Tasmanians continued to receive life-saving chemotherapy, the DHHS commencing 1 January 2013 continues to provide time limited financial support for the private preparation and supply of chemotherapy medicines so that private patients can continue to receive chemotherapy.

Whilst this funding arrangement ensures patients receive treatment in the short term, it remains a very unsatisfactory out come for Tasmania, as the State is effectively subsidising an Australian Government responsibility, which despite many months of negotiations, remains unviable and unresolved.

In addition to the risk of patient 'shift' from the private to public sector, Australian public hospitals providing PBS chemotherapy are further impacted by the price reductions as public hospitals also used trading terms to cross-subsidise the cost of preparing and dispensing other chemotherapy drugs and now are required to prepare these items at an additional cost which is unbudgeted.

B. Suggested long-term sustainable funding models for the supply of chemotherapy drugs

A long term sustainable model must include recognition of the costs of safely preparing and dispensing chemotherapy drugs in either the public or private sector.

This issue must be addressed urgently as the current arrangements are not viable in the long term and are creating great risk to chemotherapy services across the country.

It must be understood that a chemotherapy infusion is prepared by specialist staff, using specialised equipment and consumables in accordance with national standards and guidelines.

The current PBS model (first developed in 1948) is unable to appropriately support the complex demands of contemporary cancer services and as such new funding models must be considered for the supply of chemotherapy medicines.

We believe that an appropriate, transparent and sustainable model must recognise the key component costs to preparing and providing chemotherapy in a contemporary cancer service. We propose that the following component costs must be recognised as a minimum;

1. The full direct cost of the chemotherapy medicine;
2. The full direct cost of preparing the chemotherapy medicine for infusion into the patient (cost of consumables, devices, diluents);
3. Recognition of the direct and indirect costs of preparation (cost of specialist labour, protective wear, quality assurance processes, toxic drug disposal, maintenance of clean rooms and specialist equipment); and
4. The pharmacist review costs (this includes the clinical pharmacist review of each cycle of chemotherapy as part of the patient's healthcare team)

Public hospitals should receive payments relating to costs 1,2 and 3. Specialist community pharmacy providers and private hospitals should receive payments relating to all four of the cost components identified above.

Funding for payments should be investigated through quarantine of a proportion of savings generated by the PBS related EFCDI and Price Disclosure initiatives.