

Department of Health and Human Services

SYSTEM PURCHASING & PERFORMANCE – MEDICATION STRATEGY & REFORM

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Subject: Submission to the Australian Government Department of Health and Ageing – Review of Funding Arrangements for Chemotherapy Services

The Department of Health and Human Services (DHHS) Tasmania, welcomes the opportunity to provide a submission to the Department of Health and Ageing regarding the Review of Funding Arrangements for Chemotherapy Services.

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

Terms of Reference – Parts 1 and 2

Response to Questions One and Two

- 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.**

Tasmania has a high percentage of privately treated or privately referred cancer patients. This has been consistent in Tasmania for a number of years.

Generally in Tasmania patients are prescribed chemotherapy by a privately practicing Oncologist. In the situation of a prescribed infusion, the private patient elects to receive their infusion at a private hospital or to be privately referred to a public hospital. The chemotherapy infusion is dispensed by a specialist community pharmacy. The specialist community pharmacy may make the infusion or may purchase the infusion from a third party compounder.

The Oncologist determines the treatment plan in accordance with the diagnosis, laboratory parameters, performance status and organ function. The treatment (drug, dose, infusion rate, interval), as part of the treatment plan, is written on the medication chart and prescribed on a PBS compliant prescription.

When privately referred patients receive chemotherapy in a public hospital, they are admitted as a day-admitted, outside-referred-patient (ORP). The public hospital Oncology Clinical Pharmacist will liaise with the Community pharmacy provider to ensure the infusion is prepared and delivered to ensure administration occurs at the correct time during the planned admission. The Oncology Clinical Pharmacist will also double check the drug and dose against the patient's medication history, intended treatment plan, infusion rate and available clinical markers (ie pathology reports) to check that the medication is appropriate and can be given safely.

For more information about the role and actions of the Oncology Clinical Pharmacist please see the Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for the Provision of Clinical Pharmacy Oncology Services at www.shpa.org.au

Detail about the manufacture of chemotherapy infusions is provided in the answer to question six below.

The Oncology Nurse will confirm the product with the order, confirm patient parameters (blood pressure, height, weight for body surface calculation and latest pathology results). The Oncology Nurse will administer pre-treatment medications and prepare to provide the chemotherapy infusion by wearing personal protective wear. Then Oncology Nurse will administer the infusion, together with any other supportive medicines for infusion, and monitor patient parameters. The patient will be monitored for any adverse effects and be provided with counselling from the pharmacist and nurse before being discharged.

Further information about the prescribing role of the Oncologist, the dispensing role of the Oncology Pharmacist and the administration role of the Oncology Nurse can be found at the Clinical Oncological Society of Australia (COSA) Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy.

Less commonly, the patient of a public hospital receives a prescription from a public Oncologist, and receives chemotherapy treatment in a public hospital as a public patient. The hospital pharmacy department will make the chemotherapy infusion or purchase it from a third party provider.

The Oncologist determines the treatment plan in accordance with the diagnosis, laboratory parameters, performance status and organ function. The treatment (drug, dose, infusion rate, interval), as part of the treatment plan, is written on the medication chart and if relevant prescribed on a PBS compliant prescription.

When a patient of a public Oncologist receives chemotherapy in a public hospital, they are admitted as a day admitted public patient.

The clinical pharmacy and nursing administration functions for a public patient are the same as those outlined above for a privately referred patient. The Oncology Pharmacist will ensure the infusion is received at the right time for infusion. The Oncology Pharmacist will also double check the drug and dose against the patient's medication history, intended treatment plan, infusion rate and available clinical markers ie pathology reports to check that the medication can be given safely.

The Oncology Nurse will confirm the product with the order, confirm patient parameters (blood pressure, height and weight for body surface calculation, latest pathology results) administer pre-treatment medications, prepare to provide the chemotherapy infusion by wearing personal protective wear, administer the infusion together with any other supportive medicines for infusion and monitor patient parameters. The patient will be monitored for any adverse effects and provided with counselling from the pharmacist and nurse before being discharged.

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?

The provision of chemotherapy infusion services in Tasmania (as described in questions one and two) has remained largely unchanged over the past five or more years. Tasmanian consumers have access to chemotherapy infusions in both the private and public settings.

Concerns regarding consumer access to chemotherapy have not been an issue of significance until the impacts of the PBS price reduction of Docetaxel was announced for 1 December 2012. This measure, as part of the Expanded and Accelerated Price Disclosure Program created a situation in which Tasmanian community pharmacy providers of private chemotherapy infusions indicated that the funding change would cause their service to be commercially unviable.

The DHHS recognised that a commercially unviable model for private chemotherapy infusion providers would likely 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 private 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, provided time-limited financial support for the preparation and supply of chemotherapy medicines by community pharmacy providers. This enabled private patients to continue receiving chemotherapy in the private sector or as a privately referred patient of a public hospital.

The funding arrangement ceased on 1 July 2013 after Minister Plibersek announced an increased payment of \$60 per infusion for chemotherapy infusions on the PBS for a six month period pending the outcomes of the Review of Funding Arrangements for Chemotherapy Services.

It is important to note that public hospitals providing PBS chemotherapy 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.

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.

There are four key reasons as to why Tasmania has chosen to use third party compounders in Tasmanian Public Hospitals;

- a) 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 manufacturing pharmacists). Staff require training, credentialing and continued education.
 - 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 handling 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 exposure minimisation including 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. Decontamination cleaning procedure must be used together with risk minimisation strategies to prevent staff/patient exposure.
 - Constant microbial monitoring by pathology services as part of a quality control program to ensure the medicine is free of microbial contaminants.
- b) It can be difficult to maintain a pool of appropriately trained and experienced staff, especially during times of pharmacist shortages and in rural and remote locations.
- c) Efficiencies of scale; third party compounders are cost effective due to efficiencies of scale, especially for smaller sites with low order numbers and variable requirements.
- d) Increased shelf-life of products; Third party providers, licensed by the Therapeutic Goods Administration (TGA) must comply with stringent quality control and quality assurance processes. The quality measures, together with well developed storage and compatibility data, enables third party providers to manufacture larger product batches and produce products with a longer shelf-life.

Tasmania also retains some onsite manufacture for the following reasons;

- a) Tasmania is an island state with no large third party provider on the island. This exposes the State to supply interruptions in bad weather and a lag-time in ordering and receiving stock from the mainland.
- b) To maintain a pool of staff with aseptic and cytotoxic manufacturing skills.
- c) Some chemotherapeutic agents are susceptible to agitation and cannot withstand transport after reconstitution.
- d) Some chemotherapeutic agents have very short shelf lives after reconstitution (hours only) and as such must be made in the hospital pharmacy department.
- e) Some agents are required at short notice or within strict time frames from reconstitution ie chemotherapeutic agents used in clinical trials.

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.

The DHHS does not have any contractual arrangements with pharmacy businesses providing medicine infusions to private patients.

The DHHS does have a statewide contractual arrangement with a third party provider for the supply of a range of compounded pharmaceutical products (including oncology items) for public patients treated in Tasmanian public hospitals.

The DHHS did have a funding agreement with Tasmanian community pharmacy providers of chemotherapy from 1 January to 1 July 2013 to provide time-limited financial support for the preparation and supply of chemotherapy medicines to ensure that private patients could continue to receive chemotherapy in the private sector or as an ORP of a public hospital.

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?

The components of dispensing and clinical services for infusible chemotherapy medicines in comparison with tablet formulations are well documented and available in practice standards and standard operating procedures such as;

- The Society of Hospital Pharmacists of Australia Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Provision of Clinical Oncology Pharmacy Services;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Safe Transportation of Cytotoxic Drugs from Pharmacy Departments;
- The Clinical Oncological Society of Australia Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy;
- The Peter MacCallum 'Peter Mac' Cytotoxic Suite Standard Operating Procedures.

Cost of manufacture may vary from hospital to hospital depending on practice and equipment ie use of cytotoxic isolators compared with laminar flow hoods and use of closed system devices.

The average cost for each of these activities can be determined through consultation with jurisdictional representatives, private providers and the professional societies that produce practice standards in this specialty such as the Society of Hospital Pharmacists of Australia and the Clinical Oncological Society of Australia.

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).**

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.

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 or expanded funding models must be considered for the supply of chemotherapy medicines.

The DHHS 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 clinical 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.

The appropriate level of funding for each of these activities can be determine through consultation with jurisdictional representatives, private providers and the professional societies that produce practice standards in this specialty such as the Society of Hospital Pharmacists of Australia and the Clinical Oncology Society of Australia.

Funding for payments should be investigated through quarantine of a proportion of savings generated by the PBS related Efficient Funding of Chemotherapy Drugs Initiative and the Expanded and Accelerated Price Disclosure Initiative.

Part 1e: Costs and complexities involved in the provision of chemotherapy drugs

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.**

Cost of manufacture may vary from hospital to hospital depending on practice and equipment used. Those sites using a cytotoxic isolator may incur slightly less cost that those using laminar flow hoods due to variation in the personal protective wear requirements. Nevertheless in general the cost of providing an aseptic product regardless of its classification as a 'cytotoxic' agent or a 'hazardous' agent is very similar as the key cost drivers remain the same (i.e. labour, training, equipment, cleaning, maintenance, consumables, protective garments, quality assurance).

The fixed costs versus variable costs will also determine the costliness per infusion. Centres with larger throughput may experience less cost per item due to decreasing fixed costs per item with increasing item production.

The average cost for each of these activities in small, medium and large centres should be determined through focused consultation with jurisdictional representatives, private providers and the professional societies that produce practice standards in this specialty such as the Society of Hospital Pharmacists of Australia and the Clinical Oncological Society of Australia.

Part 3: Rural and regional chemotherapy provision

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.**

Rural and regional providers of chemotherapy infusions experience increased fixed costs per item due to lower production numbers. Fixed costs of significance include:

- Recruiting, training and assessing competency of specialised pharmacist, technician, cleaning, and transportation staff;
- Cost of purchase and maintenance of specialised equipment;
- Quality assurance requirements including pathology;
- Waste disposal requirements;
- Minimum stockholdings including chemotherapy medicines, consumables and personal protective wear.

The issues of cost and difficulty in recruiting/retaining specialist staff (Oncologists, Pharmacists and Nurses) in rural and regional areas mean that in Tasmania chemotherapy for cancer is provided in metropolitan and major regional centres only.

In the event that private providers do not receive sufficient remuneration to continue providing existing services Tasmanian public hospitals may need to consider further consolidating services to particular geographical areas in order to provide a sustainable service.

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.

Providers in regional areas experience additional costs including;

- Higher recruitment and salary costs;
- Increased costs in training and assessment (need to send to external competency assessment training);
- Decreased purchasing power for low volume consumables and maintenance contracts.

Consumers in rural and regional areas, incur additional costs in travelling to metropolitan and major regional centres for treatment. Key costs for consumers and their carers include;

- Transport;
- Accommodation;
- Out of pocket expenses for meals and sundries;
- Additional time away from paid employment (some consumers and carers).

Response to questions Three and Four

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?

Current funding arrangements should be inclusive of a rural loading similar to that used by the Independent Hospital Pricing Authority to acknowledge the increase costs of providing a quality service in a rural area.

It is essential that the funding model be viable in both the private and public sectors to maximise oncology service provision in metropolitan and regional areas and to provide consumer choice.

Part 3: Quality of infusion preparations

- 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?**

Tasmanian public hospitals operate in accordance with site specific policy and procedure. This policy and procedure will be linked to the DHHS Management of Cytotoxic, Hazardous and Potentially Hazardous Medicines Policy which is in the late stages of draft and consultation.

State policy and procedure is informed by the following practice standards, standard operating procedures and guidelines;

- The Society of Hospital Pharmacists of Australia Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Provision of Clinical Oncology Pharmacy Services;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments;
- The Society of Hospital Pharmacists of Australia Standards of Practice for the Safe Transportation of Cytotoxic Drugs from Pharmacy Departments;
- The Clinical Oncological Society of Australia Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy;
- The Peter Mac Cytotoxic Suite Standard Operating Procedures;
- Worksafe Tasmania: Managing risks of Hazardous Chemicals in the Workplace: Code of Practice;
- Worksafe Victoria: Handling Cytotoxics in the Workplace.
- Pharmaceutical Inspection Co-operation Scheme, Good Manufacturing Practice Guide

Hospitals are required to self audit, they are also subject to DHHS internal Audit.

Adverse drug events are reported in three ways;

- Through the DHHS Electronic Incident Management System;
- To the Therapeutic Goods Administration;
- Directly to the third party compounder (if relevant).

- 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?**

Current practice standards and guidelines developed by national professional organisations such as the Society of Hospital Pharmacists of Australian and the Clinical Oncological Society of Australia are valuable documents that are relevant, practical and current. Further development of these standards to include mandatory minimum requirements would be valuable in determining a national minimum standard for the provision of chemotherapy infusions and associated clinical services.

Currently there is a lack of formal guidance regarding the risks and therefore appropriate handling of chemotherapeutic agents that are hazardous but not cytotoxic (ie monoclonal antibody agents). Investment in formal evidence based guidance in this area is important to provide further practical guidance and support the development of more detailed standards for this sub-group of chemotherapeutic agents.

The issue of closed system devices is also currently very contentious, there is significant variation in opinion and practice regarding the place of closed system devices in chemotherapy manufacture. Investment in developing the evidence base to inform practice regarding this issue would be valuable.

There is a lack of formalised cytotoxic manufacture competency based training or credentialing in Australia. There are long waiting lists to attend high quality training such as that provided by Peter MacCallum Cancer Centre in Victoria. For states such as Tasmania the cost of sending staff to training based in another state and the cost of flying trainers and credentialing groups into the State, is considerable. A national competency based training program would be beneficial in meeting these needs in a cost effective way.

Consumers should be involved in the planning and drafting of all three activities outlined above.

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?

The requirement to meet nationally agreed minimum standards for the provision of chemotherapy infusions is appropriate. Requirements could be included in the National Safety and Quality Health Service Standards – Standard 4 Medication Safety.

Requirements for the provision of clinical pharmacy services (in accordance with the Australian Pharmaceutical Advisory Council Guidelines for medication management and continuity of care) are already included in the Pharmaceutical Reform agreement between participating states/territories and the Commonwealth. In addition Clinical Pharmacy Standards are also included in the National Safety and Quality Health Service Standards – Standard 4 Medication Safety.

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