Chemotherapy Compounding Payments Scheme (CCPS)
Draft Operational Guidelines

Joint submission by the Clinical Oncology Society of Australia, Cancer Pharmacists Group and Cancer Council Australia

August 2015

The **Clinical Oncology Society of Australia** (COSA) is Australia's peak multidisciplinary society for health professionals working in cancer research, treatment, rehabilitation and palliative care with over 1600 members. COSA is an advocacy organisation whose views are valued in all aspects of cancer care.

The **Cancer Pharmacists Group** (CPG) is a group of COSA comprised of pharmacists practising in a variety of settings including medical oncology, haematology, palliative care and cytotoxic preparation services. The CPG provides the only national multidisciplinary forum for pharmacists working in cancer services.

Cancer Council Australia (CCA) is the nation's peak, non-government, cancer control organisation. Cancer Council Australia advises the Australian Government and other bodies on practices and policies to help prevent, detect and treat cancer and advocates for the rights of cancer patients for best treatment and supportive care.

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Key Recommendations

- The federal government must ensure that, whatever the resolution to the CCPS changes, there is no disadvantage to any cancer patient in Australia in respect to cost, accessibility or safety.
- The provision of chemotherapy should be funded and reimbursed equally, irrespective of the source of manufacturing.
- Any proposed payment scheme must acknowledge the complexity of providing treatment with chemotherapy and should include funding for the pharmacy clinical service component.
- The logistics, software implications, workload and administrative burden of the proposed changes require further consideration and consultation.
- A collaborative approach is required including the Commonwealth, jurisdictions, professional bodies, licensed compounders and software providers to find a satisfactory resolution.
- All proposed procedures, methods and arrangements covered in the draft Operational Guidelines should be subject to review and change based upon further information and feedback from stakeholders **before** implementation.
- The current **transitional period** should be extended from 1 September 2015 until **at least** 31 December 2015.

1 Introduction

The Clinical Oncology Society of Australia (COSA), Cancer Pharmacists Group (CPG) and Cancer Council Australia (CCA) welcome the opportunity to comment on the draft proposal for changes to payments related to chemotherapy compounding introduced in July 2015.

In 2013, COSA made submissions during the introduction of the Efficient Funding of Chemotherapy (EFC) model. These submissions called for recognition of the clinical process of ensuring the safety of dosing and prescribing of chemotherapy as an integral part of the compounding and delivery of chemotherapy.

The current decision to remove part of the funding of chemotherapy from the health provider and increase payment to third party manufacturers (who provide no clinical verification of the product), directly impacts on the ability to provide the safety provisions currently built into the clinical healthcare setting. Reimbursement of TGA-licensed facilities at a higher rate than non-TGA-licensed facilities favours third party manufacturers and implies that the government considers the work involved in producing chemotherapy to be less involved for non-commercial hospital facilities.

All providers of chemotherapy services should comply with a minimum level of standards to manage the risks associated with poor practices in the preparation of chemotherapy. Both the European Pharmaceutical Inspection Co-operations Scheme (PICS) for Good Manufacturing Practice and Good Preparation in Healthcare Establishments are applicable, as well as the Good Manufacturing Practice standards provided by the Therapeutic Goods Administration. In addition, there are also quality standards developed by the Clinical Oncology Society of Australia (COSA)[1] and the Society of Hospital Pharmacists of Australia (SHPA)[2].

Irrespective of whether a patients' chemotherapy is obtained from a third party compounder or manufactured in-house there is a requirement for clinical pharmacy input as part of a multi-disciplinary team approach to the care of patients with cancer[1].

The splitting of the payment for chemotherapy and the proposed mechanism for claiming the payments has also created a cumbersome system that will increase workload and time requirements for the end user. The need to record and align individual CCPS Payment Infusion Numbers (C-PINs) to PBS claims will require additional resources and increase costs for hospitals. This is despite the fact that they are being financially disadvantaged whilst the commercial compounding suppliers are being financially advantaged.

COSA, the CPG and CCA believe that the provision of chemotherapy should be funded and reimbursed equally, irrespective of the source of manufacturing. Any system of funding should ensure that patient safety and outcomes are placed at the centre of the care model. The proposed system should be reviewed and if unfeasible, the original interim Efficient Funding of Chemotherapy model should be reinstated until an appropriate model is confirmed.

2 Comments on the Draft Operational Guidelines

2.1 Section 1: Implementation Stages

The "Transition" stage from 1 July to 31 August 2015 should be extended until 31 December 2015 at a minimum. The proposed commencement of the "Interim A" stage on 1 September 2015 will undoubtedly occur before feedback from the consultation has been reviewed and the model confirmed.

2.2 Section 2: Reimbursement Amount

The decision to create a two-tier payment structure for the compounding of chemotherapy will adversely affect the supply of chemotherapy under many circumstances. It will also encourage the use of third party manufacturers, which will increase the wastage of chemotherapy due to the advanced ordering process these manufacturers require.

Many healthcare services provide in-house manufacturing and the majority of public hospitals have non-TGA-licensed compounding facilities. In-house manufacturing fulfils an important role in ensuring timely administration of cancer therapy particularly for those agents that have tight time restrictions and for patients that require immediate treatment. This short turnaround time cannot occur with secondary providers. No rationale or data has been presented to justify or explain the decision to provide greater reimbursement to secondary providers.

2.3 Section 3: Identification of Infusions

The proposed C-PIN changes require significant data to be entered and/or extracted from existing IT systems used for dispensing, inventory and PBS claiming. No hospital IT system or pharmacy software currently has the capability to perform the new processes.

- Software vendors need to develop and rigorously test the new requirements. Software vendors have already confirmed they need at least 12 months lead time to build the required changes into systems.
- Software providers who support dispensing/inventory systems and information management systems require time for the changes to be implemented, as well as time for any internal testing processes required by hospitals/pharmacies.

The proposal for "physically affixing a label with the C-PIN to each infusion" may not work in practice. Compounded doses of chemotherapy often require refrigeration for stability purposes and are prepared in large infusion volumes. The proposed process requires keeping refrigerated product out of the fridge thus breaching the cold chain. The process also increases the handling of cancer chemotherapy thus increasing exposure of chemotherapy to the operator/dispenser.

2.4 Section 4: Claim Requirements

The proposed two-step process for lodging claims via a secure portal will require training for staff and create additional workload for pharmacies. This is in addition to the already high administrative burden in hospitals, especially public health. The workload and any additional staff required to manage the new processes will result in increased costs. This will have a greater impact on hospitals yet the payment advantage rests with manufacturers, thereby widening the financial disparity.

Under Option 1, compounders will be required to estimate the percentage of total infusions reported that will be subject to a subsequent PBS claim. It should be noted that this information (i.e. releasing details to a third party about activity) may be commercial-in-confidence for hospitals. It requires declaration of doses ordered which may be non-PBS or for admitted inpatients.

The proposed scheme does not define how reimbursement for chemotherapy items prepared in "good faith" under the intention to treat criteria will operate. The use of a third party compounder increases wastage as chemotherapy is ordered a few days before a patient is assessed. The ability to continue to claim for these items that have been prepared in "good faith" must continue.

2.5 Section 5: Payments

Many hospitals rely on the timely payment of pharmacy revenue for their day-to-day running budgets. Potential delays of up to 6 months in the processing of payments when using external manufacturers would have a significant impact on financial management for hospitals. This will not have been considered when setting budgets for the 2015-16 financial year.

The proposed scheme also has potential implications for regional and rural chemotherapy provision. Chemotherapy service delivery in regional and rural areas is related to administration of chemotherapy to minimise the need for patient travel. If timely payments are not made this may reduce the viability of rural services to support cancer patients.

2.6 Section 6: Review of Transition and Interim Payments

The complex process described for the review and potential adjustment of payments made during the Transition and Interim stages highlights the lack of readiness for changes to the funding of chemotherapy. As previously stated, the timeframe for software vendors and providers to develop and implement new systems as well as changes in workforce requirements make the proposed deadlines unfeasible.

2.7 Section 7: Reporting to Compounders

Compounders will also be required to institute adequate systems that integrate with multiple hospital pharmacy systems. This is likely to be associated with a considerable lead time which should be taken into account when planning implementation of the new scheme.

2.8 Section 8: Other Considerations

The procedure for a pharmacy, hospital or compounder to register as a provider is currently unclear in terms of the information needed, timeframe and any costs. The ongoing requirements also need to be transparent since these may influence future decisions regarding in-house versus external manufacturing.

COSA, the CPG and CCA support the following recommendation by the Commonwealth Department of Health that: "All proposed procedures, methods and arrangements set out in these draft Operational Guidelines are preliminary and subject to review and change based upon further information, feedback from stakeholders and experience during implementation". However, full implementation should only occur once stakeholder feedback has been taken into account.

3 Acknowledgements

COSA, the CPG and CCA thank the review panel for the opportunity to make this submission on the Chemotherapy Compounding Payments Scheme (CCPS) draft operational guidelines.

We would like to thank the COSA CPG Executive Committee for contributing their time and expertise to the development of this submission.

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5 References

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