Submission to the Pharmacy Remuneration and Regulation Review, 2016 from the Victorian Area Based Pharmacotherapy Networks

Background

Pharmacotherapy is the provision of methadone and buprenorphine services to patients accessing treatment for opioid dependence, including dependence on illicit drugs, such as heroin, and licit drugs, including over-the-counter codeine and prescribed opioids such as oxycodone and fentanyl. Pharmacotherapy is well established as an evidence-based, effective treatment for opioid dependence. Currently, in Australia, more than 48,000 patients access pharmacotherapy dosing services, mostly through Community Pharmacies. In Victoria, 100% of dosing in community settings occurs in Community Pharmacies. It is anticipated that demand for pharmacotherapy services will continue to increase, particularly with the expected up-scheduling of over-the-counter codeine in 2017 and the introduction of Real Time Prescription Monitoring in response to the well-described emerging problem of dependence on prescribed opioid analgesics.

The Victorian Pharmacotherapy Area Based Networks are a State Government funded initiative established to ensure a more local approach in connecting care, driving best practice and improving pharmacotherapy client outcomes.

Two metropolitan and three regional/rural networks each contribute to assisting pharmacotherapy providers implement a more integrated and cohesive service that is focused on improving client outcomes.

Some network activities include:

• Development of a strategic approach to address local needs through the identification and analysis of gaps in service provision in their Area and development of local solutions;
• Collaboration with relevant services across the continuum (such as hospitals, Specialist Pharmacotherapy Services, health services, general practitioners, pharmacists, other AOD services) to facilitate integrated assessment and treatment referral pathways;
• Provision of advice regarding best-practice and emerging issues relating to pharmacotherapy, opioid dependence and safe prescribing practices;
• Engagement and retention of pharmacotherapy providers to relieve pressure, mainstream opioid dependence and disperse providers in an Area;
• Provision of ongoing wrap-around support and mentoring to providers and enhance access for complex clients to Addiction Medicine Specialist support; and
• Facilitation of access to training for new and existing pharmacotherapy providers
This submission will focus only on those questions in the discussion paper that directly relate to the provision of pharmacotherapy services through Community Pharmacies.

Discussion paper references are shown in green.

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?

Pharmacists and Community Pharmacies are essential to the efficiency, quality and safety of the pharmacotherapy program in every state of Australia.

Outside of corrections and public hospital inpatient services, all Australian states rely heavily on community pharmacies to deliver supervised pharmacotherapy dosing services. Nation-wide, 88% of dosing point are pharmacies. In some states, notably Victoria, the figure is approaches 100% of community-based sites.

It is accurate to say that, without community pharmacy’s involvement, there would be no sustainable pharmacotherapy program in any state. Therefore, supporting community pharmacies in the provision of this service is paramount.

Most dosing points are located in pharmacies

<table>
<thead>
<tr>
<th>Table D1: Dosing point sites, states and territories, 2014–15</th>
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<tbody>
<tr>
<td>Dosing point sites</td>
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<td>----------------------</td>
</tr>
<tr>
<td>Public clinic</td>
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<tr>
<td>Private clinic</td>
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<tr>
<td>Pharmacy</td>
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<tr>
<td>Correctional facility</td>
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<tr>
<td>Other(b)</td>
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<tr>
<td>Total (number)</td>
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<td>Total (%)</td>
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Nationally there were 2,589 dosing points in Australia in 2014–15, a steady increase over the 10 years since 2005–06. (Table D1). Nearly 9 in 10 (88%) were located in pharmacies, which were the most common dosing point sites in all states and territories. These proportions are similar to previous years (Table S17).
— Nil or rounded to zero.

a. See the Technical notes for more information about NSW. NSW and WA correctional dosing points are reported as 2 sites.

b. The category 'other' includes hospitals, mobile dosing sites, community health clinics, non-government organisations, doctors' surgeries and dosing points 'not stated'.

Source: National opioid pharmacotherapy statistics annual data (NOPSAD) 2015 collection. Data table [Table S17].

40. What pharmacy services should be fully or partially PBS funded and what is best left to market or jurisdiction demands?

**Pharmacies are inadequately remunerated for providing pharmacotherapy services. Patients are unduly burdened by the cost of accessing essential treatment.**

Methadone, buprenorphine and buprenorphine/naloxone are all PBS listed medicines under Section 100 (S100) when used for the treatment of opioid dependence. However, the PBS listings for S100 Opiate Dependence treatments is unique in that they do not include any remuneration for the supply of the medicines and **numerous anomalies are apparent in comparable PBS listings.**

Unlike all other PBS medicines supplied through the community pharmacy channel, all remuneration for dispensing, supervision, assessment is recovered via a private agreement between the patient and the pharmacy providing the service. There are no guidelines or directives for what may constitute a reasonable fee for this service, resulting in an ad-hoc development of a de-facto fee-for-service over many decades. This ad-hoc fee has remained essentially the same for 30 years. At a minimum of $120 per month, many patients find the payments a significant barrier to initiating treatment for opioid dependence. Effectively, the patient is bearing for the full cost of dispensing.

Medications taken continuously to treat chronic disease are provided in at least one month’s supply of medicine for a single patient co-payment, and in most cases, the patient’s contribution will count toward the PBS safety net. Not only does this **not** apply for opioid dependence treatments, the patient co-payment does not apply and the ad-hoc fee-for-service does not count toward the PBS safety net.

The Australian Government funds **only** the cost of these drugs and no dispensing expenses which are paid by the patient. This may be attributed to the legacy of a time when all pharmacotherapy services, including dispensing and supervised dosing were provided through clinics and hospitals where funding for service delivery was built in to funding arrangements, as it is for the supply of other S100 drugs. Where supply of other S100 drugs is allowed outside of a public hospital, e.g.: for community access of Highly Specialised Drugs, such as post-transplant immunosuppression or HIV drugs, the PBS schedule provides for adequate
remuneration to the community pharmacy for supplying the drugs. This does not apply for opioid dependence treatments.

Another example of disparity in PBS remuneration can be found in the listing of methadone syrup when used for palliative care. In this example, Aspen Methadone Syrup, listed under the palliative care item, and the S100 item are identical products in every respect. The palliative care item is fully funded for dispensing and supply to a maximum consumer price of $27.53, including the statutory co-payment. In contrast the S100 item for opioid dependence is listed at cost price. There is no funded component for the supply of the identical item when used to treat opioid dependence.

Adding to this disparity, the palliative care item is dispensed and supplied once only, whereas a patient presenting with a prescription for the S100 item will be assessed, dispensed to and the consumption supervised and recorded many times (usually daily), as well as compounded into takeaway doses. So whilst a palliative care patient pays for multiple days’ medication in one payment, an opioid dependent patient pays for each days dispensing fee, even if multiple doses are collected at the one time.
Methadone and buprenorphine/naloxone are staged-supply medications, however, Section 100 Opiate dependence pharmaceutical benefits are specifically excluded from the Staged Supply service agreements under the 6CPA.

127. Is it reasonable for consumers to expect that all community pharmacies provide these specialist services? If so, why? If not, why not?

There are many reasons community pharmacies decline to provide this specialised service, some of which include:

- Pharmacies are commercial enterprises and can reasonably expect a fee-for-service, particularly as the nature of the work is specialised, which can be highly complex and challenging. Remuneration is limited to fees paid by patients directly to the pharmacy. Patients often find the cost of the pharmacotherapy services burdensome; At times, patients cannot fulfill their payment obligations and are either removed from the program or their debts are cancelled by the pharmacist, neither of which is ideal;
- In most states, minimal or no other remuneration or incentives exist.
- The typical fee of $5 per dose or $30 per week has remained the same for over three decades, and has not kept up with the cost of providing the service or CPI increases.
- There is no standardisation of fee-for-service. Methadone and buprenorphine/naloxone are the only PBS funded medicine for which all remuneration for supply is via a private agreement between the pharmacy and the patient. For comparison, an identical methadone product is fully-funded for supply under the PBS when used for the treatment of pain in palliative care;
- The administrative burden of providing a quality service is significant and has increased substantially in recent years;
- Overheads to the pharmacy, particularly related to takeaway doses, can be significant and are not remunerated;
- Set up costs e.g. a dedicated safe, software, dispensing pump, Drug of Addiction register, annual calibration can also be significant;
- Although training sessions are government subsidised, pharmacists undertake the training in their private time and are generally not remunerated for this time
- The cost of providing the service may actually result in a financial loss to the pharmacy,
- In some pharmacies, no-service policy is driven by pharmacy owners rather than staff pharmacists, and
- Stigma related to drug dependence is widespread and many pharmacies believe that providing these services will adversely affect other services at the pharmacy.
The World Health Organisation has designated methadone and buprenorphine as essential medicines:

“Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.”

Ref: WHO Essential Medicines http://www.who.int/topics/essential_medicines/en/

The cost burden to the consumer of this essential medicine, when compared to other PBS medicines, is untenable.

Additionally, in Australia, we have the Australian Charter of Healthcare Rights, endorsed by all Australian Health Ministers in 2008. The Charter specifies the right of all Australians to access services to address their healthcare needs. The Charter applies to all channels of health services, including Community Pharmacies, and the principles are specifically adopted by the Community Pharmacy Services Charter. Therefore, in a market where the only possible providers of methadone and buprenorphine for opioid dependence treatment are Community Pharmacies, patients should have a reasonable expectation that they be able to access this treatment at the Community Pharmacy of their choice.

Rights to legitimate access to goods and services are also informed by the Disability Discrimination Act 1986:

“Discrimination on the basis of physical, intellectual, psychiatric, sensory, neurological or learning disability, physical disfigurement, disorder, illness or disease that affects thought processes, perception of reality, emotions or judgement, or results in disturbed behaviour, and presence in body of organisms causing or capable of causing disease or illness (eg. HIV virus).”

It follows that all Community Pharmacies should be both willing and well-equipped to provide this service. However, many pharmacists, and in particular, proprietor pharmacists resist doing so and some actively and openly refuse to provide the service, even to patients well-known to them and to whom they provide other services. Patients in rural and regional areas in particular may have great difficulty finding a local Community Pharmacy willing to provide this service and some are forced to travel many kilometers or even move to a different location to access the service.
128. Would it be desirable to align the delivery of specialist services to population need in local communities? If so, what is the best way of coordinating appropriate and relevant services for populations of need?

Minimum service requirements should be established where there is a community need, and should be linked to approval to dispense pharmaceutical benefits. See also 130. Are there other inequities in terms of access to and quality use of medicines? If so, how should those be addressed and what population groups could be targeted?

129. How might access and service barriers identified above be resolved and consumer needs be better met? Is additional training and support within community pharmacy sites needed?

Across Australia, all pharmacists have easy access to no-cost, government-sponsored training to become a provider of opioid dependence treatments. In Victoria, Pharmacists additionally have the support of the Victorian Pharmacotherapy Area Based Networks.

Consideration should be given to making training compulsory with regular reassessment. Training for pharmacists could also be extended to include stigma and marginalisation, comorbidity including alcohol and other drug and mental health conditions.

Community Pharmacies are a key part of the Australian health care system and receive government support, it is not acceptable for pharmacies to be unwilling to provide service to the most marginalized in our communities. If training is a means of removing this barrier, then provision of training is a high priority.

An essential and important step in improving access to this specialist service must be to provide adequate remuneration by modifying the PBS listing of methadone and buprenorphine/naloxone to be commensurate with other similar supplies of PBS medicines. The listing must take into account the true cost of providing the service, including the cost of consumables the requirements for pre-dose assessment, dose-supervision and post-dose observation, compounding of takeaway doses, consumables and administration.
130. Are there other inequities in terms of access to and quality use of medicines? If so, how should those be addressed and what population groups could be targeted?

Prescription drug misuse, including of prescribed opioid medicines is emerging as a significant problem, particularly in rural and regional areas where the majority of referrals for treatment of dependence are for dependence on pharmaceutical opioids.

Opioid dependence is a chronic condition requiring long-term therapy, much like asthma or diabetes, and if left untreated can progress to disability or death. Access to treatment is a key ingredient to the success of this evidence-based therapy. Removal of barriers to the provision of the service (addressed in question 127) is paramount in order to increase access to treatment.

In 2015, The Australian Commission on Safety and Quality in Health Care released The Australian Atlas of Healthcare Variation for 2013-14 which found that the pharmaceutical opioid prescribing rate is up to 10 times greater in some regional and rural areas.

Figure 104: Number of PBS prescriptions dispensed for opioid medicines per 100,000 people, age standardised, by local area, 2013–14
The Commission concluded that whilst no apparent explanation is available for this, differences in access to alternative pain management included improving access to opioid dependence treatment and chronic pain services particularly to those who are socioeconomically disadvantaged and/or live in rural and regional settings. It follows that the PBS dispensing data used to inform the Commission’s findings can similarly be used to identify and improve access to pharmacotherapy dosing services where they are most needed.


Summary

- Pharmacists and Community Pharmacies are essential to the efficiency, quality and safety of the pharmacotherapy program in every state of Australia and must be adequately remunerated for providing this service.

- Pharmacies are inadequately remunerated for providing pharmacotherapy services. Patients are unduly burdened by the cost of accessing essential treatment.

- There are numerous anomalies in the PBS funding model for supplying pharmacotherapy services. Funding should be aligned with other similar medicines and should include funding for the supply component, which reflects the complex nature of the service.

- It is reasonable for a patient legitimately seeking treatment for opioid dependence to expect that they should be able to access this treatment, at reasonable cost, without undue burden. The Disability Discrimination Act 1986, The Australian Charter of Healthcare Rights, and the World Health Organisation Essential Medicines List all support this expectation.

- There is significant variation in opioid prescribing patterns in different areas with higher prescribing rates in rural and regional areas as well as lower socio-economic areas. Service gaps related to problematic opioid use, including access to dispensing of pharmacotherapy services by pharmacists, can be improved by targeting those areas.
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