Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015 - 2016, 1 – 2 June 2015

Ref No: SQ15-000380

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Funding arrangements of the compounding component of chemotherapy

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

The majority of chemotherapy that is administered to patients in Australia is funded by the PBS. The chemotherapy doses are expertly compounded into individual doses by specialist pharmacies or 3rd party compounders who are TGA licensed.

The government has announced intention to change the funding arrangements of the compounding component of chemotherapy. The proposal is to reduce the current fee of \$60 to \$40 for specialist compounding pharmacies and only pay \$60 for TGA approved compounders. This ignores the fact that many of advanced pharmacists are in regional and rural areas. These pharmacists compound their own chemotherapy so patients can get the treatments on the same day. Many TGA approved facilities are run by multinational companies such as Baxter. If they alone are allowed to provide chemotherapy, patients in regional Australia may be forced to wait 1-2 days for their treatment.

The intention of government is to set up a new payment agency that will pay the compounding fee direct to compounding pharmacy or TGA provider, separate to PBS payments.

- 1.Is the department aware that TGA approved compounders are only located in metropolitan areas of Australia? Tasmania and Northern Territory have no local TGA compounder. Considerable patient benefit comes from onsite compounding, particularly in country areas. Delays for chemotherapy to the Bunbury site are up to 48 hours on weekdays and 3 days on weekends.
- 2. Has any consideration been given to the patient benefit of on site compounding?
- 3. What discussions have been given to the effects of this policy on rural patients? The \$20 differential between onsite and TGA 3rd party compounding is described as being commensurate with the increased cost of compounding to TGA standards.
- 4. What modelling of the costs of TGA compounding vs onsite compounding has been applied to determine this figure?
- 5.Has any modelling of the increased cost of rural compounding been undertaken? Some patients need to defer or cancel their chemotherapy on the day of treatment due to poor blood results, change in therapy or change in disease. If the dose is sourced from a 3rd party compounder 48 hours notice would be required to defer the dose. Unused doses are wasted but in most cases would still be billed to PBS.
- 6.Is the department aware that onsite compounding creates saving to the PBS due to less wastage?
- 7. Has any analysis of this wastage been undertaken?

This proposal includes the creation of a new agency to pay compounding fees direct to the compounder rather than to the pharmacy via PBS. Neither the TGA compounders nor pharmacy compounders requested changes to the payment method.

- 8. Given the PBS is an efficient payment method for both government and pharmacy, what is the reasoning behind a new payment model?
- 9. What is the budgeted cost for the new payment agency above that paid to human services to administer the PBS?
- 10.Has consideration been given to making the payment of the full \$60 to compounding pharmacists in circumstances where geography or optimal patient care dictates this to be the most appropriate (or often only) choice available?

Answer:

- 1. Yes the Department is aware that TGA approved compounders are in metropolitan areas, and service all States and Territories in Australia. The Department is also aware from the 2013 Chemotherapy Funding Review report that in a limited number of instances local hospital pharmacies or providers undertake on-site compounding.
 - It is for this reason the new arrangements for the Efficient Funding of Chemotherapy which will take effect from 1 July 2015, recognise in-house compounding should continue to be supported through an additional \$40 fee for non-Therapeutic Goods Administration (TGA) licensed compounders, beyond the \$80.26 already paid for chemotherapy medicines under the PBS.
- 2. Yes. There are pharmacies outside of the hospital setting that provide compounding services as well as PBS dispensing services. These pharmacies are able to compound and dispense chemotherapy infusions on-site. They can also prepare chemotherapy infusions on behalf of non-compounding pharmacies. In-house compounders can prepare and dispense medicines for a patient at short notice and can usually wait until the treatment order is confirmed (e.g. following blood tests, review from an oncologist, etc.) before preparing an infusion.
- 3. A range of stakeholder groups, including providers of chemotherapy medicines were consulted as part of the PBS Access and Sustainability discussions which commenced in February 2015. In addition, the 2013 Chemotherapy Funding Review gave particular consideration to rural and remote access to chemotherapy medicines. Based on the Review, it is recognised that in some circumstances due to short supply timeframes, there is a need for in-house compounders in rural and remote Australia.
- 4. The 2013 Chemotherapy Funding Review highlighted different costs between third-party compounders of chemotherapy medicines and in-house compounders. In particular, the Review found that the cost of in-house compounding is an average of \$83.96 per infusion. In rural and remote areas, this cost is slightly higher at \$93.96. Under the new arrangements, remuneration payable (including the additional \$40 fee) will be \$120.26 excluding relevant mark-ups, over \$20 more per infusion than the estimated cost.

The Review further highlighted that while the direct cost of compounding is comparable between in-house and TGA-licensed compounders, there are additional costs in meeting the high-quality standards associated with a TGA-licensed facility, in addition to freight, handling and other associated costs. Accounting for these, the reported cost of purchasing from a TGA-licensed compounder was \$136 per infusion.

Under the new arrangements, remuneration payable (including the additional \$60 fee) will be \$140.26 excluding relevant mark-ups. This demonstrates based on cost of production, non-TGA licensed suppliers are actually continuing to receive a higher profit margin than TGA licensed compounders, regardless of location.

- 5. As stated under Question 4 above, the 2013 Review found costs for regional and rural areas would vary, however an additional cost of an average of \$10 per infusion was identified and considered reasonable. The Review further noted that due to the short shelf-life of a medicine, and set vial sizes for chemotherapy medicines, a level of wastage is unavoidable. This is why the EFC arrangements supports a model that inherently reduces wastage through the most efficient use of the cheapest possible combination of vials.
- 6. The Chemotherapy Funding Review found that as each dose is made up from set vial sizes, there is almost always a level of wastage, which cannot be reused due to the short shelf-life of the medicine. This level of wastage varies depending on the vial sizes chosen to make up each infusion. Wastage adds to the cost of these expensive medicines, and this occurs irrespective of whether third-party or in-house compounding is used by a provider.
- 7. The 2013 Chemotherapy Funding Review found that in-house compounders can prepare and dispense medicines for a patient at short notice and can usually wait until the treatment order is confirmed before preparing an infusion. While this has not been quantified, the report does suggest this may in some circumstances reduce wastage.
- 8. The 2013 Chemotherapy Review identified differential costs for third-party compounders in meeting the high-quality standards, with associated infrastructure and administrative costs in meeting TGA-licensing requirements. Under the new payment structure, this differential is recognised.
 - Subsequent to the 2013 Chemotherapy Review, as well as during PBS Access and Sustainability discussions with chemotherapy medicine providers and third-party compounders, it was identified that under current payment arrangements, pharmacies were not passing on the compounding costs in full to providers. The intention of the additional fee, when it was introduced in November 2013, was to support the costs associated with preparing PBS medicines, and not to provide additional remuneration to pharmacy (who already receive dispensing fees associated with the provision of these medicines). For this reason, direct payment to compounders will ensure the money is appropriately targeted to supporting the additional costs of preparing these medicines.
- 9. Australian Healthcare Associates (AHA) the agency currently responsible for administering the Community Services Obligation (CSO) and Price Disclosure arrangements will be responsible in the first instance for making direct payments under this measure, subject to a competitive tender process. AHA is not new, however an additional \$1.4 million in 2015-16 has been allocated to fund this payment arrangement.

10. As highlighted in Question 4, and based on the 2013 Chemotherapy Review, the new payment model provides adequate remuneration for both TGA licensed compounders, as well as in-house compounders (including recognition of additional preparation costs that may exist in some rural and remote areas).