Introduction:
Harm Reduction Victoria (HRV) and the Pharmacotherapy Advocacy, Mediation & Support (PAMS) Service welcome the opportunity to provide a submission to this important federal government review on pharmacy remuneration and regulation. As the statewide organisation in Victoria representing people who use or have used illicit drugs including those on Medication Assisted Treatment for Opioid Dependence (MATOD), HRV is in a unique position to represent the needs and interests of a significant number of community pharmacy consumers in Victoria.

In addition, HRV operates the Pharmacotherapy, Advocacy, Mediation and Support (PAMS) Service in Victoria. PAMS works with clients and MATOD service providers (including general practitioners and community pharmacists) to mediate better treatment and service outcomes including addressing issues such as payment of dispensing fees and debt management arrangements. PAMS is funded by the Victorian Department of Health & Human Services and is a vital component of the overall Victorian MATOD program. This submission is therefore informed by the unique understanding of HRV as a peer-based drug users organisation and the consumer engagement experiences and data collected through the PAMS Service.

While HRV/PAMS recognises that the scope of this Review extends to a wide range of questions about the broader regulatory environment in which reimbursement (including dispensing fees) may occur, for the purposes of this brief submission HRV/PAMS has opted to focus on current problems associated with the affordability of Medication Assisted Treatment for Opioid Dependence (MATOD) medications for consumers through community pharmacy. For this reason, this submission focuses on the two most relevant Terms of Reference (ToR):

a) ToR 1 – Pharmacy Remuneration for Dispensing; and  
b) ToR 5 – Consumer Experience.

1 Community pharmacies constitute 85% of MATOD dosing sites in Australia. With approximately 14,000 people on MATOD in Victoria (2016 Census Data), people on MATOD constitute a significant number of regular Victorian community pharmacy consumers. For example, it is estimated that on average Australians visit a pharmacy 14 times per year, compared to 8 – 20 times per month for MATOD consumers depending on number of take away doses they receive.
Additionally, rather than structuring our submission around the specific questions posed by the Panel in the Discussion Paper, we have sought to address these same issues through a broader discussion of current MATOD medication dispensing arrangements and the urgent need to change these arrangements in order to improve access and affordability for MATOD consumers. This includes issues such as the costs and drivers associated with MATOD dispensing, market considerations including consumer needs and expectations and possible future funding models and structures. With that said, HRV remains very open to further discussions with the Review Panel on any of the policy, regulatory or other matters arising from the views expressed in this submission.

Context:

There is significant international evidence demonstrating the effectiveness and importance of MATOD\(^2\) for treating opioid dependence and as a public health intervention that reduces many of the harms that can be associated with illicit drug use (NICE, 2007). Substitution therapies such as methadone and buprenorphine/naloxone have consistently been shown to be effective in reducing illicit drug use, retaining people in treatment and reducing the incidence and consequences of risky drug use such as BBV transmission, drug-related overdose and acquisitive crime associated with illicit drug use (Shanahan et al, 2007, Ritter and Chalmers, 2009). MATOD has also been found to improve quality of life both for the consumer and for their families in relation to housing, employment, general wellbeing, etc. (De Maeyer et al, 2011, Lord et al 2014).

Research has also shown that successful MATOD outcomes are strongly linked to the length of time an individual is retained in treatment (Mattick et al. 1998, Zhang et al, 2003). Other studies, including a Pharmacy Guild of Australia study in 2008 however, also found that affordability of treatment has a significant impact on the ability of clients to stay on MATOD (Feyer et al. 2008). Further, Victorian research into the cost of pharmacotherapy in 2008 showed that dispensing fees were one of the primary reasons for involuntary discontinuation of treatment and the single biggest barrier to retention in treatment (Rowe, 2007).

Serious concerns about the negative impact of consumer dispensing fees for MATOD have been repeatedly raised by individual consumers, consumer organisations, service providers and policy makers for over a decade in Australia (Muhleisen, et al. 2005). Indeed, it has long been said that “one of the most obvious concerns with dispensing fees is that patients simply cannot afford them” (Chalmers, Ritter et al. 2007). In Victoria, it is estimated that approximately two-thirds of MATOD consumers are on some form of government benefit and therefore rely on income support to pay their MATOD dispensing fees (Lintzeris et al, 1996).

Given the very limited nature of government benefits, dispensing fees are a considerable burden for many MATOD consumers and represent a gross inequity within the health system that is not imposed on other Australians who are managing complex and chronic health conditions and living on low/fixed incomes due to the PBS subsidy and safety net system. This is further supported by a recent study in WA which states:

> “Considering the current dispensing fees, Western Australian OST patients who obtain their OST medicines at community pharmacies pay on average $154 per month for their dosing, which is significantly more compared to patients paying for medicines for diabetes, smoking, and hypercholesterolemia. Although these conditions could also be the result of lifestyle choices, the dispensing of the medicines to treat these conditions contributes towards a patient’s Safety Net, which is not the case with OST medicines. Opioid dependence is

\(^2\) The term ‘Medication Assisted Treatment for Opioid Dependence’ or ‘MATOD’ has been used throughout this paper however other terminology is routinely used in the literature including ‘Opioid Substitution Treatment’ or ‘OST’, Opioid Pharmacotherapy Treatment’ or ‘OPT’ and ‘Opioid Replacement Therapy’ or ‘ORT’. For the purposes of this submission, all of these terms should be taken to carry the same basic meaning as MATOD.
therefore not considered at the same level as other medical conditions and OST patients are financially disadvantaged under the current PBS arrangements” (Shepard et al, 2014).

Principles of Human Rights & Health Equity:
It is HRV/PAMS view that this ongoing situation represents a fundamental human rights and health equity issue for MATOD consumers in Australia that should be addressed as a matter of urgency. According to the World Health Organisation (WHO) “the enjoyment of the highest attainable standard of health is a fundamental right of every human being” (WHO, 2015). The ‘right to health’ also contains entitlements to ensure essential medicines are accessible and affordable to key populations – these ‘essential medicines’ specifically include methadone and buprenorphine which were added to the WHO Model List of Essential Medicines in 2005 (WHO, 2015).

Further, Australia is also a signatory to a number of international conventions including the Universal Declaration of Human Rights (Article 25) and the International Covenant on Economic, Social & Cultural Rights (Article 12) that together, provide not only for an adequate standard of health and wellbeing for all people but also for non-discriminatory access to affordable health care (UNOHCHR, 2008). As noted in research conducted by the Pharmacy Guild of Australia, with only 17% of MATOD consumers on wages, “most illicit opioid users are poorly placed to pay any significant amounts towards the costs of their treatment” (Feyer et al, 2008). On this basis, it is reasonable to argue that the basic health and human rights of the majority of MATOD consumers (protected at international and domestic law) are not being met, and there is an urgent need to address the inherent structural inequities and discrimination associated with high MATOD dispensing fees.

Current Arrangements for MATOD Dispensing Fees:
Of the 2,589 dosing points in Australia in 2014–15, 88% are located in community pharmacies (AIHW, 2015). Subsequently, most people on MATOD in Australia have their pharmacotherapy dispensed through a community pharmacy with an estimated 75% of consumers dosed at a community pharmacy on a snapshot day in 2015 (AIHW, 2015). As community pharmacies are commercial entities, they typically charge consumers a ‘dosing’ or ‘dispensing’ fee (either daily or weekly) to recoup costs associated with providing the MATOD dispensing service to consumers.

For the majority of PBS (S85) prescription medications, the Commonwealth provides a set dispensing/recording fee (and as relevant, a dangerous drug fee) to the pharmacist and most consumers usually pay a maximum patient co-payment contribution per dispensed prescription (rather than per dose of medication as it is for MATOD consumers). A prescription is typically one month’s supply for most medications at the cost of $6.20 (concessional) or $38.30 (general). Further, there is a safety net provision that allows free supply/reduced rate supply after the first 60 paid prescriptions ($372.00 annually concessional and $1476.00 annually general). Further again, couples and families can accumulate their prescription numbers together to qualify for the safety net provisions in a shorter period of time (www.pbs.gov.au).

In contrast, MATOD medications fall under Section 100 Opioid Dependence of the National Health Act 1953 and different government funding arrangements apply. Although the MATOD medications are supplied at no cost to providers by the Federal Government under the PBS, dispensing/administration costs are not covered for pharmacists under these arrangements and there are no safety net provisions for consumers as there are with other PBS prescription medications (above). This results in a wide variety of MATOD dispensing arrangements and dosing fees across the different states and territories with people on MATOD charged varying amounts by community pharmacies - as dispensing agents have the mandate to set dosing/administration fees within a largely unregulated environment (Lord et al 2014).
Research shows that MATOD consumers being dosed at community pharmacies currently pay between $1.50 and $10.00 per day/per dose with a median price of $4.65 for methadone and $5.00 for buprenorphine preparations (Feyer et al, 2008) which equates to between $1800 - $3650 per annum for each consumer. This represents a significant proportion of weekly income for the majority of MATOD consumers. For example, MATOD consumers who are living on fixed incomes such as Newstart Allowance or the Disability Support Pension will on average spend between 10-15% of their weekly income on MATOD dispensing fees alone and before factoring in other associated costs such as regular transport to and from the pharmacy for dosing multiple times each week. In comparison, other Australians on a concessional health card for a chronic condition such as diabetes would pay $6.20 per monthly prescription to a maximum total of $372.00 annually under the Safety Net provisions. The only notable exception to the above circumstances is the ACT where a government subsidy of $20 per week is paid to MATOD dosing community pharmacies and consumers make a weekly co-payment of $15 per week per MATOD consumer regardless of income level (Feyer et al, 2008).

The following case study example from a MATOD consumer in regional Victoria serves to underscore the combined impact of dispensing fees along with other ‘associated program costs’ on MATOD consumers:

“I live in Manangatang and dose in Robinvale. I get 4 take aways doses per week and the trip to dose takes an hour and costs about $25 in petrol. I have to pay $25 per week for the cost of dosing and because I have to travel to the pharmacy 3 times a week, it means I also have to pay $75 just to get there! Plus, I have a toddler and a 5 year-old child to take with me. Programs in the country are just really hard…”

While some jurisdictions operate public MATOD clinics that provide dosing at no cost to the consumer these clinics dose less than 3% of MATOD consumers (AIHW, 2015), do not provide takeaway doses, have extremely limited places, generally have long waiting lists and only exist in metropolitan/large regional centres. These public clinics sometimes offer temporary ‘fee relief’ places (for people usually on a pharmacy or private program) for a limited amount of time in certain individual cases, but this is rare and not all states have public MATOD clinics – Victoria being a case in point. Currently in Victoria there is very limited emergency fee relief for MATOD consumers through the PAMS service ($14,000 per annum which equates to $1/annum per MATOD consumer in Victoria).

Non-payment of dosing fees is frequently a reason for refusal of dose and therefore, MATOD consumers can find themselves on a WHO recognised ‘essential medicine’ & registered ‘drug of dependence’ yet be unable to be dosed or even remain on the program, as they can neither pay their current pharmacy nor transfer to a new pharmacy, as this would require a reference from the previous pharmacist who would disclose the existing debt (Lord, 2015, Chalmers et al, 2009). Some pharmacies offer discounts to consumers for paying for dosing in advance, generally in the range of one free dose per week. As outlined above however, fee paying arrangements vary considerably from pharmacy to pharmacy, jurisdiction to jurisdiction, with no overarching state/national agreement and pharmacists ultimately having full discretion to refuse to dose for ‘payment related’ reasons.

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3 Anecdotal reports (from state peer-based drug user organisations within the AIVL network) indicate that some MATOD consumers could be paying as much as $12 per day/per dose. This has also been stated by MATOD providers in relation to dispensing fees at some private MATOD clinics in NSW.

4 At the time of writing Newstart Allowance (maximum single person/no children rate) = $528.70/fortnight and the Disability Support Pension (maximum basic single person rate) = $797.90/fortnight [https://www.humanservices.gov.au](https://www.humanservices.gov.au)

5 It should be noted that while some jurisdictions have very limited subsidised MATOD places for people recently released from prison, some young people, etc., the type of comprehensive government subsidy provided in the ACT is not available in other jurisdictions.
In addition to the current situation outlined above, recent data on the use of pharmaceutical opioids in Australia estimates that up to one-third of people entering MATOD are dependent on pharmaceutical opioids rather than illicit opioids (AIHW, 2015). This data highlights a growing funding trend for MATOD in Australia as people move from standard PBS prescription arrangements for ‘non-MATOD’ pharmaceutical opioids, to the current higher cost MATOD dispensing fee arrangements. Not only does it highlight a further disparity within the system – due to the inconsistencies in the funding arrangements for different types of pharmaceutical opioids – but it also serves to highlight the inequity and discrimination within the system between those on MATOD and those on ongoing prescriptions for other pharmaceutical opioids.

The problem is effectively two-fold – people already on MATOD do not feel they should be paying considerably more for their opioid medications than those on other PBS-listed pharmaceutical opioids and, people on other pharmaceutical opioids, who may benefit more from being on MATOD, postpone making such decisions due to the increased dispensing cost that will be involved. Both of these funding/cost issues need to be addressed particularly in light of the recently announced ‘Real-Time Prescription Monitoring (RTPM) System’ in Victoria which will necessarily lead to an increase in the number of people being ‘moved’ from ongoing pharmaceutical opioid prescriptions on to MATOD programs as the government and service providers seek to realise the aim of the RTPM which is to reduce overdose deaths from prescription opioids (http://www.guild.org.au/vic_branch/news-and-events/victorian-news/2016/04/26/realtime-prescription-monitoring)

The Impact of Current MATOD Dispensing Fees:

“In healthcare generally, user fees are considered by many to be the most regressive form of healthcare financing available; they contribute to the unaffordable cost burdens imposed on poor households; and they represent one facet of the social exclusion experienced by these households” (Gilson and McIntyre, 2005 in Chalmers et al, 2009).

While more research is required to fully quantify the impact of dosing fees on MATOD consumers, a research trial into funding subsidisation models for MATOD fees in community pharmacy established that “affordability is an important determinant of treatment outcome, with the higher cost being associated with significantly poorer compliance” (Feyer et al, 2008). As already evidenced above, MATOD dispensing fees have also been found to be one of the single biggest barriers to treatment retention and are a significant financial burden particularly for the majority of MATOD consumers living on low/fixed incomes (Rowe, 2007, Feyer et al, 2008). This is also supported by data from the PAMS Service that shows that upwards of 30% or approx. one-third of cases are specifically related to debt and payment problems (Lord, 2015).

One of the most cited reports into the negative impact of high and unregulated MATOD dispensing fees on consumers is the “Raw Deal?” Report in 2007 which found that many Victorian MATOD consumers experience significant hardship in relation to dispensing fees and highlighted a range of negative impacts for consumers and their families including:

- Prioritising the payment of dispensing fees over basic necessities such as food and housing;
- Relying on emergency services such as food parcels, crisis accommodation or loans from Centrelink in order to pay dispensing fees;
- Engaging in illegal activities in order to pay treatment/dispensing fees;
- Experiencing difficulties and deterioration in the relationship between the community pharmacist and client due to conflicts over financial issues particularly dispensing fees;
• Involuntary discontinuation of treatment due to accumulation of debt and payment problems due to dispensing fees which frequently is followed by a return to illicit opioid use;
• Jeopardising treatment success due to missed doses and exiting treatment prematurely (Rowe 2007).

Furthermore, a recent WA study found a strong link between quality of life and debt for MATOD consumers with over 80% of survey respondents stating that “dispensing fees impacted significantly on patients’ finances and lifestyle, specifically those patients with major debt”. The majority of the treatment providers interviewed in the study also declared cost as the primary factor in ‘compliance’ and identified a positive relationship between treatment duration and treatment outcome. Importantly, this research also stated that most service provider stakeholders, advocated for MATOD fees “to contribute towards the Pharmaceutical Benefits Scheme Safety Net, and for fee subsidy” (Shepard et al, 2014).

What’s the Solution?
There are certain important differences to the dispensing of MATOD medications compared to the supply of other PBS medications including:
• Adherence to strict legislative and regulatory requirements associated with ordering, stocking and supplying a ‘dangerous drug’.
• Daily dosing rather than ‘per prescription’ dispensing – often referred to as ‘staged supply’ – in contrast to most other medicines which are dispensed once to be used over a period of time (typically monthly) or are based on ‘repeat’ prescriptions; and
• Requirements for pharmacies/dispensaries to keep and to provide regular dosing and compliance information about MATOD consumers.

Research has highlighted that the above differences and requirements mean that providing MATOD medications is more time-consuming for the community pharmacist per consumer, than supplying other PBS medicines (Feyer et al, 2008). For this reason, individual community pharmacists and relevant representative bodies for pharmacies and pharmacists (including the Pharmacy Guild of Australia and Pharmaceutical Society, etc) have been advocating for some time for the need to review the remuneration arrangements and regulatory environment for the dispensing of MATOD medications (Feyer et al, 2008).

In this context, HRV/PAMS also believe there is an urgent need to address the now well-documented financial inequities within the system for MATOD consumers and to provide a fair and transparent process to enable community pharmacists to recoup reasonable overhead costs associated with providing such an essential public health service. Aiming to recoup these expenses however through consumer-based dispensing fees that are set in a largely unregulated environment, with little or no ability to assess individual capacity to pay, has led to a situation where MATOD consumers are frequently being asked to pay more than they can afford within a context where there is little or no choice about accepting the terms on offer. This needs to change.

The existing ‘fee-for-service’ arrangements between individual community pharmacies and MATOD consumers, tends to exacerbate the potential for conflicts between provider and consumer over payment issues. Community pharmacist providers generally state they are providing the service as much for altruistic reasons as financial. Anecdotally, the most significant reason pharmacists provide for refusing to provide MATOD services is the insufficient and unfair payment for dispensing – they believe it simply does not cover for the time, energy, expertise and responsibilities involved.
Research commissioned by the Pharmacy Guild of Australia in 2002 however, showed that funding subsidization models such as the one in operation in the ACT had a positive impact on the community pharmacies delivering the program including on their overall willingness to have a MATOD program at their pharmacy (HMA, 2007, Feyer et al, 2008). Subsequent research has also indicated that subsidisation schemes would have a positive effect on the willingness of community pharmacies to both commence and continue as MATOD providers if there were appropriate incentives and sufficient protection against the risk of accruing bad debt from consumers struggling with high dosing fees (Feyer et al, 2008, Rowe, 2007 and Lord et al, 2014).

The ‘solution’ proposed by HRV/PAMS to address the iniquitous situation described throughout this submission includes:

- Making MATOD medications standard S85 PBS items including treating them the same as other PBS items. The direct payment to suppliers for the medication component should remain as it currently is, as this will then focus the payment to community pharmacists solely on the professional services they provide;
- Provide MATOD consumers with the same allowances, support and subsidies presently enjoyed by all other PBS recipients. i.e.: same patient contributions and Safety Net provisions (see above);
- Determine an appropriate payment for community pharmacy MATOD providers based on the current PBS pricing structures. Payments to community pharmacists could be based on the following 3 components:
  - The cost of the medications - in the case of MATOD medications, this is already covered by the Commonwealth under current PBS funding arrangements which should remain);
  - A professional fee - currently $7.02 (dispensing, recording, professional advice, etc.) This should equally apply to every dispensed dose unit of MATOD medication; and
  - A ‘Drug of Addiction/Dangerous Drug’ recording fee - currently $2.95 which should also apply.

In summary, this provides for a total daily payment to community pharmacists of $9.97 (currently) and this equates to $303.25 per MATOD consumer each calendar month. This should be indexed and subject to the same rules for annual change that applies to other PBS items. The overall benefits and outcomes of this ‘solution’ would include:

- The charge to MATOD consumers would be for a monthly supply (as described above for other PBS medications) rather than a ‘per dose’ charge as currently occurs and would provide an equitable and more affordable situation for all MATOD consumers but particularly for those on low/fixed incomes such as health care card concession holders. This would enable consumers to access programs and to remain on maintenance treatment, thus producing far better outcomes for themselves and the community generally in line with the evidence outlined above.
- Even though this proposal would see general (or non-concessional MATOD consumers) paying $38.30 per month compared to $6.20 for MATOD consumers on a concessional rate, this is still considerably less than what the majority of ‘general’ MATOD consumers are paying under current arrangements which is on average $30-35 per week in many cases considerably more. Making payments the same as other PBS medications under S85 will simply bring all MATOD consumers in line with the rest of the Australian population.
- Pharmacists would receive payments in line with all other PBS supplies and adequate and appropriate to their professional expectations. This will hopefully encourage a much greater
number of community pharmacy providers to participate in the MATOD program and hence much better coverage and access for those seeking to access that program.

- The PBS would make payments directly to community pharmacists taking account of the differential between the total monthly fee ($303.25) and the particular consumer co-payment contribution ($6.20 (concession) and $38.30 (general) respectively.

**Conclusion:**

As outlined in the Discussion Paper for this Review, Australia’s National Medicines Policy (NMP) “recognises that cost should not constitute a substantial barrier to people’s access to the medicines” (Department of Health, 2016). Current MATOD arrangements however mean that dispensing costs are a substantial barrier to people accessing MATOD medications in Australia (Rowe, 2007, Lord et al, 2014). Research has also concluded that covering the cost of delivering MATOD nationally (approx. $4 million per month) would be more than off-set by the economic, social and public health benefits to the community in terms of levels of health care utilisation and reductions in drug-related crime (Chalmers & Ritter, 2012).

MATOD is a highly effective form of treatment for opioid dependence with many positive outcomes for the individual, their families and the broader community (NICE, 2007). Financial difficulties associated with MATOD dispensing fees however have repeatedly been shown to have negative implications for treatment compliance and retention. MATOD consumers pay one of the highest consumer co-payment contribution fees in the Australian healthcare system, but also experience some of the highest levels of financially disadvantage in the Australian community. Furthermore, other individuals with chronic health conditions such as people with diabetes, depression, hypertension, etc., requiring daily/regular medication are not required to pay the level of dispensing fees or navigate the structural barriers, in order to access their essential medications, that are routinely placed on MATOD consumers.

MATOD consumers often accumulate significant levels of debt to pharmacies as a direct result of MATOD dispensing fees. This is not only stressful for the individual but also creates extra work for the pharmacist in following up bad debts which can result in conflicts between the pharmacist and the individual consumer undermining the potential for a meaningful therapeutic relationship and frequently leading to involuntary removal from the program. All of the evidence surrounding MATOD dispensing fees point to the conclusion that such fees are iniquitous and discriminatory and have been allowed to run ‘unchecked’ largely because they exclusive affect a highly stigmatised and unrepresented group in the community – MATOD consumers. Action is urgently required under the terms of this review to fund MATOD dispensing fees in line with other PBS medicines and thereby remove this unacceptable burden and all its negative impacts for consumers.

Recognising the financial burden of dispensing fees on consumers, the “Victorian Pharmacotherapy Review” in 2010 reviewed a range of options for MATOD dispensing fees in community pharmacy which ranged from: dispensing fees being fully funded or at least partially subsidised by government (State or Commonwealth), having no dispensing fees, introducing means testing for dispensing fees or government paying dispensing fees for certain high risk groups, etc (King et al, 2011). Evidence from subsidised dosing trials for MATOD have observed high levels of satisfaction for both consumers and pharmacists. Consumers have noted improvement in general health and wellbeing and the sense of financial pressure being relieved allowing them to focus on other goals and life issues (Lord et al, 2014). Similarly, trials have indicated a greater level of willingness on behalf of community pharmacists to participate in the MATOD program if there are adequate financial incentives provided and equitable regulatory frameworks in place (Feyer et al, 2008).
For these and all the reasons outlined in this submission, this review must address the current issues in relation to MATOD dispensing fees in community pharmacy. As an organisation representing the needs and issues for people on MATOD in Victoria, HRV/PAMS remains very happy to talk further with the Review Panel on the issues raised and the solutions proposed in this submission. If the Panel has any questions or requires further information in relation to this submission, please do not hesitate to contact HRV/PAMS (contact details are provided on p.1). We look forward to the deliberations and outcomes from this timely and highly significant review for people on MATOD in Australia and welcome any further opportunities to participate in the development and implementation of key recommendations from this process.

Yours Sincerely,
Jenny Kelsall
Executive Officer
Harm Reduction Victoria

References:


