Submission to the Review of Pharmacy Remuneration and Regulation Discussion Paper

September 2016

National Seniors Australia

About National Seniors Australia

National Seniors Australia is a not-for-profit organisation that gives voice to issues that affect Australians aged 50 years and over. It is the largest membership organisation of its type in Australia with more than 200,000 members and is the fourth largest in the world.

We give our members a voice – we listen and represent our members' views to governments, business and the community on the issues of concern to the over 50s.

We keep our members informed – by providing news and information to our members through our Australia-wide branch network, comprehensive website, forums and meetings, bi-monthly lifestyle magazine and weekly e-newsletter.

We provide a world of opportunity – we offer members the chance to use their expertise, skills and life experience to make a difference by volunteering and making a difference to the lives of others.

We help our members save – we offer member rewards with discounts from thousands of businesses across Australia. We also offer exclusive travel discounts and more tours designed for the over 50s and provide our members with affordable, quality insurance to suit their needs.

Contact

Head Office

National Seniors Public Affairs, Level 18, 215 Adelaide Street Brisbane QLD 4001

P: 1300 765 050 F: (07) 3211 9339

E: policy@nationalseniors.com.au

W: www.nationalseniors.com.au

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Executive Summary

National Seniors welcomes the opportunity to contribute to the Review of Pharmacy Remuneration and Regulation. National Seniors is a not-for-profit organisation that gives voice to issues that affect Australians aged 50 years and over. It is the largest membership organisation of its type in Australia.

Arrangements to remunerate pharmacists for the dispensing of prescription medicines and regulate the pharmacy sector more broadly have a significant impact on the accessibility and cost of essential medicines, sustainability of the sector and cost to government.

Dispensing prescription medicines is an essential component of the public health care system. Access to prescription medicines relies heavily on the existence of a network of retail pharmacies throughout the country. To support the ongoing existence of this network, the Australia Government controls remuneration provided to the pharmacy sector, helping to make it one of the most accessible health care sites.

Under the current rules governing the pharmacy sector, government protects pharmacies from excessive competition through the imposition of strict regulations on remuneration, pricing and market entry.

While ongoing regulation is required to ensure equitable access to medicines, it is reasonable to expect that these arrangements maximise value for money and contain costs for consumers given the significant investment made by government. It is also reasonable to expect that government be able to leverage its significant investment in the pharmacy sector to support better health care outcomes for consumers.

As a government funded resource, pharmacy must continue to ensure access to essential medicines for all Australians. This is especially true for vulnerable older Australians who rely more than most on prescription medicines to manage and treat age related illnesses.

This submission addresses several key issues pertaining to remuneration and regulation. It calls for:

- an overhaul of current location rules to increase competition in areas of high demand while ensuring that communities in areas of low demand have their needs protected
- continuation of the $1 discount on the PBS patient co-payment, with a view to assessing the impact of offering a higher discount in the future
- greater scrutiny and oversight over existing and future plans to deliver primary health care services through the community pharmacy setting, and
- greater transparency about the impact of pharmacy remuneration and fees on pharmacy income, profits and sustainability; consumer costs and accessibility; and government spending.

Pharmacy location rules

Overly simplistic location rules diminish the capacity of government to maximise value for money, maintain sustainability and ensure access to affordable medicines. While it is desirable that the distribution of pharmaceuticals be subject to some regulatory constraints, this does not mean that competition should be discouraged or that competition is not beneficial. In highly urbanised areas which can readily sustain increased competition, location rules may limit competition and provide existing pharmacies with a monopoly over the market.

The current location rules, which limit a pharmacy from operating within 1.5km of another pharmacy should be removed and replaced with a more flexible and objective system that meets consumer needs while ensuring competition where this is sustainable.

In this regard, it is pertinent to examine other countries that regulate the entry and location of pharmacies to ensure access to medicines. Control of entry regulations in England, for example, provide a number of germane insights regarding the regulation of the pharmacy sector in Australia.

The pharmacy sector in England has been impacted by changes to entry regulations over the past decade or more. While entry regulations in force since 1989 make it possible to open a pharmacy anywhere, a pharmacy must first be granted a contract in order to dispense NHS prescriptions. Given that 80 per cent of pharmacy income is generated from dispensing NHS prescriptions, it is no surprise that only 1 per cent of all pharmacies operate without an NHS contract. Historically, Local Primary Care Trusts were responsible for granting these contracts, and did so on the basis that they were satisfied that a new pharmacy was 'necessary' or 'desirable' in a local area[1].

In 2003, the UK Office of Fair Trading (UK OFT) reviewed location restrictions on pharmacies and found them to be detrimental to consumers[2]. In particular, the UK OFT believed that the rules:

- restricted consumer choice and convenience
- restricted price competition on over the counter medicines
- reduced incentives for pharmacies to compete on additional customer services, and
- resulted in consumers paying £25-£30 million per year more for medicines than if competition were freer.

While the UK OFT recommended that entry regulations be completely removed, the UK Government instead amended control of entry regulations to increase competition in the

[1] House of Commons Health Committee 2003. *The Control of Entry Regulations and Retail Pharmacy Services in the UK Fifth Report of Session 2002–03.* Report and formal minutes together with oral and written evidence. Published 17 June 2003. https://www.publications.parliament.uk/pa/cm200203/cmselect/cmhealth/571/571.pdf

[2] UK Office of Fair Trading 2003. *The control of entry regulations and retail pharmacy services in the UK: A report of an OFT market investigation*. January 2003 http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft609.pdf

sector in 2005. Four exemptions were introduced which circumvented the 'necessary or desirable' test used to regulate entry. These four exemptions were[3]:

- pharmacies in large out of town retail developments
- pharmacies undertaking to open for a minimum of 100 hours per week
- pharmacies in 'new' one stop primary care centres, and
- mail order or internet pharmacies.

The aim of these exemptions was to improve access for patients. The exemptions resulted in a dramatic increase in the number of new licences. An estimated 1,200 new pharmacies were granted contracts as a result of the exemptions, 10 times more than the five years preceding the change[4].

Within the Health Act 2009, provisions were then introduced which required Primary Care Trusts to prepare and publish Pharmaceutical Needs Assessments (PNA). The new PNA was designed to provide information that could be used to objectively determine applications for new pharmacies based on the needs of local areas. One of the benefits of this process was that PNAs were public documents allowing potential applicants to view them and submit applications in areas where pharmacies were needed.

In 2012, some of the exemptions introduced in 2005 were removed. It was argued that these exemptions had created clustering of pharmacies with little improvement in access for consumers[5]. Alongside these changes, the NHS initiated changes to the regime used to control the entry of new pharmacies. Responsibility for developing PNAs was shifted to new local Health and Wellbeing boards with ultimate responsibility for assessing applications for market entry undertaken centrally by the National Health Service Commissioning Board.

As the example of England shows, there are alternative ways of regulating the location and distribution of pharmacies that are more sophisticated than simple distance-based location rules. As the example shows the liberalising of entry rules can have significant and unnecessary impacts on the pharmacy sector. Shifting to an objective needs based assessment that is consistent and comparable may have benefits over the existing location rules used in Australia where the distribution of pharmacies may be less than optimal.

As data provided in a recent Australian National Audit Office report has shown the distribution of pharmacy remuneration across Australia is not even. Data from 2012–13 and 2013–14 shows that the level of pharmacy remuneration varies dramatically with 2.8 per cent of pharmacies receiving less than $100,000 in remuneration and 17.5 per cent of

[3] Pharmaceutical Services Negotiating Committee 2016. 'Pharmaceutical Needs Assessment' Accessed online 12 September 2016 http://psnc.org.uk/contract-it/market-entry-regulations/pharmaceutical-needs-assessment/

[4] ATKearney 2016. 'The Future of Community Pharmacy in England' Accessed online 8 September 2016. https://www.atkearney.com/documents/10192/649132/The+Future+of+Community+Pharmacy.pdf/1838dede-b95a-4989-8600-6b435bd00171

[5] McKee, S. 2012. 'Pharmacy market entry rules kill off 100-hour exemption' in PharmaTimes Online. 24th July 2012 Accessed online 8 September 2016. http://www.pharmatimes.com/news/pharmacy_market_entry_rules_kill_off_100-hour_exemption_976910

pharmacies receiving over $1 million in remuneration[6]. This wide variation in remuneration implies an uneven market and may suggest that some pharmacies are located in areas with limited competition yet high demand.

National Seniors believes that the current location rules are inefficient and an alternative approach to regulating the location of pharmacies should be explored. The PNS model used in England provides one example of an alternative to the current location rules which takes an objective approach to regulating the location and distribution of pharmacies. Primary Health Networks could, for example, be utilised to develop needs analyses to regulate the distribution of pharmacies in Australia. Any new system to regulate entry should protect consumer's access to medicines and minimise costs to consumers while maximising value for money and sustainability of supply.

PBS Patient Co-Payment Discount

Given that the pricing of prescription medicine is strictly regulated, opportunities for pharmacies to compete on price are limited to over-the-counter medicines and other pharmacy products.

On 1 January 2016, pharmacists have been afforded the discretion to offer a one dollar discount on the PBS patient co-payment as a means of creating competition in the market for prescription medicines. Provided that competition does not undermine the sustainability of supply and accessibility of medicines, National Seniors believes that the introduction of this discount is beneficial. The benefits of the discount are that it generates cheaper prices for consumers, value for money for taxpayers as well as creating opportunities for market differentiation within the pharmacy sector.

National Seniors is cognisant that there is ongoing debate about the benefits of this initiative. While sections of the pharmacy lobby suggest that this discount will disadvantage consumers[7], this is not entirely accurate. It has been claimed, for example, that the discount will make it harder for consumers to reach the safety net threshold at which point consumers begin to receive discounted or free medicines. While it is true that consumers will reach the safety net later, evidence shows that they will not be worse off because the discount provides both an immediate and annual discount on prescription medicines.

Table 1, below, compares the impact of the discount for both a general and concessional consumer requiring 45 items in a single year. The analysis demonstrates the financial impact of the discount on both the consumer and government.

General patient with one dollar discount:

- A general patient requiring 45 PBS items would receive an annual discount of $12.90 on the cost of their PBS medicines if offered a one dollar discount on each item.

[6] Australian National Audit Office (ANAO) 2015. *Administration of the Fifth Community Pharmacy Agreement.* The Auditor-General ANAO Report No.25 2014–15 Performance Audit https://www.anao.gov.au/sites/g/files/net1661/f/ANAO_Report_2014-2015_25.pdf

[7] The Pharmacy Guild of Australia 2016. 'Discounting the PBS Co-payment'. Accessed online 12 September 2016 http://guild.org.au/issues-resources/pbs-public/discounting-the-pbs-copayment

- Government would spend $32.10 less annually if a general patient requiring 45 PBS items over the year was offered a one dollar discount on each item.

Concessional patient with one dollar discount:

- A concessional patient requiring 45 PBS items would receive an annual discount of $45 on the cost of their PBS medicines if offered a one dollar discount on each item.

As Table 1 clearly shows, both a consumer and the government receive a saving as a result of being offered a one dollar discount on the co-payment, with the cost of providing the discount falling solely on the pharmacy.

Those individuals not meeting the safety net will receive the full benefit of the discount. Those meeting the safety net threshold will share the saving with government. While reaching the safety net later diminishes the saving over the course of the year, a consumer is still better off overall as a result of receiving the discount.

Given that the discount is discretionary it will be up to the individual pharmacy to decide if offering the discount is sustainable for their business and suitable for their business model. They may wish, for example, to withhold the discount as part of a market differentiation strategy.

Given the discretionary nature of the discount and the impact of location rules, it is possible that pharmacies will not offer the discount in the absence of competition. Consumers, especially those in outer suburban or regional or rural areas, may not benefit as much from this policy because there is no alternative to drive a pharmacy to offer a discount unless they are able to utilise online retail options. This does raise an issue about equity as it potentially creates a two tiered system where those living in areas of higher population density and greater competition have access to cheaper medicines than those in areas with limited choices.

There are potentially greater savings for consumers and government if the discretionary discount was extended further. While extending the discount to two dollars, for example, may provide increased savings for consumers and government, this saving would need to be balanced against the potential impact on the sustainability of the pharmacy sector and therefore accessibility for consumers. This should be fully assessed before any change is made.

Table 1: Comparison of annual impact of $1 discount on patient co-payment on a consumer requiring 45 PBS items in one year	**General Patient**		**Concessional Patient**	
	No discount	**$1 Discount**	**No discount**	**$1 Discount**
Total # items per year	45	45	45	45
Safety Net Threshold	$1,475.70	$1,475.70	$372.00	$372.00
Approved retail price (example)	$50.50	$49.50	$50.50	$49.50
BEFORE REACHING THE SAFETY NET				
Number of items required before safety net threshold applies	38	39	60	71
Price paid (max) by consumer to pharmacy before reaching safety net (per item)	$38.30	$37.30	$6.20	$5.20
Price paid by consumer to pharmacy before safety net applies (per year)	$1,455.40	$1,454.70	$279.00	$234.00
Total **saving/cost** to consumer before reaching safety net	**-$0.70**		**-$45.00**	
Price paid by government to pharmacy before safety net applies (per item)	$12.20	$12.20	$44.30	$44.30
Price paid by government to pharmacy before safety net applies (per year)	$463.60	$475.80	$1,993.50	$1,993.50
Total **saving/cost** to government before reaching safety net	**$12.20**		**$0.00**	
Total paid by consumer + government to pharmacy before safety net applies (per year)	$1,919.00	$1,930.50	$2,272.50	$2,227.50
Total **saving/cost** to consumer and government before safety net applies	**$11.50**		**-$45.00**	
AFTER REACHING THE SAFETY NET				
Number of items charged at concession rate after reaching safety net	7	6	0	0
Price paid (max) by consumer to pharmacy after reaching safety net (per item)	$6.20	$5.20	$0.00	$0.00
Price paid by consumer to pharmacy after reaching safety net (per year)	$43.40	$31.20	$0.00	$0.00
Total **saving/cost** to consumer after reaching safety net	**-$12.20**		**$0.00**	
Price paid by government to pharmacy after safety net applies (per item)	$44.30	$44.30	$50.50	$49.50
Price paid by government to pharmacy after safety net applies (per year)	$310.10	$265.80	$0.00	$0.00
Total **saving/cost** to government after reaching safety net	**-$44.30**		**$0.00**	
Price paid by consumer + government to pharmacy after safety net applies (per year)	$353.50	$297.00	$0.00	$0.00
Total **saving/cost** to consumer and government after safety net applies	**-$56.50**		**$0.00**	
TOTAL				
Total paid by consumer to pharmacy	$1,498.80	$1,485.90	$279.00	$234.00
Total **saving/cost** to consumer	**-$12.90**		**-$45.00**	
Total paid by government to pharmacy	$773.70	$741.60	$1,993.50	$1,993.50
Total **saving/cost** to government	**-$32.10**		**$0.00**	
Total paid by consumer and government to pharmacy	$2,272.50	$2,227.50	$2,272.50	$2,227.50
Total **saving/cost** to consumer and government	**-$45.00**		**-$45.00**	

Primary health care services

National Seniors supports efforts to make the primary health care system more accessible and cost effective. Community pharmacists play an important role in improving access to and efficiency of primary health care services.

Community Pharmacy Programs that enhance the quality use of medicines, such as Clinical Interventions, MedsCheck, Home Medicines Reviews and Residential Medication Management Reviews, are important services which make use of and extend the core skills and knowledge held by pharmacists. National Seniors supports moves to continue existing programs and trial new programs provides they are effective in enhancing the quality use of medications and are subject to ongoing assessment of their cost effectiveness.

While National Seniors is not opposed to moves to expand the role of pharmacists in the delivery of primary health care services, we are cautious about such moves. There are three main reasons for this caution.

Firstly, it is vital that the pharmacist's role in the primary health care space is made clear. Pharmacists should only deliver those services which are compatible with their professional skills.

Pharmacists, like all other allied health professionals, have a specific set of skills and knowledge which are developed and verified through structured education and training programs. These skills and knowledge are complementary to those provided by doctors, such as GP's and specialists, who have primary responsibility for diagnosing illness, developing treatment and prescribing medicines. While pharmacists have important skills and knowledge related to the dispensing of medicines, it is doctors that have the primary duty of care for patients. Services offered by pharmacists should act as a complement to the services offered by doctors and not as a replacement. Pharmacists should only deliver services within the remit of their skills and knowledge or have their skills and knowledge upgraded and verified.

National Seniors would be very concerned if older Australians bypassed or forgo visits to a doctor as a direct result of receiving services or advice from a community pharmacist if this resulted in illnesses or complications.

Secondly, it is important to not lose sight of the purpose of expanding the role of community pharmacy in delivering primary health care services. The current Community Pharmacy Agreement delivers $1.2 billion in funding for Community Pharmacy Programs, double the amount that was provided in the previous agreement[8].

National Seniors believes that the purpose of expanding services into pharmacy is to deliver better outcomes for consumers. Government should not be expanding pharmacy into the delivery of primary health care simply for the purpose of supporting the financial sustainability of the community pharmacy sector. There are other means to do this.

[8] Australian Government Department of Health 2015. *Sixth Community Pharmacy Agreement*. Accessed online 12 September 2016. https://www.guild.org.au/docs/default-source/public-documents/tab---the-guild/Community-Pharmacy-Agreements/6cpa---final-24-may-201558b59133c06d6d6b9691ff000026bd16.pdf?sfvrsn=2

In this regard, we should not be restricting Community Pharmacy Programs, which are funded through the CPA, to the community pharmacy setting alone. If services could be efficiently and effectively delivered through a GP practice using non-prescribing pharmacists, for example, then option should be enabled.

Lastly, there are potential problems with the extension of primary health care services into the community pharmacy setting given that highly regulated pharmaceutical products are increasingly intermingled with unregulated health care products. Unregulated therapies within the pharmacy retail space could be undeservedly legitimised as pharmacy becomes more embedded with the primary health care space.

Most pharmacies have significant retail space dedicated to products, such as vitamins and other supplements, which do not have strict regulations governing efficacy and contraindications. These products augment income derived from the sale of regulated prescriptions and over the counter pharmaceutical products. While evidence of the efficacy and safety of some of these products has been established, there are many products with dubious or unfounded claims.

Pharmacy staff, whether they are pharmacists, assistant pharmacists or otherwise may be asked to promote unregulated products to consumers. There is a potential that they may do this based on inaccurate information about efficacy or interactions with medications. In a recent survey of 736 Australian pharmacists, for example, it was found that respondents scored on average 50 per cent in tests of their knowledge of the clinically proven benefit or drug interactions of certain complimentary medicines[9].

Given that older Australians are increasingly consuming complementary medicines (58 percent of those aged over 65 years used one of 17 common complimentary medicines in the previous 12 months)[10], it is important that they are not being misinformed or misled when presenting at a pharmacy.

The primary issue here is one of trust. Consumers may purchase complementary or alternative medicines, in part, because of their trust in pharmacists. As the pharmacy guild itself has reported, consumers overwhelmingly trust the advice of pharmacists[11]. It is therefore important that this trust is not abused.

There must be a clear distinction between the sale of regulated and unregulated products within the pharmacy retail space to ensure that vulnerable consumers are not being encouraged to purchase items with little or no efficacy, in part, because they are being promoted within a pharmacy setting that imbues trust. This should extend to staff to ensure that there is no confusion among consumers as to who has the appropriate skills and knowledge to advise them.

[9] Tiralongo, E., Braun, L., Wilkinson, J. Spizer, O., Bailey, M., Poole, S. and Dooley, M. 2010. 'Exploring the Integration of Complementary Medicines into Australian Pharmacy Practice with a Focus on Different Practice Settings and Background Knowledge' in Journal of Complementary and Integrative Medicine. 7, 1. http://www98.griffith.edu.au/dspace/bitstream/handle/10072/35832/66443_1.pdf?sequence=1

[10] Smith, C., Chang, E., Brownhill, S. and Barr, K. 2016. 'Complementary Medicine Health Literacy among a Population of Older Australians Living in Retirement Villages: A Mixed Methods Study' in *Evidence-Based Complementary and Alternative Medicine*.

[11] Pharmacy Guild of Australia 2016. '94% of shoppers trust advice of their community pharmacist' 10 August 2016. Accessed online 15 September 2016. http://www.guild.org.au/news-page/2016/08/10/94-of-shoppers-trust-advice-of-their-community-pharmacist

Pharmacy remuneration

PBS remuneration forms a significant part of the income of pharmacies and can make up between 40 to 80 percent of income. Average PBS remuneration per pharmacy in 2013-14 was estimated to be $650,222[12].

Under the Sixth Community Pharmacy Agreement community pharmacy has been provided with $11.1 billion for dispensing prescription medicines over five years. This includes the Dispensing Fee, Administrative, Handling and Infrastructure (AHI) Fee and Dangerous Drug Fee[13]. Based on the latest data on the number of pharmacies in Australia this represents an average remuneration of $403,266 per pharmacy per year in dispensing fees alone[14].

At a minimum a pharmacy would receive $10.42 every time they dispense a prescription medicine, made up of $6.93 in the dispensing fee and $3.49 for the AHI. The new AHI fee replaces the pharmacy retail mark-up and sets a permanent floor on dispensing remuneration. National Seniors supports the move to delink remuneration for community pharmacists from the price of pharmaceuticals. This is a more transparent and sustainable option for delivering medicines to the Australian public that avoids the issues arising from price variability within the PBS.

Given that the AHI fee maintains consumer access to PBS medicines by underpinning the economic sustainability of the pharmacy sector, it is reasonable to expect that consumers be informed about how these fees contribute to this outcome. Given that community pharmacies in Australia experience average annual turnover of $2.8 million and annual average net profit of $107,000 (excluding proprietors' salaries)[15], the public has a right to insist on greater transparency and accountability.

Given the size of the subsidy, consumers should know that the fee is operating in a way that is cost-effective. Both government and the pharmacy sector should be required to demonstrate that the AHI fee is fair and sustainable over time. This is especially important given that consumers are the ones who ultimately pay for dispensing fees through the tax system.

Government should make it clear to consumers the impact of dispensing fees, such as the AHI. What, for example, is the impact of dispensing fees on pharmacist's income and capacity to provide the full range of medicines required by consumers? How do dispensing fees impact on pharmacies based on variables such as location, size, throughput and competition?

While understanding of the cost structures and business models of retail pharmacies is limited[16], there is data available to help us to better understand the impact of dispensing fees on the sustainability of pharmacies.

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[12] ANAO 2015 *Op cit.*
[13] Australian Government Department of Health 2015. *Op cit*.
[14] Australian Government Department of Health 2016. *Review of Pharmacy Remuneration and Regulation – Discussion Paper.* July 2016 http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf
[15] Australian Government Department of Health 2016. *Ibid*.
[16] ANAO 2015 *Op cit.*

National Seniors believes that the Department of Health should make de-identified data showing remuneration to pharmacies publicly available for scrutiny. The Department should fund independent research which can ascertain the impact of dispensing fees on pharmacy income. This research should also assess the impact of dispensing fees on medicines accessibility and on the cost of medicines.

For their part, pharmacies should be required to publish basic information about their financial affairs given the large amount of income they receive from government. Greater transparency and accountability is a small price to pay for receiving significant sums of guaranteed funding from government.