Submission to the Review of Pharmacy Remuneration and Regulation of on behalf of Catholic Health Australia

Catholic Health Australia (CHA) welcomes the opportunity to provide input into the Review of Pharmacy Remuneration and Regulation.

CHA represents Australia's largest non-government grouping of hospitals, aged and community care services, providing approximately 10% of hospital and aged care services in Australia, including around 30 % of private hospital care as well as around 5% of public hospital care.

An integral part of CHA's mission is the holistic care for people who access our services and their significant others, which includes the delivery of pharmacy services through Section 94 and Section 90 pharmacies within CHA member hospitals. CHA members provide more than 72,000 chemotherapy separations per annum for the treatment of cancer in private hospitals alone, representing approximately 31% of private chemotherapy in Australia[1]. CHA members are among some of the largest chemotherapy providers across Australia.

Changes to current regulation and remuneration arrangements would allow hospital pharmacies to deliver care that is appropriate to and consistent with the clinical complexity of consumers that are treated in a hospital setting.

1. Expanding the scope of dispensing activities for Section 94 Pharmacies

CHA proposes changes to Section 94 of the *National Health Act* to allow Section 94 hospital pharmacies to dispense PBS drugs to out-patients and wider members of the community. Current regulation prohibits Section 94 pharmacies dispensing PBS drugs to out-patients and members of the community which creates a number of issues:

- Inequality of access by prohibiting dispensing across different models of care (e.g. day-patients, out-patients, ED, consultant rooms, off-site campus of the same hospital).
- Inequality of access to high-cost drugs, which are often stocked in Section 94 pharmacies but not in a community setting, for non-admitted consumers.

Changes to this policy would allow private hospitals to fully utilise their significant investment in pharmacy infrastructure to the benefit of the community. This will result in improved access to quality pharmaceutical services for consumers. Such a change would improve:

[1] The Department of Health. Report to the Minister for Health: Review of Funding Arrangements for Chemotherapy Services 2013.

- **Timeliness of access,** including after-hours dispensing of prescriptions. This is particularly important to consumers who use the emergency department
- **Access to specialised high-cost drugs** that are difficult to access via community pharmacies (e.g. palliative care medications)
- **Quality and safety** outcomes through specialised pharmacy advice, including post-discharge medication review and prescription compliance.
- **Expertise** in the management of specialised pharmaceutical treatments (e.g. chemotherapy)
- **Continuity of care** particularly for out-patients who require interventions in medication management for complications that may have arisen during their admission. This can be provided by pharmacists familiar with their hospital admission.

2. Changes to funding of medication reviews

a. Introduce financial incentives for Section 94 pharmacies to provide medication reviews

Section 94 pharmacies are currently unable to access funding for medication reviews, although they have significant capacity and expertise to contribute towards the management of patient care, particularly for patients that have been discharged from the same private hospital.

b. Introduce funding arrangements for Section 90 pharmacies to provide medication reviews in private hospitals

A mechanism is in place to allow Section 90 pharmacies to claim funding for medication reviews conducted in a patients home (Home Medicine Reviews) and in nursing homes (Residential Medication Management Reviews). However, no similar mechanism is in place to allow Section 90 pharmacies, which service private hospitals, to claim for in-hospital medication reviews, or review conducted during the discharge process.

Some examples of areas requiring significant pharmacist input are outlined below:

- Often patients are admitted to hospital because of medication misadventure. Pharmacist review is critical in identifying medication related adverse effects that may not be recognised by other staff. This allows for implementation of strategies for optimising medication management, and preventing further complications.
- Medication Reconciliation is another area where significant pharmacist input is required. This is critical to ensure that accurate medication information is ascertained at the points of admission, transfer and discharge. Inadvertent errors/omissions in medication lists can result in serious adverse outcomes for patients, and potentially extended hospitalisation. Medication Lists provided by GP surgeries as part of a Patient Health Summary cannot be relied upon as an up-to-date medication history.
- Pharmacist clinical review of in-patient medication orders is necessary to ensure safe use with patients' other medicines, medical conditions, renal function, and to monitor and ensure optimal therapy.
- There is no mechanism of funding for Section 90 pharmacies to produce a Discharge Medicine List for patients being discharged back into the community. This is a critical element of the NSQHS standard on Medication Safety (Standard 4). It is a time consuming exercise, involving discharge medicine reconciliation, comparing to the pre-admission

medication orders, explaining medication changes and new medicines to the patient, and providing copies of the updated Medicines List to relevant parties eg. hospital record, patient's GP and community pharmacy. This process requires specialist software not commonly available in all Section 90 pharmacies.

Provision of the above services in small private hospitals with Section 90 pharmacy providers is often currently sub-optimal, due to lack of adequate resourcing and funding.

c. Remove the 12/ 24 month restriction on funded medication reviews

With an aging population with increasing chronic disease burden, consumers often require more than one medication review per 12 or24 months, particularly if they have had hospital admission/s which often results in many medication changes.

3. Electronic information linkage between PBS Online system and Safety Net values

There are significant potential gains for consumers if PBS Online was electronically liked with calculations of safety net values.

- Currently consumers are required to keep records of all their PBS scripts in a calendar year by collecting stickers on a Prescription Record Form. Once they have reached the Safety Net limit they may apply to have a Safety Net card issued at a Pharmacy and it is only after this time that they are entitled to PBS scripts at a cheaper rate.
- Often consumers are unclear, unable or do not understand how to keep track of their Safety Net records, particularly when prescriptions are filled at multiple pharmacies.
- In the current system pharmacists are unable to ascertain a consumer's PBS Safety Net status if they do not carry their Safety Net Card or Prescription Record Form with them.
- The complexity of the system with the onus on the consumer, as well as lack of transparency for pharmacists as to the consumers Safety Net Status, means that many consumers pay more for their PBS scripts than they should be, as they are unaware that they have passed the Safety Net limit.

All PBS scripts are submitted by pharmacies to Medicare via PBS Online. Linkage of the PBS Online system with automatic calculations of Safety Net values would allow for issue a Safety Net number when the limit is reached. This would allow for real-time adjustment of the consumer contribution to the lower rate.

The Medicare system for the medical benefit Safety Net is already automated in this way. The PBS system should also be updated to allow for this linkage to ensure that the pharmacies can dispense at the correct PBS Safety Net price.

4. <u>Remuneration for chemotherapy compounding in non-TGA licensed Section 94 pharmacies</u>

Our members welcomed the government's commitment to providing $372m of funding over 5 years in the 6CPA to support the provision of chemotherapy to cancer patients across Australia. However, changes in the 6CPA have significant impact on the viability of chemotherapy provision by our members.

CHA proposes:

a. CHA proposes immediate re-instatement of $60 as a minimum for non-TGA licensed compounders

This will ensure viability of compounding pharmacies is maintained. CHA supports an additional review of compounding costs, in order to inform policy decisions based on robust data.

b. Alternatively, the development of a separate level of accreditation under the auspices of the TGA for on-site compounders.

This would require on-site compounders to regularly undertake a periodic process that would assure regulators and consumers that an appropriate benchmark of safety and quality has been attained. Compounders satisfying this requirement would continue to receive a $60 compounding fee.

Background

The reduced compounding fee to $40 is not reflective of the costs of maintaining quality chemotherapy compounding.

This figure is based on a report commissioned by the Department of Health in 2013[2]. The report itself identifies that the accuracy of compounding costing data could not be verified due to lack of adequate data and aggregated and non-audited data sets (Appendix I).

CHA has serious concerns about the impact of the fee reduction on the ongoing ability of non-TGA compounders to continue to undertake compounding, and in some cases, their ongoing continuation to provide chemotherapy services – potentially reducing access to consumers.

CHA members report that the cost of compounding is approximately $60.35-63.94 per infusion in a non-TGA licensed hospital pharmacy.

Reduction in compounding fee will have unintended costs to the PBS from increased "non-administrable infusions"

In Australia in 2012, the PBS paid for 830,000 chemotherapy infusions at a cost of $570million to the PBS[1]. On-site hospital compounding provides 30%[1] of PBS chemotherapy infusions (249,000 infusions).

- Reduction in the compounding fee will likely result in increased out-sourcing to 3rd party compounders
- Pre-ordering of chemotherapy from a 3rd party compounder results in higher non-administrable infusion (NAI) rates compared to on-site hospital compounding. These are PBS-claimable chemotherapy infusions compounded in good faith that are not able to be used due to cancellation (either by patient or by oncologist).
- Our data indicates that Section 94 in-house compounding pharmacies have much lower rates of NAI (<1% compared to potential 5-20% NAI from cancellation of patients within the last 24hrs)
- PBS claiming for NAI may increase by up to $39.2million p.a. if Section 94 hospital compounders change their business-model to using 3rd party compounders (see Appendix II).
- Reducing the compounding fee from $60 to $40 is estimated to come at a maximum savings of only **$4.98 million** p.a. to the government[1].

TGA licensing requirements are not suited for hospital compounding facilities or financially sustainable for small/medium providers

- On-site facilities provide "just-in-time" chemotherapy, prepared after the patient has been approved for the procedure on that day by an oncologist. Consequently, preparations are not stored long-term and therefore do not require prolonged shelf life, which is more appropriate for a TGA licensed facility.
- Minimum cost of TGA licensing for currently non-TGA licensed Section 94 pharmacies (estimated by the Centre for Biopharmaceutical Excellence.
- Estimated minimum 18 month time-frame to obtain TGA licensing

Reduced access to chemotherapy services in regional Australia

- Fee reduction is likely to impact on the ongoing ability of non-TGA licensed Section 94 and Section 90 compounders to continue to undertake compounding – potentially reducing access to consumers.
- Pre-ordering from 3rd parties creates built in transit time and prohibits just-in-time chemotherapy, which significantly disadvantages rural/remote chemotherapy providers and patients.

5. Other matters

24. Given that very high cost drugs are likely to become more common on the PBS, should this remuneration structure for hospitals change to more closely reflect the remuneration structure of community pharmacy?

CHA would support this given the costs and infrastructure required to manage very high cost drugs.

25. As medicine specialists, what are the professional programs and services that pharmacists should or could be providing to consumers in order to best serve the consumers?

CHA considers that hospital pharmacies should be funded to undertake Home Medicines Reviews.

Summary of proposed changes to pharmacy regulation and remuneration:

1. **Change regulation of Section 94 pharmacies to allow dispensing to out-patients and community**

2. **Changes to current regulation of funding for medication reviews**
    a. **Introduce financial incentives for Section 94 to provide medication reviews**
    b. **Introduce funding arrangements for Section 90 pharmacies to provide medication reviews in private hospitals**
    c. **Remove the 12/24 month restriction on funded medication reviews**

3. **Electronic information linkage between PBS Online system and Safety Net values**

4. **Changes to current funding arrangements for chemotherapy compounding**
    a. **Increase chemotherapy compounding fee to $60 for non-TGA licensed compounding pharmacies**
    b. **Development of a separate level of accreditation under the auspices of the TGA for on-site hospital chemotherapy compounding pharmacies**

Appendix I

Cost of compounding in a non-TGA licensed Section 94 pharmacy

Figure 1: Department of Health template for chemotherapy compounding calculation

Cost category
Labour (include on-costs of super + entitlements)
Cytotoxic infusion preparation
Clinical services (associated with chemotherapy)
Other (please provide details)
Containers/consumables
Devices
(name of device)
Consumables
Containers and related costs
Syringes
Viaflex bags
Syringe driver
Clave
Direct compounding costs
Diluent
Micriobiology monitoring
Quality control
Heating, ventilation and air conditioning
Building monitoring
Aseptic garments
Maintenance
Cleaning
Cleanroom cleaning
Waste removal
Administrative costs
Stock ordering and handling
PBS administration
Rental for administrative area
IT costs for chemotherapy-related systems (ongoing, not capit
Sundry administrative and related costs
Bank charges, printing & stationery
Insurance
IT
Third party compounder fees and markup
Rent
Chemotherapy manufacturing training and validation
Delivery and cold chain costs
Compliance costs
Capital costs
Total costs for period

Template sent to stakeholders towards calculation of compounding cost included in *the Review of Funding Arrangements for Chemotherapy Services 2013. The Department of Health.*

It is unclear what components of this have been used to calculate $40 as a compounding fee for non-TGA licensed in the report. It is also not clear what is included in each component (eg. staff training etc.)

Appendix II

Non-Administrable infusions

Figure 2: CHA Section 94 on-site non-TGA licensed NAI

	Average per annum
Potential NAI (Cancelled products as a % of total PBS Chemotherapy Claims)	**17.49%**
Potential cost NAI per annum	**$2,376,023.84**
Actual NAI s94	**0.03%**
Actual cost NAI s94	**$3,791.27**

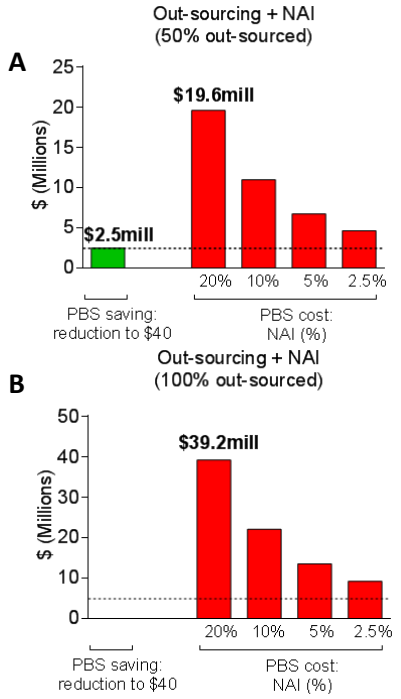
The potential (% and cost) to PBS of NAI based on chemotherapy cancelled within 24hrs of intended infusion.

This has the potential to cost the PBS >$2million p.a. for chemotherapy provider.

However, as chemotherapy compounding in an Section 94 on-site non-TGA licensed compounding pharmacy only occurs on the same day, after treatment is approved, actual NAI is <1% and costs the PBS <$4000 p.a.

Data collected over a 3month period, extrapolated to 1 year.

Figure 3: Projection of NAI cost to PBS Australia-wide



Reduced compounding fee creates incentive to out-source compounding, which may increase NAI.

Fig 3 shows the potential cost of NAI to PBS Australia-wide based on CHA data extrapolated Australia-wide (DoH report 2013[1]) if:

(A) 50% or

(B) 100%

of non-TGA licensed compounding pharmacies out-source compounding to TGA-licensed 3rd party compounders.

Increased NAI could potentially cost the PBS up to **$39.2million**.

Data based on *the Review of Funding Arrangements for Chemotherapy Services 2013. The Department of Health.*

- PBS subsidised 830,000 chemotherapy infusions
- PBS cost $570 million
- Public/private hospitals that undertake in-house compounding (30 per cent market share)