Negotiation of the first Pharmaceutical Wholesaler Agreement

Final Impact Analysis (Second Pass)

Prepared by the Department of Health & Aged Care

Executive Summary

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Executive Summary

This Impact Analysis (IA) has been prepared to support government consideration at each major decision point in the negotiations of a dedicated Pharmaceutical Wholesaler Agreement (PWA). The purpose of the PWA is to reform Pharmaceutical Benefits Scheme (PBS) wholesaler arrangements to support a stronger and more sustainable sector that continues to support Australian patients in-line with the National Medicines Policy (NMP).

Pharmaceutical wholesalers (wholesalers) have an important role in Australia's medicines supply chain. Wholesalers are the link between pharmaceutical manufacturers and the community pharmacy network. Stock is imported into Australia by pharmaceutical manufacturers and stored in bulk third-party logistic (3PL) facilities. Wholesalers procure this stock, warehouse it in accordance with stocking requirements, and distribute directly to community pharmacies on request. The efficiency and continued viability of this key link in the supply chain is crucial to support patient access to medicines.

The IA identifies six key problems in relation to wholesaler distribution arrangements for PBS medicines.

1. Guaranteeing access to medicines through community pharmacy
2. Aligning government investment in the wholesaler sector with the refreshed National Medicines Policy
3. Industry sustainability
4. Aligning wholesaler remuneration with business costs
5. Keeping the cost of medicines down
6. Improving stakeholder engagement

On 7 August 2023, the Minister for Health and Aged Care, the Hon Mark Butler MP (the Minister), announced the government's decision to initiate negotiations for an Eighth Community Pharmacy Agreement (8CPA)[1]. It was also decided that the Department of Health & Aged Care (the department) would enter into negotiations to establish a dedicated agreement between the Commonwealth and the peak body for Community Service Obligation (CSO) wholesalers (wholesalers), the National Pharmaceutical Services Association (NPSA). To be known as the Pharmaceutical Wholesaler Agreement, this new agreement would consider wholesaler remuneration arrangements for the delivery of PBS subsidised medicines to community pharmacies. These arrangements were previously negotiated through the Community Pharmacy Agreement (CPA) process with the Pharmacy Guild of Australia (the Guild). This includes determination of the wholesale mark-up (WMU) and the CSO funding pool.

[1] https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/negotiations-for-an-eighth-community-pharmacy-agreement?language=en

As part of the 8CPA consultations and prior to the announcement of negotiations towards a dedicated PWA, the NPSA submitted a proposal to government outlining three key reforms:

1. A dedicated agreement between government and the NPSA
2. A reformed funding model for wholesaler remuneration, that aligns with the cost to distribute PBS medicines
3. A fit-for-purpose and sustainable funding envelope for wholesalers.

The NPSA proposal for a dedicated agreement follows years of advocacy by the NPSA as well as findings from an independent review into pharmacy regulation. Recommendation 8-2 of *The Review of Pharmacy Remuneration and Regulation*[2] led by Professor Stephen King in 2017 (the King Review) found that "the Australian Government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements". This recommendation arose from the difficulties presented by the Pharmacy Guild of Australia, which represents the interests of community pharmacy owners and negotiates each CPA with the Government, negotiating on arrangements for funding of the stakeholders (here wholesalers), which the Guild does not represent.

NPSA Funding Model Proposal

The key points of the final 1PWA arrangements are summarised below.

1. A five-year agreement between the Commonwealth and NPSA setting out wholesaler funding arrangements, including WMU Payments and CSO Payments.
2. Changes to the WMU structure, including updated calculation arrangements and a new four-tier structure for PBS medicines supplied through community pharmacies.
3. Continued CSO funding arrangements through the CSO Wholesale Funding Pool to support timely and reliable supply of PBS medicines to community pharmacies across Australia.
4. CSO funding to be demand-driven.
5. Indexation arrangements for CSO funding over the agreement term.
6. Inclusion of eligible section 100 PBS medicines supplied through community pharmacies in the reformed wholesaler funding and CSO delivery arrangements.
7. Information redacted as commercially sensitive

Options

This IA considers three options for government consideration in relation to its negotiation position for a PWA.

[2] Review of Pharmacy Remuneration and Regulation

1. No PWA. Maintain existing wholesaler arrangements negotiated through 7/8CPA (status quo)
2. Establish PWA and accept NPSA proposal in-full

3A. Establish PWA, implement structural policy reforms (including CSO demand-driven reforms), and align remuneration with wholesaler costs.

3B. Establish PWA, implement structural policy reforms (not including CSO demand-driven reforms), and align remuneration with wholesaler costs.

Preferred option

The preferred option is option 3B. This option represents the highest net benefit and does not present a regulatory burden significantly higher than other comparable options.

Implementation

Implementation of option 3B will require negotiation and signing of the 1PWA with the NPSA. This is the next decision point for government. If an agreement can be reached, the department would be required to conduct a joint assessment with the Guild as to whether the terms of the 1PWA are likely to lead to a reduction in the estimated total pharmacy remuneration as set out in table 2 of the 8CPA. This is the preferred option's first key milestone.

Where that assessment concludes there is likely to be a reduction in estimated total pharmacy remuneration, government is required to adjust pharmacy dispensary remuneration such that the estimated total pharmacy dispensary remuneration to Approved Pharmacists under the 8CPA is received. This is the next key milestone.

Evaluation

Following implementation of the preferred option, the department will evaluate the extent to which the objectives above have or have not been met. This evaluation will monitor the performance of the policy during and after implementation.

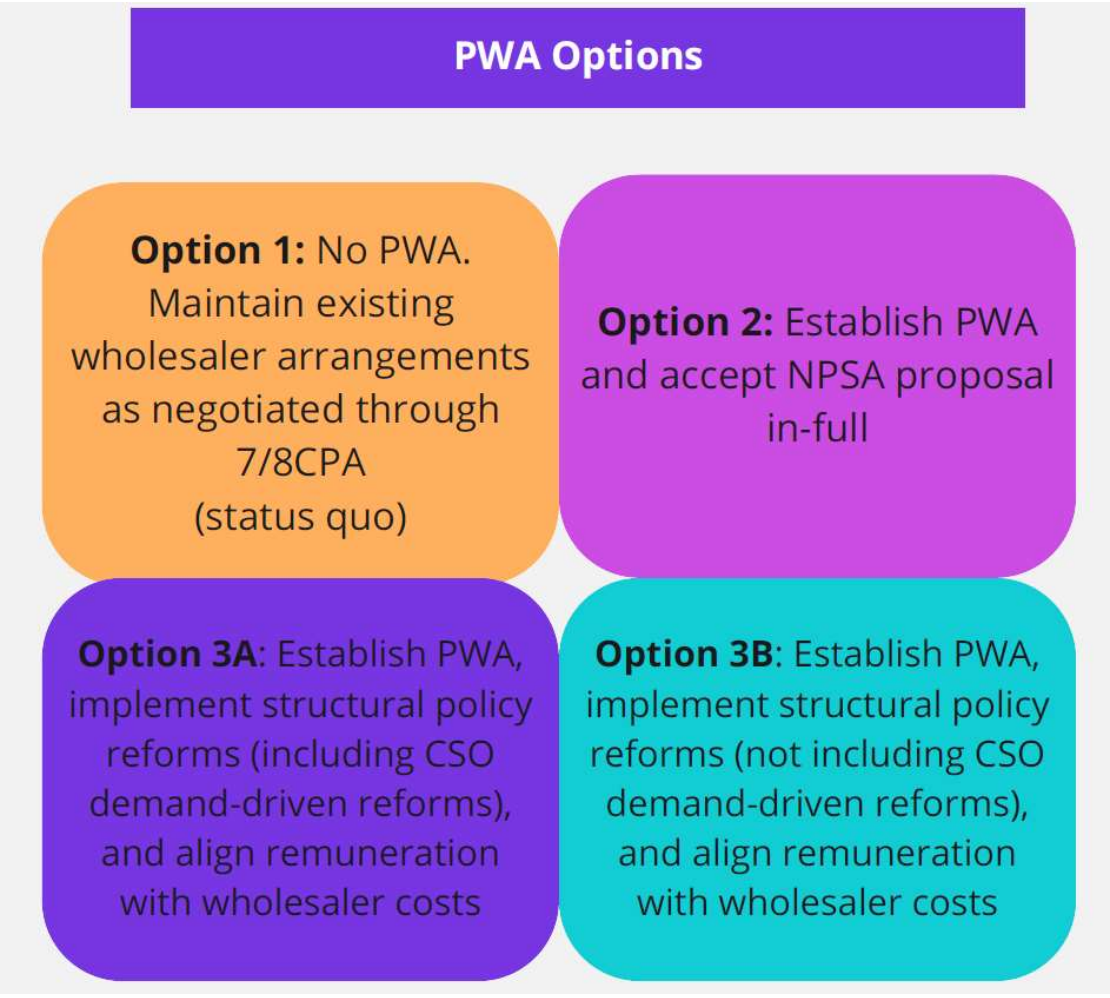
The evaluation will take place in two distinct phases. The first is the ongoing monitoring and evaluation during policy implementation. This phase will monitor risks and provide mitigation strategies should unforeseen circumstances arise. A significant part of this evaluation will be informed by regular stakeholder engagement with affected parties.

The second phase of the evaluation will commence at the beginning of 2027, six months after the introduction of WMU reforms on 1 July 2026.

Preparation of this IA commenced following government decision to enter into a separate negotiation with pharmaceutical wholesalers. In accordance with the Australian Government Guide to Impact Analysis, this IA has been utilised at each major stage of the policy development process. An Early Assessment IA was submitted to the Office of Impact Analysis (OIA) in August 2024 ahead of government consideration of a negotiation position for the PWA. The options presented in the Early Assessment IA supported the department's advice to government and ultimately informed government's consideration.

As is best practice, further versions of the IA have been updated to incorporate input received from stakeholders and decision makers.

A First Pass IA was submitted to support government consideration prior to finalisation of a PWA. This Second Pass IA is submitted to the OIA prior to a final government decision on the PWA.



Background

The Pharmaceutical Benefits Scheme (PBS)

The PBS is the Australian Government's national medicines subsidy program. Managed by the department and administered by Services Australia, the scheme began in 1948 providing free medicines for pensioners and a list of 139 'lifesaving and disease preventing' medicines free of charge for others in the community.[3] Today, the PBS supports access to subsidised medicines for all Australian residents who hold a current Medicare card, primarily through community pharmacies, but also in hospitals and other settings. The continued operation and management of the scheme is a critical part of Australia's healthcare system and a cornerstone of the Australian Government's broader NMP.

Medicines that are subsidised on the PBS are listed on the Schedule of Pharmaceutical Benefits (the Schedule). Not all medicines approved for use in Australia are listed on the Schedule and attract government subsidy.

The decision to fund medicines under the PBS is made by government based on a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body appointed by government. Under section 101 of the *NHA,* the PBAC must consider the cost and clinical effectiveness of the proposed medicine in comparison with other treatments available for the same condition. In the event that the PBAC recommendation is not positive, the sponsor may choose to reapply or to sell the medicine in Australia via private prescription.

PBS expenditure is uncapped and will increase as demand grows and more new drugs are added to the schedule. As at 30 June 2023, the PBS had 928 medicines listed in 5,261 brands[4]. In financial year 2022-23, the Government spent $17 billion for supply of section 85 and section 100 medicines under the PBS, compared to $14.7 billion in 2021-22, amounting to a 15.6% increase. The volume of PBS subsidised prescriptions also increased by 3.7% in 2022-23 to a total of 223.1 million, compared to 215.1 million in 2021-22 year.

Since 1 January 2024, patients pay up to a maximum of $31.60 for most PBS medicines, or $7.70 for concession card holders. The Australian Government subsidises the remaining cost (with the exception of brand premiums and certain other allowable charges).

[3] Pharmaceutical Benefits Scheme (PBS) | About the PBS

[4] Pharmaceutical Benefits Scheme (PBS) | Expenditure and Prescriptions Report 1 July 2022 to 30 June 2023

Australia's National Medicines Policy (NMP)

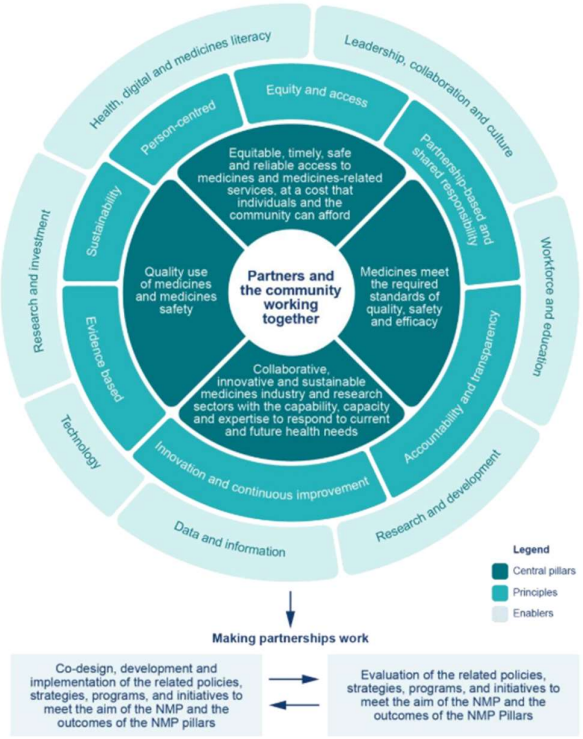
The Australian Government's National Medicines Policy is a high-level framework focused on the availability and the use of medicines and medicines-related services.[5] The NMP's vision is *to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.*

Critical to this vision are four central pillars.

1. Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford.
2. Medicines meet the required standards of quality, safety and efficacy.
3. Quality use of medicines and medicines safety.
4. Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

The NMP is founded on these four interconnected central pillars, which together with the principles and enablers, are fundamental to achieving the vision and aim of the NMP (figure A).

Figure A – Overview of the NMP



[5] national-medicines-policy.pdf (health.gov.au)

Pharmaceutical Wholesalers

Wholesalers play a critical role in achieving the aims of the NMP. Medicine stock is imported into Australia by pharmaceutical manufacturers and stored in their bulk 3PL facilities. Wholesalers procure this stock and are responsible for the efficient storage, transportation and wholesale distribution of these medicines to community pharmacies, hospitals and other healthcare facilities. This promotes greater efficiency for pharmacy businesses, which receive goods from a single channel rather than as separate deliveries from hundreds of different vendors. These products must be stored under appropriate conditions to ensure their stability, potency and integrity throughout their shelf life. *The Australian code of good wholesaling practice for medicines in schedules 2,3,4 & 8* sets out the appropriate standards to ensure medicines in Schedules 2, 3, 4 and 8 are stored and distributed in accordance with label requirements of the sponsor, State and Territory legislation and this Code.

Wholesalers are a critical link in the medicines supply chain, connecting patients through community pharmacies across Australia with medicines manufactured locally and in Australia. The proficiency of their supply chains has a significant impact on the patient access to medicines outcome, including timeliness, safety, quality, equity and reliability (key elements of the NMP).

The CSO funding pool, first established in 2006 as part of the CPA process, is the ongoing mechanism that ensures that all Australians have ongoing and timely access to all PBS medicines through community pharmacies. Under the CSO, all eligible CSO wholesalers receive payments from the CSO Funding Pool for supplying PBS medicines to community pharmacies.

CSO wholesalers are private companies, mostly large corporations publicly listed on the Australian Stock Exchange. Pharmaceutical supply to community pharmacies is largely dominated by four companies on a national level, that being Australian Pharmaceutical Industries (API); National Pharmacies Distribution (NPD); Sigma Healthcare; and Symbion Pty Ltd. There are also other smaller companies, some of which focus efforts on individual States and Territories.

CSO wholesalers delivered 421,087,327 units of PBS Medicines in 2023-24, an increase of 3.3% over 2022-23 (404,290,928 units) on a per working day basis, to support over 5,600 community pharmacies in Australia. CSO wholesalers are also remunerated for the responsible delivery of National Diabetes Services Scheme (NDSS) products, vaccines and other immunisation products (National Immunisation Program, NIP) and supporting the safe disposal of unwanted medicines through the National Return of Unwanted Medicines Program (NatRUM). Additionally, wholesalers also fulfil orders for more than 2 million non-PBS medicines and other healthcare products per day into community pharmacies which is done separately to Commonwealth funding.

Wholesaler arrangements for NDSS and NatRUM programs are not within the scope of the PWA and are not considered in this IA.

In addition to delivering pharmaceuticals, wholesalers play an important role in the management of medicines shortages. Wholesalers monitor and track supply data, enabling the network to identify

and respond to issues such as short-term shortages or high-volume orders, product recalls or major unforeseen events[6]. During the height of the COVID-19 pandemic, pharmaceutical wholesalers supported the management of unprecedented surges in demand for healthcare products. Wholesalers distributed more than 70 million PBS medicines during March and early April 2020, representing an 80% uplift on normal PBS volumes.

The NPSA is the peak body representing full-line CSO wholesalers in Australia. NPSA members, of which there are four (API, NPD, Sigma, and Symbion) have been operating in Australia for over 100 years. In that time, these wholesalers have built a complex, efficient and integrated supply chain that supports the efficient distribution of medicines across Australia.

The Community Service Obligation (CSO)

To ensure Australians can access PBS medicines safely, when and where they need them, the Australian Government provides financial incentives to pharmaceutical wholesalers that meet a set of compliance requirements and service standards. This is known as the CSO. The CSO is currently structured as a fixed funding pool from which CSO wholesalers who have been found suitable through a tender process can be remunerated based on the units of CSO products they distribute to community pharmacies. A CSO product refers to a PBS medicine. This can vary depending on the form the product can take. For PBS medicines, it is generally a single pack.

To receive these payments, CSO wholesalers must meet all of their obligations under the CSO Deed of Agreement (the Deed) with the Commonwealth. Principally, these are set out in the CSO Compliance Requirements and CSO Service Standards [7]. The CSO's requirements and standards are largely consistent with the aims and intended outcomes of the NMP.

There are three CSO Compliance Requirements and nine CSO Service Standards that must be met by CSO wholesalers as part of their obligations under the Deed.

[6] Microsoft Word - FINAL NPSA background for website .docx

[7] community-service-obligation-cso-for-pharmaceutical-wholesalers-funding-pool-operational-guidelines-guidelines.pdf (health.gov.au)

CSO Compliance Requirements

CSO wholesalers must:

1. Provide a single-entry point for Distribution Points to order CSO Products, receive information and resolve queries
2. Maintain access to the established infrastructure and sufficient financial capacity to meet the CSO standards and CSO Compliance Requirements, and
3. Maintain the quality of CSO products that they supply, including meeting all applicable storage condition requirements, holding all necessary State and Territory licences and complying with the Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8.

CSO Service Standards[8]

CSO wholesalers are also required to meet the following CSO Service Standards:

1. Supply to any Distribution Point
2. Supply to any Rural and Remote Pharmacy and ensure that they meet the set Threshold for Sales to Rural and Remote pharmacies
3. Supply any Brand of CSO Product
4. Stock in their warehouses or distribution centres at least one Brand of each PBS medicine (except for those that are out of stock, unavailable or subject to Exclusive Supply Arrangements)
5. Supply any Low Volume PBS Medicine and ensure that they meet the set Threshold for Sales of Low Volume PBS Medicines
6. Supply any PBS Medicine at or below the relevant CSO Price for that PBS Medicine
7. Not impose Prohibited Financial Imposts on Distribution Points
8. Supply any Brand of CSO Product within the Guaranteed Supply Period:
    a. PBS Medicines within 72 hours (for products listed in the High Volume List) or 24 hours (for all other PBS medicines) of the Regular Order Cut Off Time.

CSO Administration Agency

The CSO Administration Agency is an independent agency that is responsible for administering the CSO Funding Pool and monitoring the performance of CSO wholesalers. The agency works with the CSO wholesalers to ensure that they understand their Obligations under the Deed and comply with these obligations. The agency reports to the department.

[8] *Relating to PBS medicines only.*

Wholesaler Remuneration

To support wholesalers' ongoing viability and ability to guarantee the timely and safe distribution of medicines, the Australian Government provides remuneration to wholesalers in two ways: the CSO Funding Pool and through the Wholesale Mark Up (WMU) within the Commonwealth Price. Wholesalers may also have other financial arrangements with certain pharmacy banner groups for delivery of non-PBS medicines and/or over-the counter (OTC) products. These are beyond the scope of this IA.

Under the remuneration arrangements for the CSO in 7CPA, the Commonwealth provides a fixed CSO funding pool of up to $1.083 billion over five years (FY2020-21 to FY2024-25) to remunerate eligible pharmaceutical wholesalers for the additional costs they incur in complying with the CSO service standards and compliance requirements. These costs include fuel and labour costs, as well as warehousing and specific medicine safety infrastructure.

Under the 7CPA, payments for CSO deliveries only apply to section 85 (general schedule medicines). Section 100 Special Arrangement medicines are not included in these remuneration arrangements, including the obligation to deliver within specified timeframes. Distribution of section 100 medicines operates outside of the CSO compliance requirements, with wholesaler remuneration determined via commercial arrangements between wholesalers and the dispensary (mostly community pharmacy or hospital settings).

The WMU is an additional payment provided by the Commonwealth to eligible wholesalers to hold and deliver subsidised PBS medicines to community pharmacies. Wholesale mark-up is currently structured in tiers based on the Approved Ex-Manufacturer Price (AEMP) of the PBS medicine. Where the AEMP is up to and including $5.50, wholesalers receive $0.41 per dispense. Where the AEMP is over $5.50 and up to and including $720, wholesalers receive 7.52% of the AEMP per dispense. Where the AEMP is over $720, wholesalers receive $54.14 per dispense.

The wholesale mark-up forms part of the Commonwealth Price which is subject to agreement from the Guild, as required by Section 98BAA of *the National Health Act*.

The estimated Commonwealth contribution to wholesale mark-up from 1 July 2020 to 30 June 2025 on signing of the 7CPA was $1.746 billion.[9]

[9] Seventh Community Pharmacy Agreement, Table 1: Components of the remuneration and funding

NPSA Proposal

During consultations for the 8CPA, NPSA submitted a proposal to government outlining reasons in support of a dedicated agreement with pharmaceutical wholesalers. Principally, NPSA noted that the current wholesaler remuneration arrangements were no longer fit-for-purpose and that the Australian Government should enter into a direct agreement with the NPSA in relation to CSO and wholesale mark-up. A new agreement should include a reformed funding model which accounted for the increasing complexity, cost and future efficiency gains of medicines distribution in Australia.

Information redacted for Commercial in confidence reasons.

1. What is the policy problem you are trying to solve and what data is available?

The following policy problems have been identified with relevance to pharmaceutical wholesaler arrangements and their role in the medicines supply chain.

1. Guaranteeing access to medicines through community pharmacy
2. Aligning government investment in the wholesaler sector with the refreshed National Medicines Policy
3. Industry sustainability
4. Aligning wholesaler remuneration with business costs
5. Keeping the cost of medicines down
6. Improving stakeholder engagement

These six policy problems have been identified through an extensive process of stakeholder consultation to inform the 8CPA as well as the findings of independent reviews into the pharmacy sector. They represent a broad range of problems for a variety of stakeholders, not exclusive to the wholesaler sector. For example, *guaranteeing access to medicines through community pharmacy* and *keeping the cost of medicines down* are key problems that are of significant importance to consumers.

In his announcement of the early commencement of 8CPA negotiations[10], the Minister noted the department would begin consultation with a broad range of stakeholders. This included the signatories to the 7CPA, the Guild and the Pharmaceutical Services Association (PSA), patient groups, pharmaceutical wholesalers, and other groups who have an interested in the growth and development of pharmacy services for the benefit of all Australians.

Several government-commissioned Independent Reviews, including the King Review, have recommended "the range of stakeholders included for consultation [should] represent those who deliver on the agreed services… to improve the overall transparency and sustainability of the sector".

Due to commercial and financial sensitivities, consultation was undertaken in-confidence. The confidentiality and legislated requirement for agreement with the Guild limited the approach to stakeholder consultations, with non-disclosure agreements in place for all parties involved in relevant discussions.

[10] https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/negotiations-for-an-eighth-community-pharmacy-agreement

Other reviews into the pharmacy sector have informed the identification of these six problems, such as the King Review.

If these problems are not addressed, there would be a range of impacts on stakeholders along the medicines supply chain and ultimately, patients. Impacted stakeholders include:

- Patients that rely on affordable, safe and timely access to PBS medicines through their local community pharmacy.
- CSO wholesalers that rely on government subsidy to remain viable while supporting the CSO requirements
- Manufacturers that rely on wholesalers to distribute their products to patients across Australia
- Pharmacies that depend on CSO wholesalers for guarantee of timely supply. Rural and remote pharmacies are most dependent due to their often reliance on a single wholesaler

Previous attempts to address these problems

Since their inception in the 4th CPA (2006), the CSO and WMU have been negotiated as part of the CPA process with the Guild. Prior to 2006, supply of PBS medicines was inconsistent and unreliable, particularly for communities in rural and remote locations. Patients requiring critical, but low volume medicines, such as lapatinib for breast cancer, would not be able to easily obtain their medicines.[11]

In the 7CPA, wholesalers directly negotiated CSO arrangements with government for the first time. However, the Guild maintained final authority over the arrangements as the CSO remained part of the CPA with the Guild as the primary signatory.

In 8CPA, government decided to remove the CSO from the CPA. Government would establish a dedicated agreement with wholesalers to support better stakeholder engagement and policy making outcomes. The Act requires that any changes to the Commonwealth Price, of which the WMU is a part, requires the Guild's approval. Clauses 3.2.6 – 7 of the 8CPA outlines this requirement.

3.2.6 - Where separate negotiations between the Commonwealth and NPSA in relation to PBS wholesaler remuneration (Pharmaceutical Wholesaler Agreement) result in a change in the Commonwealth Price, the Pharmacy Guild and the Commonwealth will, as soon as practicable after the signing of the Pharmaceutical Wholesaler Agreement, jointly make an assessment as to whether the terms of the Pharmaceutical Wholesaler Agreement are likely to lead to a reduction in

[11] https://npsa.org.au/about-npsa/the-cso/

the estimated total pharmacy remuneration set out in Table 2.

3.2.7 - Where the assessment conducted under clauses 3.2.6 concludes there is likely to be a reduction in estimated total pharmacy remuneration, the parties agree to an adjustment that is designed to ensure the estimated total pharmacy dispensary remuneration to Approved Pharmacists under the Agreement is received. The Commonwealth notes it is the Pharmacy Guild's preference to deliver any such adjustment through elements of the Commonwealth Price.

Data gaps

Government has access to significant data resources through the CSO Administration Agency in relation to CSO and the extent to which CSO wholesalers are complying with the CSO requirements. This includes performance against each of the CSO service standards as well as sales and payment data, market share and supply trends, non-performance and audits and complaints.

This data collection is critical to ensuring CSO wholesalers are meeting their requirements under the CSO Deeds. However, government does not possess data on wholesaling businesses and their profitability. For example, the extent to which the level of government funding CSO wholesaler receive through the CSO funding pool and/or WMU payments supports the viability of each wholesaler. Data collection on these elements would support government in better calibrating wholesaler remuneration arrangements. For example, government does not know with certainty the actual cost of distributing particular PBS medicines to particular community pharmacies. Building a greater evidence-base with respect to wholesaler costs and the impact of increased efficiencies from new technologies, such as Artificial Intelligence and greater levels of automation in warehousing and distribution, will support future government policy considerations.

Collecting data on private businesses that are supported with government funding is difficult due to commercial confidentiality issues. Government is often reliant on data provided by industry to inform its considerations. These data gaps should factor into government decisions on wholesalers funding.

1. Guaranteeing access to medicines through community pharmacy

Guaranteeing patient access to essential medicines is a core issue in considering the future of wholesaler arrangements. The continuation and further strengthening of requirements on wholesalers to support patient access to medicines is a critical policy issue that has arisen through stakeholder consultation. The continuation of existing arrangements under the CSO supports predictable, timely and safe patient access to essential medicines. The CSO's aim is to ensure all Australians can enjoy timely and ongoing access to PBS medicines through community pharmacies.

The CSO Funding Pool acts as a financial incentive for wholesalers to tender for inclusion in the CSO as a CSO wholesaler. Without the Funding Pool, government could not guarantee the health policy outcomes that the CSO supports under its operational guidelines. These include, but are not limited to requirements to:

1. Supply to any community pharmacy in Australia (including rural and remote pharmacies) and supply any brand of PBS medicine.
2. Stock in their warehouses at least one brand of each PBS medicine.
3. Supply any PBS medicine within 24 hours or within 72 hours for products listed on the High Volume list.

Without the CSO Funding Pool (or some other incentive mechanism), these policy outcomes are not guaranteed and are not likely to be delivered in a timely manner, in particular to regional, rural and remote community pharmacies.

2. Aligning government investment in the wholesaler sector with the refreshed National Medicines Policy

Current wholesaler remuneration is not aligned with the refreshed NMP[12] that was released in December 2022.

The NMP was first published in 2000. In 2019, the Australian Government commissioned a review of the NMP in recognition of the substantial changes across the health, medicines and medical technology landscape since the first edition in 2000.

The government established an Expert Advisory Committee to lead the Review, chaired by Professor Michael Kidd AM, with Emeritus Professor Lloyd Sansom AO, Mrs Janette Donovan, Dr Sarah Dineen-Griffin and Mr David Herd. The committee undertook extensive stakeholder engagement to ensure a broad range of issues and diverse experiences informed the refresh of the NMP as a high-level policy framework.

In addition to its broader policy aims, the NMP notes its vision (to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment) can be realised through effective partnerships, structures and processes with defined responsibilities to support the NMP.

Partnership and collaboration

The NMP places significant emphasis on the role of partners in achieving the NMP's vision.

The NMP notes that *each partner must be engaged in a collaborative, cooperative manner to achieve the best health, social and economic outcomes for Australians. Each partner has a role in progressing the NMP through demonstrating respect and recognising the expertise and contribution of other partners, with some partners also having additional responsibilities so the NMP's objectives can be achieved.*

To date, wholesaler remuneration has been a component included in the CPA negotiation process with the Guild being the major stakeholder negotiating terms of the CPA for all parties. NPSA as the peak stakeholder representing all CSO wholesalers nationally, have not been a formal party to discussions on WMU or CSO remuneration, both of which have a direct impact on their ability to continue to ensure equitable medicines distribution to pharmacies throughout Australia. Through the PWA, NPSA is able to directly negotiate and collaborate with the government to ensure continued supply of medicines at a fair price to all CSO wholesalers.

[12] national-medicines-policy---final-consultation-report.pdf (health.gov.au)

Policy Aims

The NMP outlines three key aims:

1. Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians.
2. Medicines are used optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care.
3. Support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research, and the successful development of medicines and medicines-related services in Australia.

Aligning CSO and wholesale remuneration with these NMP aims ensures government investment decisions and policy settings are in line with this framework.

3. Industry sustainability

The ongoing sustainability and viability of the pharmaceutical wholesaler sector was a key policy problem that was raised during stakeholder consultation. The successful operation of the CSO relies on well-functioning and sustainable wholesaling sector.

High-level summary

The sector has suggested wholesaler funding as a proportion of the total cost of PBS medicines has fallen over the last decade and remains the smallest cost component for government (compared with pharmacies and manufacturers). During this time, cost pressures on wholesalers, largely driven by increasing costs of fuel and labour, have added to their cost bases. Wholesalers argue additional remuneration, coupled with policy reform is needed to support the sector's ongoing sustainability.

NPSA argue that despite the critical services that wholesalers provide, wholesaler funding as a proportion of the total cost of PBS medicines has decreased since 2015, and remains the smallest cost component for government (at approximately 6%) in the PBS supply chain (compared with pharmacy and PBS medicine manufacturers).

As relative remuneration stagnates, wholesalers suggest their costs are increasing, driven by a series of factors. Without change, the industry has warned that the viability of the sector is in jeopardy, and by extension, the objectives of the NMP and the successful delivery of the CSO arrangements.

First, the size and scale of the PBS is growing. More medicines are being listed on the PBS with a 13% increase in section 85 prescriptions between FY2016-23. Higher value medicines (AEMP $1,001+) are also growing as a proportion of total PBS medicines, up 7.6% between FY2015 – 23. Many of these medicines need special handling, such as cold-chain storage, which is increasing wholesaler costs that are not fully reflected in current funding arrangements.

The volume of prescriptions dispensed under the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS) have been steadily increasing each year from 2017 (297 million dispensed) to 2023 (335 million). More Australians are living longer with chronic diseases which also increases the medicine use in these populations. Dispensing rates of PBS prescriptions increases with age with 58% of PBS and RPBS medicines dispensed to people aged 65 and above in 2022-23. People aged 65-74 had the highest number of dispensed prescriptions and accounted for the highest Australian Government expenditure.[13]

Second, the operational complexity of PBS distribution is also increasing. Between FY2016-17 and FY2022-23, there has been a 27% increase in PBS item codes listed on the PBS and more complex molecules, are represented in this expansion, including more biologic medicines and personalised therapies. This has required pharmaceutical wholesalers to meet additional service requirements, such as more specialised infrastructure and cold-chain storage for innovative medicines (many with complex storage and handling requirements).

[13] Australia's health 2024 - in brief (aihw.gov.au)

An increasing rate of national emergencies and weather disasters is also adding to the operational complexity burden which are not accounted for in the funding model. Significant weather events can impact wholesaler's ability to operate transport vehicles and prevent the distribution of PBS medicines. This often has a disproportionate impact on patients in rural, regional and remote areas of the country due to the transportation required to service community pharmacies in these areas. By comparison, pharmacies in metro areas can be serviced more easily through major airports, shipping ports and well-connected arterial roads that are most resilient to significant weather events.

Third, wholesaler remuneration needs to keep pace with external price increases. Exposure to a high inflation and cost-volatile environment has added additional cost-to-serve pressure, primarily driven by increasing labour and fuel costs **[REDACTED]**. Under the 7th CPA, neither wholesale mark-up nor the CSO funding pool were indexed.

NPSA have proposed the CSO be indexed to account for the realities of cost-related factors in the macroeconomic environment. Labour **[REDACTED]** and fuel/ transport costs **[REDACTED]** are the two largest operating and maintenance cost components in wholesaler operations, both of which are exposed to an inflationary environment, particularly in recent years. NPSA have proposed the indexation of CSO using a combination index of the Wage Cost Index-3 (WCI-3) and the automotive fuel index[14].

The WCI-3 [15]is a composite index published by the Department of Finance and comprises a wage cost component (weighted at 60%) and a non-wage cost component (weighted at 40%). The Australian Bureau of Statistics (ABS) maintains the automotive fuel index.

As a measure of transparency to government, the NPSA have proposed that the indexation mechanism leverage cost inflation indices available from government (e.g. from the ABS or the Commonwealth Department of Finance), with indexation to apply annually.

This IA will support government in making a decision to either enter into a dedicated pharmaceutical wholesaler agreement as a means of considering these arguments or not.

4. Aligning wholesaler funding with business costs

The NPSA have put to government that the current legislative and agreement structure in-place with all stakeholders that support the PBS is becoming overly complex and no longer fit-for-purpose. The reformed remuneration model structure proposed offers a closer reflection of the actual operational cost structure of wholesalers.

For example, the operational cost of distribution to rural areas, compared with metro areas is reflected in the separate CSO per unit-fee proposed. **[REDACTED]**. This is largely driven by

[14] Automotive fuel in the CPI | Australian Bureau of Statistics (abs.gov.au)
[15] Budget Paper No. 3. See Table A.7 on page 119.

increased costs of freight, packing labour and packaging materials. These costs compound when considering low volume medicines and medicines with specialised storage and handling requirements. Growth in the number of medicines listed on the PBS, alongside a growing rural and regional population, will add increasing pressure and an overall cost-to-serve to these areas **[REDACTED]**[16]. These increasing pressures are in contrast to the fixed CSO pool that remains capped.

[16] ABS; Office of Impact Analysis; NPSA member data; L.E.K Consulting analysis

5. Keeping the cost of medicines down

The cost of medicines is a significant factor in patient access to medicines. If the cost of medicines were to rise, this could have a significant impact on the ability of Australians to access their essential medicines.

The Australian Government's existing investments in the pharmaceutical wholesaler sector, through the WMU and CSO funding pool, subsidises the cost of storage, handling and transportation of PBS medicines. Without these investments, the cost of distribution would likely fall on community pharmacies and be passed on to patients through higher priced medicines, notwithstanding the impacts on equitable, timely and reliable distribution. The cost to patients would largely be reflected in higher costs for medicines that fall under the general co-payment but could also be an additional charge as has been practice for section 100 medicines in some circumstances.

The NPSA propose to reduce the WMU from the current 7.52% to 4.3%. Doing so would contribute to a lower Commonwealth price, creating some savings for patients on medicines below the general and concessional co-payment amounts (noting this requires savings to be passed on to patients by pharmacy outlets. A reduced wholesale mark-up would reduce the overall price to pharmacists. Table A outlines the current wholesale mark–up arrangements as part of the Commonwealth Price and Table B outlines NPSA's proposed changes to these arrangements, respectively.

Table A: Components of the Commonwealth Price

Payment type	Value of payment	
wholesale mark-up[17][18] (for Ready-Prepared Pharmaceutical Benefits)	Where the Ex-Manufacturer Price is up to and including $5.50	$0.41 per dispense
	Where the Ex-Manufacturer Price is over $5.50 and up to and including $720	7.52 per cent of the Ex-Manufacturer Price per dispense

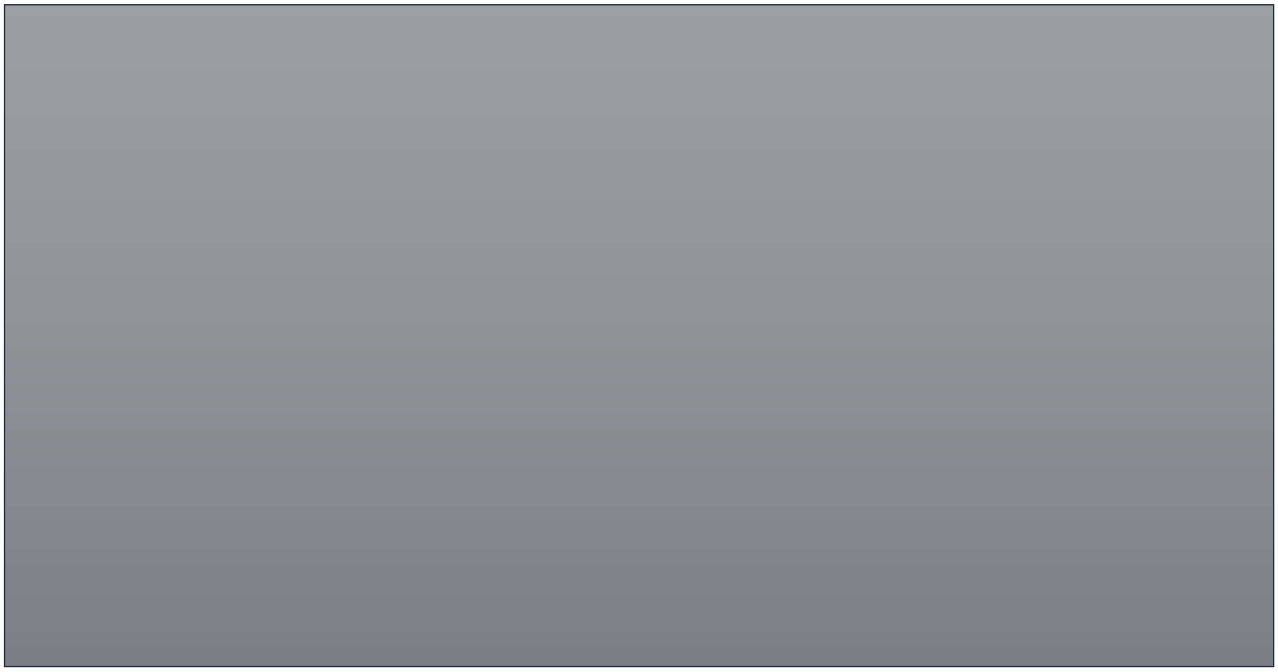
[17] The wholesale mark-up for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.
[18] The wholesale mark-up applying for the period from 1 July 2020 to 31 December 2020 will be the wholesale mark-up applying in the last year of the Sixth Community Pharmacy Agreement. The wholesale mark-up arrangements set out in Table 2 will commence from 1 January 2021.

Payment type	Value of payment		
	Where the Ex-Manufacturer Price is over $720		$54.14 per dispense
Administration, Handling and Infrastructure Fee AHI[19]	Tier One AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than $100	$4.28 per dispense of Maximum Quantity
	Tier Two AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity from $100 and up to and including $2,000	Tier One AHI Fee plus 5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds $100, per dispense of Maximum Quantity
	Tier Three AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity over $2,000	Tier One AHI Fee and $95 per dispense of Maximum Quantity
dispensing fee (for Ready-Prepared Pharmaceutical Benefits)	$7.74 per dispense		
dispensing fee (for Extemporaneously-Prepared Pharmaceutical Benefits)	Dispensing fee for Ready-Prepared Pharmaceutical Benefits, plus $2.04, per dispense		

[19] The AHI Fee accounts for the costs entailed in dispensing medicines by the pharmacy including associated infrastructure costs. This is calculated from the per pack price with the AHI Fee applied for the Maximum Quantity proportionate to the number of packs required for the Maximum Quantity and will be adjusted if less or more than the Maximum Quantity is supplied.

Payment type	Value of payment
Dangerous Drug fee	$4.80 per Dangerous Drug dispensed

Table B: NPSA proposed changes to the wholesaler mark-up comparison with 8CPA settings (including changes to WMU ceiling price and tiers) [REDACTED]



6. Improving Stakeholder Engagement

The establishment of a dedicated PWA (as currently committed to as an outcome of the 8CPA) improves the stakeholder engagement process for the negotiation of wholesaler remuneration and the CSO. Wholesaler remuneration and the CSO are currently negotiated and determined through the CPA process. Pharmaceutical wholesalers have not been formally involved or included in this process, despite the critical role they play in the supply chain and the impact of the determinations on them.

The lack of formal consultation or a genuine mechanism for engagement process with pharmaceutical wholesalers in relation to these arrangements is not consistent with the APS' stakeholder engagement framework, the APS *Principles for Engagement and Participation*

2. What are the objectives, why is government intervention needed to achieve them, and how will success be measured?

The efficient and cost-effective distribution of PBS medicines forms a critical part of Australia's healthcare system. The availability and affordability of medicines in Australia supports the health and wellbeing of Australians, leading to longer and healthier lives lived and reduced downstream costs for the health system and pressure on acute care services.

The Commonwealth Government provides financial incentives to CSO wholesalers to ensure they deliver a minimum level of distribution service to support a high-level of health. Commonwealth funds support the ongoing operational and maintenance costs (O&M) of wholesalers as well as their future investments in working capital. This is essential for wholesalers to keep pace with the growing size and complexity of the PBS and the growing dispersion of the community pharmacy network across Australia. No other entity but the Commonwealth of Australia is willing or able to intervene in the market for medicine distribution in this same way to guarantee this policy outcome.

Direct collaboration and engagement between the Australian Government and pharmaceutical wholesalers is critical to ensuring government policy is delivering for the Australian community. Equally it is critical that government investment and policy decisions in the medicines supply chain are aligned with the refreshed NMP.

Specifically, government action is required to do the following:

1. Evaluate current pharmaceutical wholesaler remuneration arrangements in line with the objectives of the refreshed NMP.
2. Determine an appropriate level of investment and associated policy measures in line with the NMP.
3. Finalise arrangements that advance the objectives of the NMP, potentially through the establishment of a dedicated agreement with CSO wholesalers.

Limitations of government intervention

As within any government intervention into the market, there are limitations on the extent to which that intervention can occur. Several factors should be considered when determining the appropriate level of government intervention. These include financial constraints, time constraints, skill and knowledge constraints, and the impacts of intervention on stakeholders (including intended and unintended consequences).

The following central pillars of the NMP have been identified as most relevant to the role of wholesalers.

Pillar 1: Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford.

Pillar 4: Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

To support a more detailed analysis, these pillars have been further broken down into specific 'sub-objectives' with a corresponding 'intended outcomes' in tables C and E to draw out the key elements of these sub-objectives in relation to pharmaceutical wholesalers and associated stakeholders. These details have been developed in conjunction with the overarching aims and objectives of the NMP in the context of the wholesalers' role.

The NMP does not rank particular elements or pillars of the policy above others. To maintain consistency with the intentions of the NMP and to avoid adopting unintended interpretations of the NMP, this IA has not sought to rank particular NMP elements above one another. The exception to this is in the circumstance of balancing respective elements to enable a net benefit calculation in question 4.

Please note the sub-objectives are not formal elements of the NMP and have derived for the purpose of the IA only.

Table C – NMP Pillar 1

NMP Pillar 1	Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford.
Intended Outcome	Medicines and medicines-related services are affordable and accessible in an equitable, timely and safe manner, leading to the achievement of the best health, social and economic benefits for all Australians.

Table D – NMP Pillar 1 sub-objectives

Sub-objective	**Intended Outcome**
Equity of access	Support patients to access PBS medicines regardless of their background, income or location. Seeks to reduce inequities that are experienced by vulnerable population groups, including First Nations Australians and Australians in non-metropolitan areas.

Timeliness of Access	On-time access to PBS medicines. Ensures that consumers can get the medicines they need, when they need them. Avoids the health impacts of delayed access due to supply or distribution network issues, with these challenges particularly impacting rural and remote Australians that cannot easily access a community pharmacy.
Safety of access	PBS medicines are stored, handled, and transported safely and in accordance with the requirements of the manufacturer. Ensures medicines are safe for patients at the point of use.
Reliability of access	PBS medicines are reliably supplied to community pharmacy. Particularly critical for patients with chronic conditions, such as diabetes, that require a reliable supply of medicines. Management of weather events and other disruptions to ensure reliability of access.
Individual affordability	Australians can afford the medicines and medicines-related services they need. Particularly critical for Australians with multiple health conditions who take multiple medicines, people with low incomes, and individuals or families experiencing high out-of-pocket health care costs.
Community affordability	Initial and continued investment decisions are informed by rigorous value for money assessment to ensure value for taxpayer money.

Table E – NMP Pillar 4

NMP Pillar 4	Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.
Intended Outcomes	Thriving, dynamic medicines industry and research sectors that are proactively supported to contribute to meeting current and future health needs in Australia and internationally. The sectors work within a positive, sustainable and responsive policy environment that delivers and promotes world-class innovation, including encouraging the development and commercialisation of medicines, new technologies and related services.
	A diverse medical research sector that generates high-quality evidence, strategies, systems and processes, which support ongoing improvements in the quality use of medicines and medicines safety.

	Collaborative, robust, efficient and reliable supply chains and networks that deliver equitable, timely, affordable and safe access to medicines and medicines-related services throughout Australia.

Table F – NMP Pillar 4 sub-objectives

Sub-objective	Intended Outcome
Collaboration with industry	Supporting the pharmaceutical wholesaler industry with strategic investments to support ongoing costs and enhanced efficiency. Aiming to build a more reliable and integrated medicines supply chain.
Encouraging industry innovation	Encouraging the development and commercialisation of innovative and cutting-edge distribution activities that are increasingly cost-effective and efficient.
Supporting sustainability	Sustainability for both industry and government. Fostering a positive and sustainable policy environment to drive innovation and investment, within an investment level that government can afford.

Barriers & Constraints

Achieving consensus

While the Commonwealth and wholesalers share similar goals and aspirations to deliver improved health and wellbeing outcomes for Australians, there is some differences of views in relation to how this can and should be achieved.

Unlike the Commonwealth, wholesalers are private companies which are often publicly listed and driven by shareholder expectations for revenue and profit growth. Equally, there are also market-based incentives to provide a high level of service to clientele (pharmacies), such as a desire to grow, win new clients and maintain existing clients. These market-based incentives encourage innovation and efficiency-improving investments from wholesalers to win new pharmacy clients and then distribute higher volumes, subsequently leading to higher remuneration.

The combination of these incentives partially contributes to the provision of quality medicine delivery services to support access to PBS medicines nationally.

The Commonwealth as the financier of many public goods and services, is driven by a desire to achieve improved health and wellbeing outcomes, within a constrained budget. Competing spending priorities across the health system must be considered and evaluated, such that scarce resources can allocated in the most effective way.

There is likely to be disagreement between parties in relation to the level of government financial support required to enable wholesalers to maintain a high quality medicine distribution service, driven by competing incentives.

Actions to overcome barriers & constraints

To overcome the challenges in achieving consensus (and therefore agreement) with the wholesaler sector, government must ensure its offer to industry is sufficiently attractive to reach agreement (if required). This requires a strong evidence-base for policy decisions, including reasoning for aspects of the government offer and consideration of the risks of industry rejection.

Alternatives to government action

The alternative to government action is for the Commonwealth not to enter into a PWA with the NPSA. Doing so would see arrangements negotiated through the 7CPA, and later 8CPA, continue as outlined in those agreements.

The impacts of doing so are explored in this IA under option 1. The key assumptions of government intervention (options 2, 3A and 3B) are outlined in part three of the IA. The success factors of each option and how success against the metrics identified by this IA are outlined in part four of the IA.

3. What policy options are you considering?

This IA will consider three options.

1. No PWA. Existing wholesaler arrangements negotiated through 7/8CPA continue (status quo)

2. Establish PWA and accept NPSA proposal in-full

3A. Establish PWA, implement structural policy reforms (including CSO demand-driven reforms) and align remuneration with wholesaler costs.

3B. Establish PWA, implement structural policy reforms (not including CSO demand-driven reforms) and align remuneration with wholesaler costs.

The first option available to government is to maintain current wholesaler arrangements previously negotiated through the 7CPA and extended under 8CPA. This option is explored as it is the default position for government, should it wish not intervene in the market. There is no scenario whereby government funding of PBS wholesaling would cease over a 10-year horizon. In the absence of a PWA, wholesaler arrangements outlined in 8CPA would continue until 1 July 2029. At this point, the Act requires that a new CPA be established (which includes wholesaler arrangements). In the absence of an agreement between the Commonwealth and the Guild for a 9CPA, the Act requires the Pharmaceutical Remuneration Tribunal (PBRT) to conduct an inquiry to determine the Commonwealth Price (of which the WMU is a part).

Under this scenario, wholesaling funding would continue at some level as determined by the PBRT.

The second option under consideration is to establish a PWA with all elements of the NPSA proposal to government. This option represents the views of the NPSA to the fullest extent and the impacts of adopting such a position should be fully explored.

The third option this IA will consider is split into two sub-options. The first sub-option (3A) is to establish a PWA that accepts the policy reforms that NPSA have proposed, and with an expanded budget envelope that delivers benefits to patients, recognises wholesaler cost pressures, and supports activities that are currently unfunded, but is not at the level NPSA have requested. This option includes the significant reforms to the CSO that NPSA have requested, including the change to an uncapped demand-driven program, with separate metro and non-metro unit rates.

The second sub-option (3B) would see government establish a PWA that accepts many of the policy reforms industry has proposed as in option 3A, but while maintaining a fixed CSO pool to

support greater budgetary certainty.

All options can achieve the stated policy objectives of this IA as this section will discuss.

While there are a range of potential options open to government in relation to subsidy of distribution arrangements for PBS medicines, the above options represent the range of genuine and viable policy options, given existing feasibility constraints. Primarily, this involves existing government commitments, including ongoing funding for the PBS (of which wholesalers play a critical role in supporting) and its position to negotiate a dedicated agreement with PBS wholesalers.

None of these options were election commitments from the current government.

Option 1 – No PWA. Continuation of existing arrangements negotiated through 7CPA & 8CPA (Status Quo)

This option would extend existing wholesaler remuneration arrangements and CSO compliance obligations as negotiated in the 7CPA (and extended in the 8CPA). It should be viewed as the 'status quo' option for government, given it is the default policy position should government not wish to intervene further into the wholesaling market.

The current pharmaceutical wholesaler remuneration arrangements commenced on 1 July 2020 as part of the 7CPA and continue in the 8CPA. Table G below outlines the WMU payments and tiers whereas a medicine's ex-manufacturer price rises, the value of WMU increases.

In addition to these mark-up arrangements, the Australian Government committed to providing up to $1.083 billion over five years or up to $223 million in the first year and $215 million per year thereafter to remunerate eligible pharmaceutical wholesalers. These funds support the range of additional wholesaler costs associated with ensuring the timely supply of PBS medicines to approved pharmacists across Australia through the CSO funding pool. An additional $10 million per year was provided in September 2023 for two years to support wholesalers following the introduction of increased maximum dispensed quantities. CSO funding as outlined in the 7CPA continues and is considered ongoing.

There is a significant risk under this option whereby existing CSO wholesalers would withdraw from CSO, leading to its collapse if alternate suppliers are not able to be identified. Wholesalers have warned existing remuneration levels are insufficient to maintain their operations in accordance with the CSO service standards and compliance requirements. The impacts of this scenario are explored in this IA.

Table G – Components of the Commonwealth Price (wholesale mark-up only)[20]

Payment type	Value of payment	
wholesale mark-up[21] (for Ready-Prepared Pharmaceutical Benefits)	Where the Ex-Manufacturer Price is up to and including $5.50	$0.41 per dispense
	Where the Ex-Manufacturer Price is over $5.50 and up to and including $720	7.52% per cent of the Ex-Manufacturer Price per dispense
	Where the Ex-Manufacturer Price is over $720	$54.14 per dispense

Stakeholder roles and responsibilities

Consumers

- Under the status quo, there is a significant risk wholesalers may withdraw from the market due to inadequate public funding affecting the sector's ongoing viability. Should this scenario materialise, consumer access to medicines via their local community pharmacy could be significantly impacted as the CSO which currently places strict requirements on PBS medicine distribution to pharmacies across Australia may not continue to operate.
- Consumers may also face significant price increases on PBS medicines as wholesalers, in the absence of government funding, and push distribution costs onto pharmacies which are likely to pass these costs on to consumers. This would likely affect consumers in rural and regional areas the most, as distribution costs to these areas are higher compared with metropolitan areas.

Pharmaceutical Wholesalers

- There would be no increased compliance burden or requirement on pharmaceutical wholesalers under the status quo. Wholesalers may continue delivering the same category of medicines under the same compliance requirement but are more likely to withdraw from the CSO entirely and continue their operations in the private market.

[20] Table 3, Eighth Community Pharmacy Agreement as at 1 July 2024. Some components of the Commonwealth Price will be subject to Indexation.

[21] The wholesale mark-up for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.

- Wholesalers have noted that continued investment in the supply chain has led to increased efficiencies in its activities and therefore, a reduction in the estimated real operational cost per unit. However, this reduction on a per-unit basis is falling and they require continued investment from government to support further investments to meet the needs of a growing PBS. **[REDACTED]**.

Figure E – Yearly operational efficiency investments per unit comparison



Pharmacies

- Under the status quo, there may be no change to pharmacy remuneration, compliance burden or supply if wholesalers remain in the CSO. Pharmacies will continue to receive a dispensing fee of $8.37 per dispense plus an Administration, Handling and Infrastructure (AHI) fee per dispense of a month's supply of a medicine of $4.62 (as at May 2024).
- The AHI fee for a listed brand of PBS medicine is tier-based in accordance with the price to pharmacist. Table S in appendix B outlines the current AHI structure.
- The AHI is a component of the Commonwealth Price, as is WMU. Under a status quo arrangement, there would be no change to WMU and in-effect, no flow-on impact on the Commonwealth Price via the AHI.
- However, there is more likely to be a significant impact on pharmacies if wholesalers withdraw from the CSO. This would likely particularly impact pharmacies unaligned with a wholesaler, as existing wholesalers are likely to support their banner pharmacy groups with security of supply under a scenario where the CSO ceased. Pharmacies may have significantly increased costs in ordering stock from many different manufacturers/suppliers, rather than through CSO wholesalers.

Government

- There would be no change to government expenditure or processes.

CSO Administration Agency

- There would be no change to the current requirements of the CSO Administrator.

Option 2: Establish PWA and accept NPSA proposal in-full

Option 2 proposes that the Australian Government enter into a PWA with the NPSA that accepts its proposal for the agreement in its entirety. This includes adoption of the NPSA's proposed structural changes to WMU and CSO:

1. Restructure and lower the WMU, with a reinvestment of the estimated government save from the implementation of a new agreement into the CSO.
2. Replace the CSO Funding Pool with a CSO with per-unit prices from 1 July 2024 that:
    a. Is recognised as a demand driven funding arrangement
    b. Has separate per-unit prices for metropolitan (MMM1) and regional, rural and remote (MMM2-7) distribution of PBS medicines
    c. Includes arrangements for delivery of section 85 and section 100 medicines to community pharmacies
    d. Pursues strengthened medicines shortages management requirements.

NPSA Proposal

NPSA's proposed reformed funding model recommends adaptations of various funding components (policy settings, CSO, and WMU) to more closely reflect the operating environment of CSO wholesalers.

Table H – NPSA reform proposals by component

Proposed policy change	Rectification of the issues which had significant consequences for wholesalers (e.g. 60Day Dispensing (60DD), multiple pack, Medicines Australia (MA) / Generic Biosimilar Medicines Association (GBMA) agreement.
CSO **[REDACTED]**	**CSO per unit fee (available only to wholesalers who sign up to the CSO Deed and associated service standards).** • Represents the average operational cost per unit of the industry. • The implementation of a metro and rural & remote CSO per unit to reflect the differences in cost-to-serve: - CSO per unit fee (FY2025) of **[REDACTED]** for **metro** distribution **[REDACTED]** - CSO per unit fee (FY2025) of **[REDACTED]**for **rural & remote** distribution **[REDACTED]**. • **Indexation of the CSO** to a combination of the Wage Cost Index-3 (WCI-3) and the ABS automotive fuel index (Combination Index), revisited annually to reflect real-time changes in operating environment. • Reduce the level of indexation by a committed efficiency gain which will be shared with government: (Net CSO index % = Combination Index % less 0.8% p.a. efficiency gain).
WMU **[REDACTED]**	• **WMU %:** Lower the WMU % from current 7.52% to 4.3% such that it contributes to a lower Commonwealth price, creating savings for patients. • **WMU floor price:** Maintain at existing floor price at $5.50. • **WMU ceiling price:** Lift current ceiling price from **[REDACTED]**and introduce a second WMU tier for medicines with AEMP value **[REDACTED]** (at an incremental 2% WMU mark-up).
Section 100 & NDSS	• Fund the distribution of section 100 medicines to community pharmacy under the above model to reflect the importance of equitable and fast access to medicines for Australians. Section 100 volumes have been growing, and the distribution of these medicines is currently not funded by government. • Fund the distribution of NDSS products at the new CSO per unit rate.[22]

[22] Note: Distribution of NDSS products will be transitioned from the CSO arrangements to alternate market options. This decision was taken outside of the 1PWA negotiations. NDSS distribution arrangements are therefore beyond the remit of this IA.

Importantly, have proposed a shift in the total composition of wholesaler funding away from WMU and towards CSO as in figure F below.

Figure F – Comparison of wholesaler funding composition



[REDACTED]

CSO per unit cost-to-serve breakdown

NPSA propose that remuneration through the CSO cover the majority of O&M costs incurred by wholesalers when distributing PBS medicines, in-line with the Deed. NPSA claim this typically represents 75% - 80% of total CSO wholesaler costs.

NPSA have provided some details to justify its proposal for different per-unit fees for distribution to metro and rural/ remote/ regional areas. These include that current policy settings do not account for the differences in cost-to-serve to pharmacies across Australia. CSO units, regardless of their end destination, are paid for by government at the same price through the fixed CSO funding pool.

NPSA contests that every order to every pharmacy across Australia is unique and will involve an array of medicines with different care requirements. This requires specialised handling from purpose infrastructure, with distribution to rural and remote locations more complex and costly.

Table I below demonstrates some of the differences across key operational areas of the wholesaler business where different requirements are needed for standard medicines and high care medicines (i.e. those requiring specific handling and transport requirements, such as cold chain, Schedule 8 (S8)[23] Controlled Drugs or cytotoxic medicines).

Table I – Area breakdown: distribution management of high care medicines (source: NPSA) [REDACTED]



Figure G below describes the various components of the cost-to-serve between metro areas (MMM1) and rural/regional/ remote (MMM2-7). The most significant component in both is labour, followed by freight. NPSA contest that a substantial labour component is usually needed to meet delivery cut-off times or to package rural and remote medicines. For example, with thorough and multiple layers of packaging to protect integrity and safety of deliveries.

In relation to freight, costs rise as the distances required to travel rise. For rural and remote

[23] Schedule 8 medicines are drugs of addiction, drugs of dependence or controlled drugs subject to strict legislative controls due to their high potential for misuse, abuse and dependence.

deliveries, longer distances, additional paperwork and greater reliance on multiple freight providers to deliver medicines typically leads to higher freight costs. Reverse logistic costs (additional paperwork/ handling for returns of packaging or unused medicines) are also captured under freight costs.

Non-metro distribution also requires additional packaging, typically with the use of disposable totes as opposed to re-useable totes typically used in metro deliveries. Additional packaging is often required for high-care drugs, including manual recording system, ice packs, internal packaging and outer box for rural distribution.

Other factors that can contribute to greater cost-to-serve in non-metro areas are the overall loss of economies of scale and higher prevalence of natural disasters in non-metro areas, which can add to costs by causing re-routing of deliveries.

Figure G – Metro and rural/ remote cost-to-serve breakdown comparison (source: NPSA) [REDACTED]-

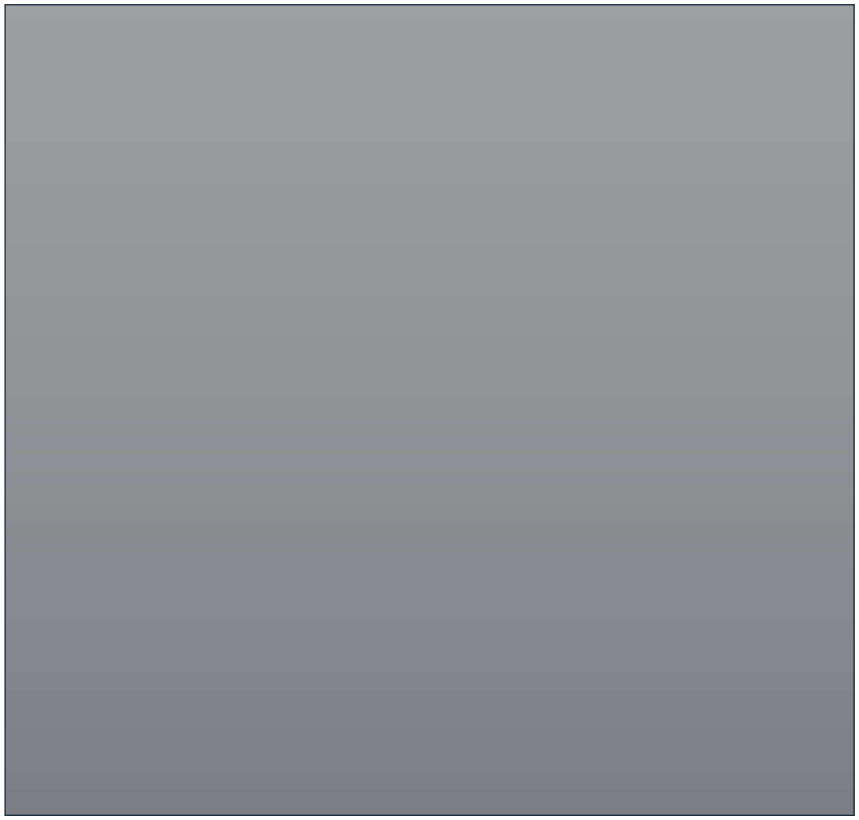


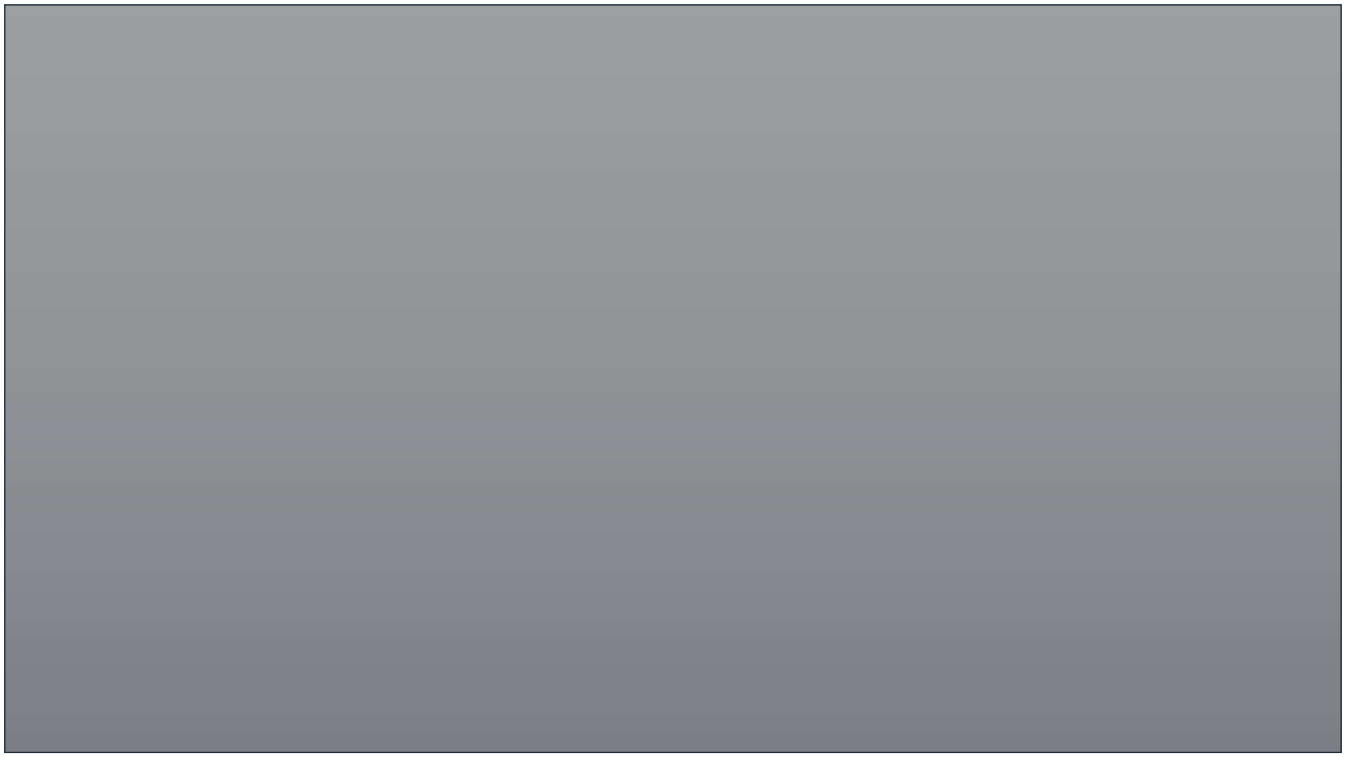
Table J below further outlines differences between metro and rural/remote distribution, broken down by primary cost driver. Across each cost driver, rural/remote distribution represents a greater distribution complexity and therefore, cost.

Table J – Metro and rural/ remote cost drivers comparison (source: NPSA) [REDACTED]



Figure H below provides an illustrative comparison of these differences in a flow-chart diagram.

Figure H – Metro and rural/ remote distribution management comparison [REDACTED]



Definition Changes

As part of the reform proposal, the NPSA have proposed the alignment on the 'per unit' definition applied to ensure remuneration for volume of medicines distributed under the CSO Deed. The NPSA have put forward the following points in support of a change to the unit definitions.

1. The PBS is based on the historical principle that a single box of medicine is a single script.

1. The CSO reflects this principle with the fund reflecting the number of medicines delivered NOT the number of scripts dispensed for those medicines.
2. The cost of distribution and delivery of single boxes does not change based on how it is dispensed – as single item or part of multiple items under one script.
3. Multiple pack pricing driven by clinical need combined with the government taking advantage of biosimilar savings has resulted in a pricing approach that does not adequately fund the costs required to deliver those medicines to the patient.

4. While the NPSA supports the use of multiple packs to serve patient needs based on their clinical circumstances, the issue arises due to the way changes are made to funding calculations which erode the value of the critical supply chain delivery (WMU).
5. NPSA proposes aligning the definition of the "unit" distributed by wholesalers across both the CSO and WMU components of the funding to address the multiple pack issue such that unintended consequences for wholesaler funding are avoided during the period of a PWA.

NPSA unit definition proposal

The NPSA have put forward the following changes to the unit definitions used to calculate the wholesale mark-up.

1. A unit is equal to the "pack quantity" delivered not dispensed.
2. This reflects where the pack quantity is equal to the manufacturer's pack size or Stock Keeping Unit (SKU)[24], being the quantity of packs delivered.
3. In this definition, a "unit" is an individual pack delivered and it has the same cost to deliver, whether it is dispensed to one or three customers.
4. NPSA proposes removing concepts of maximum quantity and relevant quantity from the calculation of wholesaler remuneration.

WMU

NPSA propose that payment of the WMU covers wholesalers' return on capital, stockholding and inventory costs (including essential debtor funding community pharmacies) and other capital and tax costs, as well as a proportion of operating costs to support non-CSO wholesale activities. Tables K and L provide a comparison between the current WMU tier structure and the NPSA proposal.

[24] A Stock Keeping Unit (SKU) are retailer codes that track product, manufacturer and price information used for inventory and sales tracking.

Tables K & L: Components of the Commonwealth Price

Current Components of the Commonwealth Price (8CPA)
***(current from table 3 of 8CPA)**

Payment type	Value of payment	
wholesale mark-up (for Ready-Prepared Pharmaceutical Benefits)[1]	Where the Ex-Manufacturer Price is up to and including $5.50	$0.41 per dispense
	Where the Ex-Manufacturer Price is over $5.50 and up to and including $720	7.52% of the Ex-Manufacturer Price per dispense
	Where the Ex-Manufacturer Price is over $720	$54.14 per dispense

[1] The wholesale mark-up for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.
*Only incudes payments relevant to wholesalers

Proposed Components of the Commonwealth Price (NPSA PWA Proposal)
***(based on table 3 of 8CPA)**

Payment Type	PWA Value of payment (NPSA Proposal)	
wholesale mark-up (for Ready-Prepared Pharmaceutical Benefits)[1]	Where the Ex-Manufacturer Price is up to and including $5.50	$0.24 per dispense
	Where the Ex-Manufacturer Price is over $5.50 and up to and including $1,000	4.3% of the Ex-Manufacturer Price per dispense
	Where the Ex-Manufacturer Price is over $1,000 and up to and including $10,000	$43.00 plus 2% for every dollar the Ex-Manufacturer Price exceeds $1,000 per dispense
	Where the Ex-Manufacturer Price is over $10,000	$223.00 per dispense

[1] The wholesale mark-up for a Pack Quantity of a Listed Brand is no longer calculated using the Relevant Quantity. Instead the WMU is per individual unit delivered.

Stakeholder roles and responsibilities

Consumers

- Consumers will continue to access their PBS medicines through community pharmacies as they currently do. There would be no additional cost impacts on consumers as a result of adopting option 2. For some patients, there will be a small decrease in the cost of their medicine due to the reductions in WMU (component of the price to pharmacist). This is estimated to be a net save of $46.3 million over five years or an average of $9.26m in each year of the agreement (see Table U in Appendix B). This is an estimate only and the actual savings generated by consumers are not fully determined.
- The inclusion of section 100 medicines dispensed via community pharmacy only under the CSO arrangements guarantees patient access to these medicines. Section 100 medicines are a category of drugs that are also available as pharmaceutical benefits but are currently distributed under separate commercial arrangements between pharmacies and wholesalers (not the CSO). These include patients accessing the following programs:
    - Highly Specialised Drugs Program.
    - Efficient Funding of Chemotherapy.
    - Botulinum Toxic Program.
    - Growth Hormone Program.
    - IVF Program.
    - Opiate Dependence Treatment Program.
    - Take Home Naloxone Program.

Pharmaceutical Wholesalers

- CSO wholesalers that are members of the NPSA will be required to participate in a negotiation process with the government.
- Wholesalers will continue to operate under the status quo but will be remunerated in greater alignment with their operating and maintenance costs via a per-unit CSO payment.
- Wholesalers will be required to deliver section 100 medicines in accordance with the CSO compliance requirements and service standards, although the wholesalers already deliver these medicines (without the CSO guarantee) to a range of dispensing settings, including pharmacies and hospitals.
- Wholesalers will be required to adjust their internal payment and IT systems to adapt to the per-unit remuneration model, WMU changes and additional compliance activities associated with the inclusion of section 100 medicines under the CSO.
- Wholesalers will receive greater remuneration in option 2 than option 1, largely due to the increase in CSO funding (see Table U in Appendix B).

Pharmacies

- Pharmacies will continue to receive PBS medicines under the current service standards.
- Pharmacies engaged in the dispensing of section 100 medicines will benefit from CSO-guaranteed distribution service delivery. CSO service standards will also require that wholesalers supply PBS medicines at a price no higher than the Price to Pharmacist, ensuring pharmacies can on-sell the medicines at a profit.
- There will be a small negative impact on total pharmacy remuneration (through the AHI) due to the WMU changes. The estimated negative impact on pharmacy remuneration is $19.9 million over five years or an average of $3.98m in each year of the agreement (see Table U in Appendix B).
  The 8CPA contains clauses which ensure that any negative impact on the pharmacy sector due to changes agreed in the PWA is equally compensated by government.
- Clauses 3.2.6 to 3.2.8 of the 8CPA note that in the event that changes to the WMU would result in a reduction in the total pharmacy remuneration set out in Table 2 of the 8CPA, an adjustment would be required to elements of the Commonwealth Price to ensure the total pharmacy dispensary remuneration is received. A minor negotiation process with the Guild would be required to agree on how to account for the reduced dispensing related income.

Government

- Government (through Services Australia) will be required to implement the policy reforms that NPSA have sought. Government (via Services Australia) is responsible for administration and operation of WMU payments, which forms part of the broader Commonwealth Price used to calculate community pharmacy remuneration for dispensing PBS medicines.
- The two key changes to WMU that Services Australia will be required to implement are:
  1. WMU tier changes: WMU percentage for tier 2 is reduced from 7.52% to 4.3% and other associated tier changes.
  2. WMU quantity calculation changes: WMU calculations for a pack quantity of a listed branch are adjusted to remove 'relevant quantity' as the calculation method. WMU would be calculated with reference to the pack quantity and ex-manufacturer price for the pack quantity dispensed
- The overall cost to government will rise significantly in option 2, compared with option 1 (see Table U in Appendix B).

CSO Administration Agency

- The CSO Administrator will be required to significantly alter its operations to accommodate the structural changes to wholesaler remuneration.

- Primarily, this is to facilitate the transition from a fixed CSO funding pool to a per-unit CSO payment, with separate fees for metro and non-metro distribution.
  The CSO Administrator may be required to update its compliance systems to monitor compliance with metro (MMM1) and non-metro (MMM2-7) areas.

Option 3A: Establish PWA, implement structural policy reforms (including demand-driven CSO reform), and align remuneration with wholesaler costs

Option 3A offers the opportunity to establish a PWA that incorporates policy reforms sought by industry to better align remuneration with wholesaler cost structures.

NPSA requested reforms included within option 3A include:

1. Restructure and lower the WMU, to reduce the price of medicines for patients and ease the cost of living.
2. Replace the CSO Funding Pool with a volume-based CSO with per-unit prices from 1 July 2024 that:
    a. Is recognised as a demand driven funding arrangement
    b. Negotiates an equal risk share mechanism to minimise over-expenditure beyond forecasts
    c. Has separate per-unit prices for metropolitan (MMM1) and regional, rural and remote (MMM2-7) distribution of PBS medicines
    d. Includes arrangements for delivery of section 85 and section 100 medicines to community pharmacies
    e. Pursues strengthened medicines shortages management requirements

Option 3A provides an opportunity for phased implementation of the policy reforms, unlike option 2 which seeks the immediate commencement of policy reforms. This would provide for two distinct

phases over the course of the agreement: implementation and evaluation.

The implementation phase provides time to implement much of the structural changes that NPSA have sought. During the implementation phase, current policy settings would be extended.

Phase two is the evaluation phase where the reforms would commence, including a shift from a fixed funding pool to a volume-based per-unit system, and a series of changes to the WMU, including establishing a new fourth tier for high cost medicines with an AEMP greater than $10,000.A two year period of implementation would provide government with 12 to 18 months of data in relation to the new arrangements. Together with the stakeholder feedback that will follow, this data would support future government policy considerations.

In summary, option 3A provides for much of the same structural reforms to WMU and CSO as in option 2. But differs on several aspects, including:

1. An increased funding envelope that is aligned with wholesalers' cost structures, but with annual indexation using the Consumer Price Index (CPI) to account for increases in wholesaler operational and maintenance costs. The two largest components being labour (~50%) and fuel (~25%).[25]

2. Delayed implementation of the WMU and CSO changes until at least 18 months into the agreement to allow for implementation by Services Australia and other necessary tender processes to be completed.

Despite these differences, many aspects of the NPSA proposal could be adopted. These include:

1. Improving patient access to specialised medicines listed under section 100 of the *NHA* by funding their inclusion under the CSO arrangements.

2. Restructuring the WMU tiers with the aim of reducing the cost of medicines for consumers.

3. Restructuring of the CSO from a fixed funding pool to a per-unit, volume-based model that better aligns with the cost-to-serve of pharmaceutical wholesalers.

4. Continuation of existing CSO compliance requirements and service standards arrangements for section 85 PBS medicines to community pharmacy.

[25] NPSA proposal, 8CPA Consultation.

Option 3B: Establish PWA, implement structural policy reforms (not including demand-driven CSO reform), and align remuneration with wholesaler costs

Option 3B largely mirrors the approach in 3A, with the exception of the demand-driven CSO reforms.

The CSO has remained a fixed funding pool since its establishment in 2006 under the 4th CPA. The existing operation and structure of the CSO has underpinned safe and equitable access for all Australians to PBS medicines for over 20 years. Altering the CSO in this way presents many risks, including a significant budgetary risk to Commonwealth. The proposed demand-driven (i.e. fee-for services) approach under Option 3A may also lead to disincentives of adopting more efficient operating models and place upwards pressure on distribution costs over time.

It is for this reason that this IA has elected to consider this reform in isolation through a sub-option to option 3.

Other aspects of option 3B are consistent with those in 3A, including the changes to the WMU structure and the expansion of the CSO to better mirror wholesaler cost structures.

Stakeholder roles and responsibilities (options 3A & 3B)

Consumers

- As in the above options, consumers will continue to access pharmaceutical benefits through community pharmacies in the same manner.
- There would be no additional cost impacts on consumers as a result of adopting option 3A or 3B. For some patients, there will be a small decrease in the cost of their medicine due to the reductions in WMU (component of the price to pharmacist). This is estimated to be a net save of $28 million over five years or an average of $5.61m in each year of the agreement (see Table U in appendix B). This is an estimate only and the actual savings generated by consumers are not fully determined.
- As in option 2, patients accessing section 100 medicines through community pharmacy will be supported by the CSO.

Pharmaceutical Wholesalers

- Pharmaceutical wholesalers that are current CSO wholesalers will continue their operations through the extension of their existing deeds until the period of an approach to market is completed and new CSO wholesalers are appointed or re-appointed.
- Wholesalers that are successful in re-entering the CSO will be required to adjust their internal payment and IT systems to adapt to the changes in remuneration payment structure (as in option 2) under option 3A. These changes will not be required under option 3B.
- Wholesalers will receive less remuneration in options 3A and 3B than option 2, but more than option 1 (see Table U Appendix B).

Government

- Government (via Services Australia) will be required to implement the policy reforms that NPSA have sought in option 3A. Only changes to the wholesale mark-up will be required under option 3B.
- The overall cost impact to government in options 3A and 3B will be less than under option 2 (see Table U in Appendix B).
- Options 3A and 3B allow for phased implementation of these changes over an 18-24 month period. Government (via the Department of Health and Aged Care) would be required to facilitate a rapid-review process of the policy reforms following at least 12 months of data collection.

Pharmacies

- As in the above options, pharmacies will continue to dispense pharmaceutical benefits in the same manner.
- The CSO service standards will also require that wholesalers supply section 100 PBS medicines at a price no higher than the Price to Pharmacist. This will ensure pharmacies can on-sell the medicines at a profit and viably dispense these medicines to patients or avoid passing on the costs of distribution to patients.
- There will be an impact on total pharmacy remuneration due to the WMU changes. The estimated impact on pharmacy remuneration is $28 million over the agreement (five years) or an average of $5.61m in each year of the agreement (see Table U in Appendix B).
- Clauses 3.2.6 to 3.2.8 of the 8CPA note that in the event that changes to the WMU would result in a reduction in the total pharmacy remuneration set out in Table 2 of the 8CPA, an adjustment would be required to elements of the Commonwealth Price to ensure the total pharmacy dispensary remuneration is received. A minor negotiation process with the Guild would be required to agree on how to account for the reduced dispensing related income.

CSO Administrator

- The CSO Administrator will be required to significantly alter its operations to accommodate the change from a fixed funding pool to a per-unit model in option 3A only. The scale and detail of these changes will be set out in a future open tender process for a new CSO Administration Agency, once wholesaler remuneration arrangements are agreed in the PWA. This is required under the current CSO deeds.

Alignment with Policy Objectives

This section of the IA outlines how each of the options are linked with the stated government objectives. As outlined in part 2 of the IA, government market intervention is required to achieve the following objectives:

1. Evaluate current pharmaceutical wholesaler remuneration arrangements in line with the objectives of the refreshed NMP.
2. Determine an appropriate level of investment and associated policy measures in line with the NMP.
3. Finalise arrangements that advance the objectives of the NMP through the establishment of an agreement with CSO wholesalers.

The analysis below provides a breakdown of the links between each of the policy options available to government and its stated objectives.

NMP Pillar 1: *Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford.*

	Policy Options		
NMP Sub-Category	**Option 1:** No PWA. Maintain existing wholesaler arrangements (status quo)	**Option 2:** Establish PWA and accept NPSA proposal in-full	**Options 3A/ 3B:** Establish PWA, implement structural policy reforms (including/ not including demand-driven CSO reforms), and align remuneration with wholesaler costs
Equity	Equity is a critical part of the PBS whereby all Australians with a Medicare card can access subsidised PBS medicines at the co-payment amount or the concession co-payment amount. The CSO plays a critical role in ensuring that when patients arrive at their local community pharmacy and seek to purchase their subsidised PBS medicines, that pharmacy is holding the stock it needs to service that patient. The CSO ensures that the supply of these medicines extends to all Australians, irrespective of diversity,	The execution of a dedicated PWA will likely see the continuation of reformed CSO obligations arrangements. NPSA have confirmed that adopting its proposed remuneration structure would not lead to any change in service delivery or CSO compliance rate. Currently, only section 85 PBS medicines are supplied under the CSO obligations. The inclusion of section 100 medicines (such as HIV antiretrovirals, clozapine for treatment of schizophrenia, hepatitis B medicines and opioid dependence treatments) dispensed through community pharmacies under the CSO will ensure more equitable access of these	As in option 2, options 3A/ 3B would see the continuation of existing CSO arrangements, securing identical equity outcomes for patients accessing general schedule 85 medicines. Similar to option 2, including section 100 medicines under the CSO may result in improved equity of access outcomes by ensuring any approved pharmacy that orders a section 100 medicine, receives it. Anecdotal evidence also indicates that the lack of CSO coverage for section 100 medicines has meant wholesalers are able to charge pharmacies an amount above the Price to

	background, age, disability, location or personal circumstance. The status quo is likely to lead to a scenario where existing wholesalers may withdraw from CSO, endangering equitable access to PBS medicines.	medicines for those chronic disease patients for whom timely access of these specialised medicines is essential. While these medicines are also delivered by pharmaceutical wholesalers, they are not subject to CSO compliance requirements or service standards, and therefore, pose potential for inequitable access.	Pharmacist (the approved ex-manufacturer price and the wholesale mark-up). In these cases, some pharmacies may decide not to stock section 100 medicines, leading to worsening access outcomes of patients reliant on these medicines. Inclusion of these medicines under CSO arrangements would prevent wholesalers charging above the Price to Pharmacist (CSO service standard 6: requirement to supply any PBS medicine at or below the Price to Pharmacists).
Timeliness	Timely access to essential medicines is a fundamental part of the CSO. This is achieved through the following CSO service standard: *Requirement to supply any brand of CSO product within the guaranteed supply period.* This service standard requires CSO wholesalers to supply any brand of PBS medicine to any community pharmacy within their CSO jurisdiction[26]. The guaranteed supply period for PBS medicines is 24 hours of the Regular Order Cut Off Time or within 72 hours for product listed on the High Volume List. The Regular Order Cut Off Time is the specified time agreed between the CSO wholesaler and a distribution point by which orders must be lodged with the CSO wholesaler. Orders received after the Regular Order Cut Off Time are considered to be received on the next business day. All CSO wholesalers must comply with this requirement, unless: A. The distribution point specifies otherwise; or	The reforms proposed in this option would not have an impact on timeliness of access for general schedule section 85 medicines. NPSA have confirmed that adopting its proposed remuneration structure would not lead to any change in service delivery or CSO compliance rate. The inclusion of section 100 medicines under the CSO provides for improved timeliness outcomes for these patients. For patients that rely on timely access to section 100 medicines through the Opioid Dependence Program, for example, these patients will benefit from the CSO requirements in relation to timeliness of deliveries. These patients are often highly dependent on access to these therapeutics and would be significant affected if supply were not timely.	As in option 2, options 3A and 3B would see the continuation of the CSO service standards under the CSO, requiring unit deliveries within 24 hours of the guaranteed supply period to community pharmacy in most cases. Similar to option 2, section 100 medicines would be subject to CSO service standard 9: *supply any brand of CSO product within the guaranteed supply period.*

[26] CSO Jurisdiction means the jurisdiction(s), either National or State Based, in which the Company is Supplying CSO Product and is seeking to access the CSO Funding Pool

	B. The location (postcode) of the distribution point is on the list of locations provided by the Commonwealth that falls outside the requirement to supply CSO products within the guaranteed supply period; or C. The company is unable to meet the service standard due to a force majeure event. Timely access to PBS medicines is under threat under option 1 where wholesalers are likely to withdraw from the CSO entirely.		
Safety	The current CSO compliance requirements are clear in their requirement for CSO wholesalers to ensure the safety of CSO products. The following compliance requirement supports this outcome: *Requirement to maintain the quality of CSO products.* The requirement to maintain the quality of CSO products is critical in ensuring all CSO products are in a fit state to be supplied to customers by ensuring that these products have been maintained appropriately in accordance with approved storage requirements. There may be implications for the safety of PBS medicine distribution under a scenario where the CSO were to stop.	Option 2 will extend the CSO compliance requirement for safety. NPSA have confirmed that adopting its proposed remuneration structure would not lead to any change in service delivery or CSO compliance rate. Including section 100 medicines under the CSO means that distribution of these medicines is also subject these CSO compliance requirements. Companies are required to maintain the quality of all CSO products that they supply, including meeting all applicable storage condition requirements. This includes compliance with the *Australian code of good wholesaling practice for medicines in schedules 2,3,4 & 8 as set by the* Therapeutic Goods Administration, where compliance with the Code is not already mandatory under the necessary State and Territory licences and/or certificates.	As in option 2, the existing protections and measures in place for CSO products would apply in options 3A and 3B. As new drugs with specialised storage requirements come onto the PBS, ensuring wholesalers handle these medicines safely remains critical. An increasing number of these listings are section 100 listed medicines.

Reliability	The CSO in its current form requires CSO wholesalers to maintain access to established infrastructure and sufficient financial capacity. The requirement to maintain "infrastructure" refers to "physical infrastructure, such as warehouses, distribution centres, and transport and logistic services". It includes the systems that CSO wholesalers use to operate this infrastructure and provide these services. CSO wholesalers must inform the CSO Administration Agency if they experience financial difficulties, or have difficulty maintaining access to established infrastructure for any reason, and must notify the CSO Administration Agency as soon as it is known if those difficulties are likely to impact on the CSO wholesaler's ability to carry out any of their obligations under the Deed. Distributors must also inform the Administration Agency of any significant planned changes to its infrastructure and systems. For example, the closure/opening/upgrade of a warehouse. These requirements are important in ensuring any potential disruptions that may impact on the safety of medicines can be accounted for and managed. Reliability of access to PBS medicines is likely under threat under option 1.	Option 2 will extend the CSO obligations, particularly in relation to requirements to maintain established infrastructure and sufficient financial capacity. Extending these provisions to section 100 medicines may also result in some additional improvement in reliability. But this is not clear, as many CSO wholesalers already maintain infrastructure and financial capacity to service their existing section 85 CSO and non-CSO section 100 distribution activities.	As in option 2, the existing provisions set out in the CSO Compliance Requirements will apply in option 3A and 3B under the CSO.
Individual & Community Affordability	Existing wholesaler remuneration mechanisms, of which there are two, subsidise the cost of distributing medicines across Australia. Importantly, the government subsidy means wholesaler costs are not borne by community pharmacies and later passed on to consumers through increased prices for medicines.	Unlike option 1, the series of reduction in wholesale mark-up will result in an overall saving to patients of approximately $46.3 million over five years. Overall reductions in wholesale mark-up will further reduce the cost of medicines for patients, by reducing the price to pharmacist.	Option 3A represents a significant risk to achieving community affordability. While government maintains assumptions and estimates for PBS volumes each year, an un-capped funding arrangement leaves open the possibility of significant cost blow-outs due to unexpected demand for particular PBS medicines. Compared with current settings (or option 1), options 3B

	This is particularly the case for medicines that are below the co-payment amount (the maximum amount a patient will pay for a PBS medicine). This is because it is these medicines that have the potential to rise in cost up to the co-payment amount due to increased costs to pharmacies, such as distribution, storage and handling that is currently borne by government through these wholesaler remuneration arrangements. From 1 January 2024, patients may pay up to $31.60 for most PBS medicines, or $7.70 for concession card holders. The Australian Government pays the remaining cost (with the exception of brand premiums and certain other allowable charges). This option will see the cost of medicines for consumers remain at their current level. On the other hand, government has a responsibility to ensure value for money and that the quantum of funding for wholesale delivery of medicines reflects an efficient price. The department's modelling indicates that if these arrangements were to be extended for a further five years from FY2024-25 to FY2029-30, the total cost to government would be $3.57bn (including both CSO and wholesaler mark-up). See Table U in Appendix B. Table U in Appendix B provides a detailed breakdown of the cost impacts of option 1 for patients and the community (through government). Under the status quo, there is a significant risk wholesalers may withdraw from the CSO and operate in the private market without government subsidy for distribution. This would likely result in distribution costs being passed on to pharmacies and then on to patients, particularly impacting rural	Pharmacies will be no worse off under option 2 due to the provisions in the 8CPA which ensure any decrease in remuneration due to PWA is compensated in-full. Option 2 will result in a significant increase in government investment in wholesaler remuneration. Table U in Appendix B provides a detailed breakdown of the cost impacts of option 2 for patients and the community (through government).	represents a modest increase in the current budget envelope through indexation of the CSO, with risk mitigation through a fixed funding pool that is divided as a share of the total volume of PBS medicines dispensed in each financial year. A large proportion of this increase is also offset by reductions in the WMU. Patients will benefit from a reduction in the cost of medicines of approximately $28 million over five years. Pharmacies will be no worse off under options 3A and 3B due to the provisions in the 8CPA which ensure any decrease in remuneration due to PWA is compensated in-full. Table U in Appendix B provides a detailed breakdown of the cost impacts of option 3 for patients and the community (through government).

	and regional Australians where distribution is more expensive. This is already occurring in the case of section 100 medicines which are not currently covered by the CSO. Patients accessing these medicines are often subject to additional fees and charges to support distribution costs as government does not currently fund distribution of these medicines.		

NMP Pillar 4: *Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.*

	Policy Options		
NMP Sub-Category	**Option 1:** No PWA. Maintain existing wholesaler arrangements (status quo)	**Option 2:** Establish PWA and accept NPSA proposal in-full	**Options 3A/ 3B:** Establish PWA, implement structural policy reforms (including/ not including CSO demand-driven reforms) and align remuneration with wholesaler costs
Collaboration with Industry	Wholesalers will continue to collaborate with pharmaceutical manufacturers and function as the connecting link between pharmaceutical industry and community pharmacy in their role as on-shore distributors of medicines. Wholesalers are likely to cease engagement with the CSO Administration Agency on the Australian Government's behalf through regular compliance reporting activities. Additionally, wholesalers also likely to cease collaboration with the Therapeutic Goods Administration through a range of data sharing activities that currently help to manage on-shore medicine shortages.	Similar to option 2 continues the collaboration between the Commonwealth and the wholesaler sector. This collaboration is further strengthened through a direct agreement between the peak body of pharmaceutical wholesalers, NPSA, and the Australian Government. An agreement supports improved stakeholder engagement outcomes in line with the aspirations of the NMP and provides the opportunity for more direct collaboration with pharmaceutical wholesalers and other stakeholder groups that may be impacted by the policies in question. The NPSA is the peak body for CSO wholesalers and is therefore the most appropriate stakeholder with which to engage directly. The department has appointed six CSO wholesalers. Four national, namely Sigma, Symbion, Australian Pharmaceutical Industries (API) and Clifford Hallam Healthcare (CH2) and two state based CSO wholesalers. **[REDACTED]**. The NMP commits all partners to coordinating and aligning service delivery and health, research and education and industry policy and would be further strengthened by a direct wholesaler agreement.	As in option 2, a dedicated agreement can support improved collaboration between industry and government through active participation in a genuine negotiation process. If new CSO wholesalers were to be identified following a tender process, government's collaboration with a growing number of industry stakeholders will also increase. This collaboration also extends to work in relation to medicines shortages.
Encouraging Innovation	Wholesalers have demonstrated that within the existing funding envelope, they have been able to make strategic investments in their supply chains to reduce the per unit real operational cost of	A dedicated agreement with wholesalers provides the opportunity for government to encourage and negotiate additional initiatives and measures from wholesalers which could further improve medicine access, supply and	Similar to option 2, options 3A and 3B continue to encourage innovation from wholesalers by supporting a proportion of their investment costs. Beyond productivity enhancements outlined in option 1, wholesalers have also invested in and deployed

	operations. The source of these investments have included the following:[27] 1. Investments in right-sizing the capacity and geographic placement of facilities and distribution centres. 2. Optimisation of existing distribution capacity. 3. Technological improvements to support operations, including: o New warehouse management systems to continue driving efficiencies in operations (e.g. order and inventory management, optimising picking routes). o Ongoing distribution centre flow operation investments ensure CSO wholesalers can respond to change in demand for different brands. o Investments in head office technology and enterprise systems, such as ERPs (Enterprise Resource Planning) and CRM (Customer Relationship Management). **[REDACTED]** o Investments in cyber security as a growing focus to ensure integrity of patient data. 4. Enhancements in warehousing facilities and equipment, including specialised storage capabilities. o Since 2016, Sigma has invested over $400m into its distribution centre (DC) network, including its new Kemps Creek DC which has absorbed an 80% spike in volumes. o API built a new highly automated Sydney DC (opened early 2023)	further support policy outcomes. Within the current funding envelope, wholesalers have initiated many technological innovations to improve their performance and efficiency. Medicines shortages management is a particular area of reform that has been identified in consultation with the TGA where the role of wholesalers could be expanded or amended to support improved medicines shortages management. Medicines shortages are a significant, but complex challenge. A shortage occurs when there is unlikely to be enough of a medicine in Australia for the people who need to take it. According to the TGA, a shortage is officially declared when the supply of a medicine is not likely to meet the normal or projected consumer demand within Australia at any point during the next six months. As of 5 August 2024, there are 414[28] current medicine shortages in Australia of which 44 have a Critical shortage impact rating[29]. Managing medicines shortages requires cooperation and collaboration from many diverse stakeholders along the medicines supply chain as it managed by the TGA. Although many improvements have been made, medicines shortages continue to impact on the health and wellbeing of Australians. While option 1 does not preclude the Australian Government from seeking additional measures from wholesalers, option 2 provides an improved platform and mechanism by which these measures can be directly negotiated on with the NPSA and other non-NPSA CSO	Environmental, Social and Governance (ESG)[30] initiatives throughout their distribution centre networks to increase efficiency and reduce their impact on the environment. These initiatives include: • Installation of solar panels to provide up to 50% of the site's daily electricity needs. • Onsite recycling programs to manage up to 80% of site waste. • On-site rainwater capture. Introduction of recyclable battery-operated eskies to transport cold chain product. Options 3A and 3B also provide a sufficient time period ahead of a further negotiation process for future wholesaler arrangements to evaluate the effectiveness of the policy changes introduced in this agreement. This evaluation phase will provide government with reliable and robust information and evidence to support future evidence-based policy development that encourages industry innovation.

[27] NPSA Member Data and Company Reports

[28] Medicine Shortages Information Initiative | Therapeutic Goods Administration (TGA)

[29] Included on the Medicines Watch List, or if the shortage has the potential to have a life threatening or serious impact on patients and there is not likely to be sufficient supply of potential substitutes.

[30] A movement for businesses to operate in a transparent, environmentally and socially responsible way and to practice good governance.

	○ Symbion invested over $100m into its DC network to extend capability and maintain technology. This followed a period which saw over $200m invested in new facilities in Brisbane, Melbourne, and Sydney. However, ongoing investments in innovation are unlikely under the current level of funding under the status quo.	wholesalers.	
Supporting Sustainability	Continuation of existing arrangements is not likely to support a sustainable and predictable policy environment. This likely would not provide businesses and government the certainty to invest and make decisions within a stable policy environment, while ensuring a predictable revenue stream for wholesalers.	Wholesalers have reported that the scale of distribution activity undertaken by CSO wholesalers has grown between FY2016 to FY2023 in terms of absolute volumes (13%) and the number of item codes (27%). The growing scale of the PBS is driving increasing distribution costs. Total section 85 PBS prescription volumes increased by approximately 13% between FY2016-23 from 291m units in 2016 to 330m units in 2023. During this period, wholesalers have continued to invest in expanding and optimising their supply chain and network to continue supporting greater volumes of medicines distributed. Adopting the structural changes proposed offers greater alignment with the operating and maintenance costs of the wholesalers, albeit at a significantly higher budget envelope. The NPSA have told government that alignment of wholesaler remuneration, critically the move to a per-unit-based CSO payment, rather than a capped funding pool, is an important adjustment that will support a more sustainable sector.	As in option 2, a restructuring of wholesaler remuneration to more closely align with the cost base of pharmaceutical wholesalers will support a policy environment that is better calibrated to the stakeholders that operate within it.

4. What is the likely net benefit of each option?

The following scoring system has been used across each objective to support a clearer comparison of the net benefit calculation of each of the options explored in this IA.

1. Not at all
2. Somewhat
3. Mostly
4. Fully

This IA has utilised a multi-criteria analysis (MCA) to conduct its net benefit analysis. This approach has been chosen as it provides an analytical framework for considering options against the broad policy document that is the NMP. A MCA allows the IA to consider impacts against a range of policy parameters as outlined in the NMP.

Objectives of the NMP identified as relevant to pharmaceutical wholesalers have been further broken down (see figure I) with relative weightings assigned to each for the purposes of a quantitative net benefit analysis (see figure J). While the NMP does not assign weightings or a scale against each of these objectives or sub-objectives, this IA has sought to ensure each sub-objective is proportionate to the overall net benefit evaluation of each option.

Figure I – National Medicines Policy Breakdown (wholesaler relevant only)

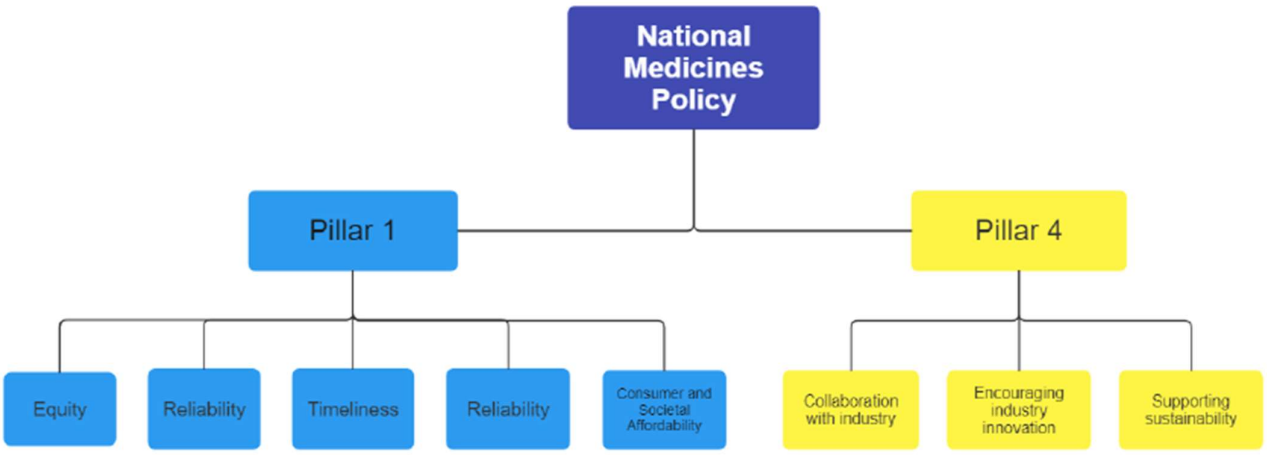
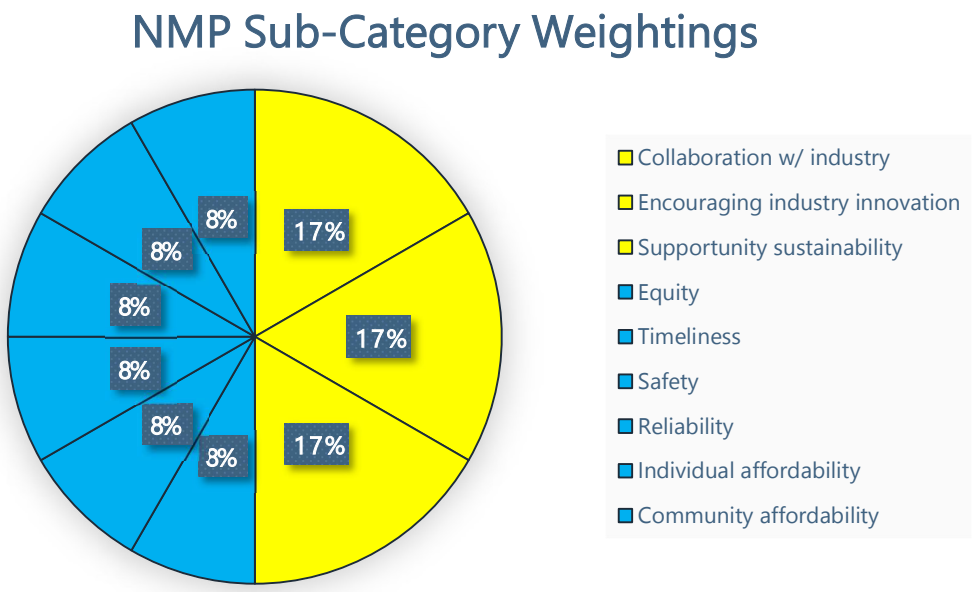


Figure J – NMP Sub-Category Weightings



**Blue, NMP pillar 1. Yellow, NMP pillar 4.*

The sub-category weightings above have been allocated on the basis that the NMP does not have predetermined rankings or importance weightings. Therefore, to prevent unintended interpretation and to provide a sufficient basis to support a MCA, the IA has assumed each NMP pillar is of equal weighting. The sub-category weightings outlined in Figure J above provide for this, noting there are a different number of sub-categories within each pillar.

Equity of access

The CSO in its current form is largely consistent with the intended NMP objective of equity of access. All patients that hold a Medicare card are able to access PBS medicines through any community pharmacy in Australia. This policy outcome is guaranteed through the CSO service standards that require CSO wholesalers to supply to any distribution point, including any rural and remote pharmacy. In addition, CSO wholesalers must ensure that its PBS medicine sales volumes to rural and remote pharmacies within its CSO jurisdiction are not more than 10% below the industry average (the threshold) for each year and each month within each year within the term.

The industry average is calculated by determining the average sales volume of PBS medicines to community pharmacies per CSO wholesaler under the CSO arrangements.[31] The amount derived following the application of the 10% tolerance level to the industry average becomes the applicable threshold. For example, if the current industry average for sales to rural and remote community pharmacies is 31.3 for every PBS medicines supplied, then no less than 28.2 PBS medicines or 28.2% of all sales must be supplied to rural and remote pharmacies.

The CSO also requires that CSO wholesalers supply any brand of CSO product. This is a particularly critical requirement to ensure equity of access for patients. The aim of this service standard is to ensure that all Australians have access to their preferred brand of CSO product. This is an important factor for many consumers that are comfortable using one particular brand over another over an extended period of time and want to avoid any particular differences between brands.

Distributors are not required to supply CSO products under the following conditions:

1. Not available because of an exclusive supply arrangement.
2. Out-of-stock with the manufacturer.
3. Cannot be supplied by the manufacturer.
4. To the extent and for the timeframe specified in a written direction issued by the Department.

Options 2, 3A and 3B would all result in at least this same level of equity in access for consumers and for the businesses that are stocking and dispensing these products to consumers. Option 1 would likely result in significant impacts on equitable access for consumers if wholesalers withdraw from the CSO.

The inclusion of section 100 medicines under the CSO arrangements in option 2, 3A and 3B would ensure these medicines are available within any community pharmacy that chooses to stock and dispense the medicine (which would likely increase as a result of government intervention through either of these three options). This could lead to an increase in the net equity benefit for patients

[31] Community Service Obligation Operational Guidelines

reliant on these medicines.

Timeliness of access

On-time access to medicines is a critical component of a well-functioning and efficient health system. For patients that rely on regular medicines for their health and wellbeing, the ability to access them when they need them is key to good public health outcomes. This is also an important factor that assists pharmacies in supplying stock that meets demand at the point of sale and no later.

The CSO requires that CSO wholesalers supply any brand of CSO product within the guaranteed supply period of 24 hours (or 72 hours for products listed on the high-volume list) of the regular order cut off period (the specific time agreed between the CSO wholesaler and a distribution point by which orders must be lodged with the CSO wholesaler).

One exception to this requirement is the occurrence of a force majeure event. In those circumstances, the distributor must promptly give the CSO Administration Agency written notice of the fact, including:

1. Full particulars of the force majeure event
2. An estimate of its likely duration
3. The obligations affected by the force majeure event and the extent of its effect on those obligations
4. The steps taken to rectify it.

If, in the CSO Administration Agency's reasonable opinion, the written explanation and reasons are sufficient, a non-performance will not be recorded against the distributor.

All options support the continuation of this existing requirement, except for option 1 as wholesalers are expected to withdraw from the CSO. Consumers will continue to access PBS medicines within the same supply period requirements that have previously underpinned access. Similarly, pharmacies will continue to benefit from these requirements, supporting their ability to meet consumer demand, without having to hold significant stock on premises with added cost associated with doing so. Wholesalers have largely optimised their operations to meet these requirements and will not be required to alter their investments or supply chains to meet different requirements.

Inclusion of section 100 medicines under the CSO arrangements would require wholesalers to distribute these medicines to a community pharmacy within 24 hours of the order (or 72 hours in some cases). This would lead to an increased net benefit for patients reliant on these medicines.

Safety of access

One of the core CSO compliance requirements is for wholesalers to maintain the quality of all CSO products supplied. This includes meeting all applicable storage condition requirements. Wholesalers must also hold all necessary state and territory licences and/or certificates for their warehouses and distribution centres. Compliance with the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4, and 8* is also mandatory. Published by the Therapeutic Goods Administration, the code is concerned with ensuring quality is maintained during wholesaling and sets out appropriate standards to be applied. In short, medicines in these schedules must be stored and distributed in accordance with the label requirements of the sponsor, State and Territory legislation and the code.

All options considered in this IA support the continuation of these existing safety and handling requirements, although there may be some implications if wholesalers were to withdraw from the CSO under option 1.

Reliability of Access

All options will continue the existing requirements on CSO wholesalers in relation to maintaining access to established infrastructure and sufficient financial capacity to meet the CSO service standards, except for option 1.

Individual Affordability

The Australian Government's investments in eligible pharmaceutical wholesalers through the CSO and WMU ensures, among other things, that the cost of storing, handling and transportation of PBS products from manufacturers to community pharmacies is not borne by patients, nor the pharmacy sector

This funding is critical in ensuring consumers only pay the co-payment amount for their PBS medicines and that any distribution costs are carried by the Commonwealth. This is equally the case for pharmacies that receive subsidised delivery costs for their stock. The frequency of stock deliveries to pharmacies, often 2-3 times per week depending on the type and location of a pharmacy, means pharmacies are not required to hold significant stock levels, keeping their working capital lean.

Option 2, 3A and 3B would see benefits for individual affordability as a result of the changes and net overall reductions to the wholesale mark-up. Option 1 would likely see consumer affordability

worsen as distribution costs are passed on to consumers in the absence of government subsidy.

Community Affordability

The affordability and continued viability of government investment in the pharmaceutical wholesaling sector is an important consideration and is consistent with the aims of the NMP. In the absence of an increased overall budget, increased investment in one area of the medicines supply chain often results in an opportunity cost of investment in a separate area.

Option 1 represents the most socially affordable alternative of the four considered in this IA.

The continuation of existing arrangements is expected to result in a total cost to government of $3.56 billion over five years, with $1.068 billion towards the CSO funding pool and $2.49 billion towards wholesale mark-up. Option 2 has been costed at over $5 billion over five years, representing an additional estimated cost to government of $1.44 billion over five years. Options 3A and 3B has been costed at $4.20 billion over five years, noting option 3A represents significant risk of overspends as a result of an un-capped CSO arrangement. This represents an additional government investment of $632 million over the course of the agreement (including implementation costs).

Collaboration with industry

Collaboration between government and industry is critical to maintaining an efficient and well-functioning medicines supply chain. Collaboration helps to promote shared interests and goals, including equitable, timely, affordable and safe access to medicines-related services throughout Australia.

Options 2, 3A, and 3B represent a new model of collaboration through the execution of a direct agreement with the NPSA. Signing of this agreement follows many weeks of negotiation meetings between the department and the NPSA in relation to the potential make-up of a PWA.

The negotiation and determination of these arrangements with the NPSA ensures that the department is working with the right stakeholders in relation to these matters.

Encouraging industry innovation

Fostering industry innovation is an important part of the NMP. A supportive and responsive policy environment is critical to achieving the intended outcomes of industry innovation, which include more productive and cost-effective wholesalers. Wholesalers have invested over $750m since 2020 in their operations.[32]

All options provide the opportunity for new market entrants to contest to become an eligible CSO wholesaler through an approach to market. This increase in competition in the marketplace supports innovative proposals from existing distributors and potential new entrants.

Supporting sustainability

Sustainability is a multi-faceted outcome, with sustainability for one party not always equating to sustainability for another. Sustainable access to medicines requires all components of the medicines supply chain to remain viable and competitive. Government has an important role to play in supporting industry to remain financially viable but within a budget that taxpayers can sustain.

Consumers

Sustainable patient access to medicines relies on collaboration and viability of all parties in the supply chain. Option 1 would likely see the sustainability of consumer access to PBS medicines reduced if wholesalers were to withdraw from the CSO. Options 2, 3A and 3B would see the continued success and sustainability of current CSO service standards ensuring patients can continue to access medicines.

Industry

The NPSA have put to government that due to a series of factors, the cost and complexity of doing business in Australia has increased. These include, but are not limited to:

1. Growing scale of the PBS, including distribution volumes to handle/ manage (+13% increase in number of section 85 prescriptions between FY2016 – 23).
2. Growing operational complexity with new item codes added to the PBS (+27% increase in PBS item codes between FY2016 – 23).
3. Exposure to a high inflation and cost-volatile environment, especially in recent years [REDACTED].
4. Growing proportion of high care medicines to be distributed, requiring specialised infrastructure across the country, which is costlier [REDACTED].

[32] NPSA Member Data, Company Annual Reports

5. Higher rate of intensity of national emergencies and disasters, which adds to overall operational complexity (since 2020, there have been almost 200 natural disasters in Australia).
6. Increasing distribution to rural & remote areas, where some of the critical medicines are needed (slightly faster population growth in recent years in rural and remote areas **[REDACTED].**

To compensate industry for these factors, the NPSA have sought **[REDACTED]** in additional remuneration (over a five-year agreement) (option 2).

Options 2, 3A and 3B provide industry with an improved platform to collaborate with government through a direct agreement and the establishment of ongoing working groups, but without the total increase in investment requested.

Government

It is incumbent on policymakers to ensure taxpayer funds are allocated efficiently, particularly given the current pressures on the health budget. Options 2, 3A and 3B provide government with an improved platform to engage the stakeholders most impacted by the proposed changes (pharmaceutical wholesalers).

The inclusion of section 100 medicines in the CSO in options 2, 3A and 3B also provide for a greater level of accountability and consistency for compliance activities across medicines distributed via community pharmacy. This would provide for a higher level of assurance in wholesaler service deliver to community pharmacy for all patients.

Table M: Net benefit analysis of each option

Policy Objective	**Option 1:** No PWA. Maintain existing wholesaler arrangements (status quo)	**Option 2:** Establish PWA and accept NPSA proposal in-full	**Option 3A:** Establish PWA, implement structural policy reforms (including demand-driven CSO reforms), and align remuneration with wholesaler costs	**Option 3B:** Establish PWA, implement structural policy reforms (not including demand-driven CSO reforms), and align remuneration with wholesaler costs
Equity of access (8.33%)	Not at all (1) Consumers are highly likely to not continue to benefit from existing CSO service standards that support equitable access to PBS medicines through community pharmacies across Australia.	Fully (4) Consumers continue to benefit from existing CSO service standards that support equitable access to PBS medicines through community pharmacies across Australia. Net equity benefits are improved due to expansion of CSO to section 100 medicines.	Fully (4) Consumers continue to benefit from existing CSO service standards that support equitable access to PBS medicines through community pharmacies across Australia. Net equity benefits are improved due to expansion of CSO to section 100 medicines.	Fully (4) Consumers continue to benefit from existing CSO service standards that support equitable access to PBS medicines through community pharmacies across Australia. Net equity benefits are improved due to expansion of CSO to section 100 medicines.
Timeliness of access (8.33%)	Not at all (1) Consumers are highly likely to not continue to benefit from existing CSO service standards that support timely access to PBS medicines through community pharmacies across Australia.	Fully (4) Consumers will continue to benefit from existing CSO service standards that support timely access to PBS medicines through community pharmacies across Australia. Net timeliness benefits are improved due to expansion of CSO to section 100 medicines	Fully (4) Consumers will continue to benefit from existing CSO service standards that support timely access to PBS medicines through community pharmacies across Australia. Net timeliness benefits are improved due to expansion of CSO to section 100 medicines.	Fully (4) Consumers will continue to benefit from existing CSO service standards that support timely access to PBS medicines through community pharmacies across Australia. Net timeliness benefits are improved due to expansion of CSO to section 100 medicines.
Safety of access (8.33%)	Somewhat (2) Consumers are highly likely to not continue to benefit from existing CSO service standards that	Fully (4) Consumers will continue to benefit from existing CSO service standards that support safety of	Fully (4) Consumers will continue to benefit from existing CSO service standards that support safety of	Fully (4) Consumers will continue to benefit from existing CSO service standards that support timely

	support safety of access to PBS medicines through community pharmacies across Australia. However, other legislative requirements will continue to support safety of PBS medicines through distribution.	access to PBS medicines through community pharmacies across Australia.	access to PBS medicines through community pharmacies across Australia.	access to PBS medicines through community pharmacies across Australia. Net timeliness benefits are improved due to expansion of CSO to section 100 medicines.
Reliability of Access (8.33%)	Not at all (1) Consumers are highly likely to not continue to benefit from existing CSO service standards that support reliability of access to PBS medicines through community pharmacies across Australia.	Mostly (3) Consumers will continue to benefit from existing CSO service standards that support reliability of access to PBS medicines through community pharmacies across Australia. A full score is not awarded as reliability of medicines supply is subject to non-wholesaler factors (i.e. manufacturer availability).	Mostly (3) Consumers will continue to benefit from existing CSO service standards that support reliability of access to PBS medicines through community pharmacies across Australia. A full score is not awarded as reliability of medicines supply is subject to non-wholesaler factors (i.e. manufacturer availability).	Mostly (3) Consumers will continue to benefit from existing CSO service standards that support reliability of access to PBS medicines through community pharmacies across Australia. A full score is not awarded as reliability of medicines supply is subject to non-wholesaler factors (i.e. manufacturer availability).
Individual Affordability (8.33%)	Not at all (1) Consumers are highly likely to not continue to benefit from existing investments that subsidise the cost of medicines distribution, ensuring pharmacies do not pass these costs on to patients.	Mostly (3) Consumers will continue to benefit from existing investments that subsidise the cost of medicines distribution, ensuring pharmacies do not pass these costs on to patients.	Mostly (3) Consumers will continue to benefit from existing investments that subsidise the cost of medicines distribution, ensuring pharmacies do not pass these costs on to patients.	Mostly (3) Consumers will continue to benefit from existing investments that subsidise the cost of medicines distribution, ensuring pharmacies do not pass these costs on to patients.
Community Affordability (8.33%)	Fully (4) The cost of option 1 is equivalent to the anticipated cost of extending existing arrangements. No new spending is sought.	Not at all (1) The cost of option 2 is represents a significant increase in investment of approximately $1.4bn over 5 years. This is not	Not at all (1) There are significant budgetary risks associated with option 3A. A demand-driven CSO may lead to uncontrolled and unpredictable increases in government expenditure beyond budget	Mostly (3) The cost of option 3 is represents a modest increase to the anticipated cost of extending existing arrangements. Some investment is sought for annual indexation of the CSO. There will

		feasible.	forecasts. The growing and unpredictable nature of new and amended PBS listings increases the likelihood of further unplanned cost increases. The agreed parameters of a risk-share mechanism to cap expenditure or volume growth is not clear and would be subject to negotiation. It would, nonetheless, create additional uncertainty for overall government expenditure on the CSO.	be some implementation costs that government will bear.
Collaboration with industry (16.7%)	Not at all (1) NPSA will not be signatory on an official agreement with the Australian Government and will likely cease all collaborations with the Therapeutic Goods Administration in relation to medicine shortages.	Fully (4) NPSA will be signatory on an official agreement with the Australian Government. This will follow from a formal negotiation process where NPSA will be directly consulted on all aspects of wholesaler remuneration and CSO arrangements.	Fully (4) NPSA will be signatory on an official agreement with the Australian Government. This will follow from a formal negotiation process where NPSA will be directly consulted on all aspects of wholesaler remuneration and CSO arrangements.	Fully (4) NPSA will be signatory on an official agreement with the Australian Government. This will follow from a formal negotiation process where NPSA will be directly consulted on all aspects of wholesaler remuneration and CSO arrangements.
Encourage industry innovation (16.7%)	Somewhat (2) Existing public investment in the industry will continue to support industry investment and innovation in the supply chain to a small extent. A formal tender process will encourage innovative approaches and ideas from existing and prospective CSO wholesalers.	Somewhat (2) Existing public investment in the industry will continue to support industry investment and innovation in the supply chain. A formal tender process will encourage innovative approaches and ideas from existing and prospective CSO wholesalers.	Fully (4) In addition to existing investments in the industry and the tender process, option 3A allows time for proper implementation and then data collection and further evaluation of the reforms introduced in year three of the agreement. This data will support future negotiation processes by building an	Fully (4) In addition to existing investments in the industry and the tender process, option 3B allows time for proper implementation and then data collection and further evaluation of the reforms introduced in year three of the agreement. This data will support future negotiation processes by building an

			evidence-base for government that can be used to encourage industry innovation in future CSO tender processes.	evidence-base for government that can be used to encourage industry innovation in future CSO tender processes.
Supporting sustainability (16.7%)	Not at all (1) Option 1 does not support the ongoing viability of the medicines supply chain.	Not at all (1) Option 2 represents a significant increase in government cost that is not sustainable, without a commensurate improvement in patient/ social benefit.	Not at all (1) Option 2 represents a significant increase in government cost that is not sustainable, without a commensurate improvement in patient/ social benefit.	Fully (4) Option 3B supports the ongoing viability of the medicines supply chain at a cost that society can afford, with benefits for consumers, industry, and government. The introduction of reforms to WMU and CSO mid-way through the agreement will further support a more sustainable wholesaler sector.
Weighted Average (%)	38.9%	72.2%	77.8%	91.7%
Regulatory Burden Estimate (discussion in next section)	$0	$19,088,568.70	$17,640,677.70	$17,040,677.70

Regulatory Burden Estimates

The impact of regulatory burden changes with the three proposed policy options on key stakeholders is examined below.

Option 1- No PWA. Maintain existing wholesaler arrangements (status quo)

Option one would see no additional regulatory burden on stakeholders relative to the extension of current policy settings.

There will be no additional burden on the NPSA and its members (business) to compile a proposal and participate in the negotiation process. Well-developed systems are already in place through the existing CSO Administration Agency to ensure eligible CSO wholesalers continue to receive the existing payments in accordance with agreed levels in 7CPA. Services Australia's systems and process are also already calibrated to the existing policy settings, particularly in relation to WMU payments.

CSO reporting requirements would remain the same as those prior to the PWA establishment.

The increasing size and complexity of the PBS due to new PBS listings could be seen to potentially increase the burden for wholesalers. However, this is to be expected with increasing growth of this program and is not an additional regulatory burden per unit of PBS medicine distributed.

An approach to market for a new CSO Administration Agency operator will also be conducted under option 1, although this represents no additional regulatory burden on pharmaceutical wholesalers.

Table N below has been compiled across a five year horizon.

Table N: Regulatory burden estimate (RBE) table – Option 1

Average annual regulatory costs				
Change in costs	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$0	$0	$0	$0

Options 2 – Establish PWA and accept NPSA proposal in-full

In addition to the regulatory burden from negotiations discussed in option 1, the majority of the regulatory burden from option 2 relates to start-up costs. This is largely due to the initial system changes that businesses (CSO wholesalers) will be required to adopt in the implementation phase of the PWA.

The first would be the change in CSO payment structure from a fixed-pool to a per-unit model. CSO wholesalers' systems are currently calibrated to receive payments from the fixed pool. This change will require some technical adjustments to alter systems for the CSO per-unit payment structure.

Other IT payment changes required of wholesalers are the result of changes to: WMU tiers, WMU quantity definitions, and administrative costs on pharmacies as a result of changes to remuneration structures for section 100 medicines, such as re-negotiation of commercial arrangements with their wholesalers. While an exact cost estimate for these changes is not known, it is estimated that all CSO wholesalers would be required to introduce the changes.

There are also additional ongoing administrative regulatory burdens on businesses (wholesalers) due to the inclusion of section 100 medicines under the CSO. This includes completion of relevant compliance activities, including monthly reporting, ad hoc reporting, and ongoing communication with the CSO Administration Agency. Appendix C.2 provides a further outline of these costs and impacted stakeholders.

Table O below has been compiled across a five year horizon.

Table O: Regulatory burden estimate (RBE) table

Average annual regulatory costs				
Change in costs	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$0	$19,088,568.70	$0	$19,088,568.70

Option 3A – Establish PWA, implement structural policy reforms (including CSO demand-driven reforms) and align remuneration with wholesaler costs.

The regulatory burden costs in option 3A are identical to option 2.

Table P below has been compiled across a five year horizon.

Table P: Regulatory burden estimate (RBE) table – Option 3A

Average annual regulatory costs				
Change in costs	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$0	$17,640,677.70	$0	$17,640,677.70

Option 3B – Establish PWA, implement structural policy reforms (not including CSO demand-driven reforms) and align remuneration with wholesaler costs.

The regulatory burden costs in option 3B are identical to option 3A, with the exception of those burdens created by the CSO demand-driven reforms. This is primarily the start-up cost of upgrading CSO systems to integrate with a demand-driven CSO model (total impact of $600,000).

Table Q below has been compiled across a five year horizon.

Table Q: Regulatory burden estimate (RBE) table – Option 3B

Average annual regulatory costs				
Change in costs	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$0	$17,040,677.70	$0	$17,040,677.70

5. Who did you consult and how did you incorporate their feedback?

Background

On 7 August 2023[33] the Minister for Health and Aged Care, the Hon Mark Butler MP announced early negotiations for an 8CPA would commence (prior to an announcement regarding a dedicated wholesaler agreement). The Minister noted the department would consult with a broad range of stakeholders including patient/consumer groups and pharmaceutical wholesalers with a stake in the growth and development of pharmacy services that benefit all Australians, in addition to the Guild and PSA, who were the signatories of the 7CPA.

The consultation process that informed the options and considerations for the development of this IA were conducted at this time (i.e. alongside consultation for the 8CPA). The purpose of this consultation was to gather the range of views across the sector in relation to the structure, scope and purpose of the CPA. These views would help to inform government's approach to the negotiations.

In each of the initial bilateral discussions, participants were asked to provide input on what they would like to see included in (or excluded from) an 8CPA, as well as any other general input regarding the scope and structure of the agreement. Key questions included:

1. How could an 8CPA be patient centric/ focused? What needs to change from current arrangements?
2. Are there any changes you wish to see to the structure of the CPA and if so, why?
3. Are there any changes you would like to see to the content of the CPA and if so, why?
4. Are there reforms you wish to see within the existing pool of funding for remuneration and/or programs?
5. What should government stop paying for? Why?
6. What, for your organisation, should be the key focus of a new Agreement? Why?

[33] Negotiations for an eighth Community Pharmacy Agreement | Health Portfolio Ministers | Australian Government Department of Health and Aged Care

The department met with the following organisations for without prejudice, bilateral consultations:

Aged & Community Care Providers Association (ACCPA)
Australian Council of Social Service
Australian Friendly Societies Pharmacies
Australian Medical Association (AMA)
Australian Patients Association
Australian Rural Health Education Network
Chemist Warehouse Group (CWH)
Consumers Health Forum of Australian (CHF)
Credentialed Pharmacist Association of Australia
DHL Supply Chain
Embedded Health Solutions
Generic and Biosimilar Medicines Association
National Aboriginal Community Controlled Health Organisation (NACCHO)
National Pharmaceutical Services Association (NPSA)
National Rural Health Alliance
Painaustralia
Pharmaceutical Society of Australia (PSA)
The Pharmacy Guild of Australia
Professional Pharmacists Australia (PPA) (known as Professional Australia)
Royal Australian College of General Practitioners (RACGP)
Rural Pharmacy Network Australia (RPNA)
Rural and Remote Pharmacist Association of Australia (RIPAA)
Society of Hospital Pharmacists of Australia (now Advanced Pharmacy)

Evaluation of consultation process

Critical evaluation of the consultation process has been conducted based on the OIA's Best Practice Guidance Note. OIA identifies four consultation options: full public, targeted, confidential and post-decision, with full-public consultation being the appropriate level for all proposals unless there are compelling reasons for limiting consultation.

In this case, a combination of confidential and post-decision consultation is most appropriate due to the significant level of commercial confidentiality and market sensitive information involved.

Confidential consultation for a dedicated wholesaler agreement was conducted as part of the pre-8CPA consultations which took place in the fourth quarter of 2023. All affected parties were consulted with (insofar as the confidentiality limits would allow) in individual meetings with the department.

While in some ways, the confidentiality requirements limited public transparency of these discussions, in other ways, it improved the quality of the consultation by allowing stakeholders to speak openly and freely with the certainty of non-disclosure obligations. Through bilateral discussions, individual stakeholders were able to present their specific views and the confidential nature of these discussions may in many respects have encouraged greater input than what group consultations or publicly published consultation results would allow. An exception to this may be the consumer focussed stakeholder groups as in multiple instances these groups noted to the

department that their preference would be to run consumer surveys prior to providing input. The government-commissioned *Review of Pharmacy Remuneration and Regulation*, released in 2018, recommended future community pharmacy agreement processes consult the range of stakeholders that deliver on the agreed services. The Review noted increasing the breadth of consultation would improve the overall transparency and sustainability of the sector. Additionally, the 7CPA Post-Implementation Review[34] noted "Stakeholders considered 7CPA implementation activities were hampered by a lack of adequate stakeholder engagement and lack of communication on progress".

The confidential and commercially sensitive nature of negotiations limits the approach to stakeholder consultations with non-disclosure agreements in place for all parties involved in relevant discussions. The department also faced time limitations with which to conduct consultation, which meant some stakeholders could only be consulted on one occasion. This limitation could potentially be overcome in future negotiations by allowing more time for negotiations. Negotiations would typically commence at least 12 months ahead of the expiry of a CPA.

A post-decision consultation process is also proposed to commence once the initial policy decision is made and announced publicly, but before it is implemented. This consultation would focus on implementation of the policy, including timeframes and planned reviews.

Key metrics for effective consultation

OIA's *Best Practice Consultation* Guidance Note identifies nine key elements for effective consultation. Below is a reflection against these metrics of the consultation that has occurred (or will occur) as part of this IA.

1. **Continuous**

Consultation with key stakeholders will be continuous as the department continues to consult with affected stakeholders through a post-decision consultation process. The consultation process began as early as possible, noting negotiations for an 8CPA were brought forward.

Having completed initial consultation prior to the submission of the Impact Analysis for Early Assessment enabled the IA to better define the problem and objectives, options and identify the potential impacts of the options on stakeholders.

Once a decision was made and publicly announced regarding the government's plans to negotiate a dedicated wholesaler agreement, further consultation was conducted with stakeholders in a

[34] Post-Implementation Review of the Seventh Community Pharmacy Agreement (pmc.gov.au)

confidential manner to inform policy considerations.

Post-decision consultation will continue to work with stakeholders to outline key timeframes, deadlines and any implementation challenges.

2. **Broad-based**

Because the scope of the proposed policy changes were large, the scope of consultation was wide. This is reflected in the large and diverse range of stakeholders that contributed to the initial consultation phase (over 20 different groups and organisations). A similarly large and diverse range of stakeholders will be consulted with in the continuous post-decision consultation processes.

3. **Accessible**

Stakeholders were informed of proposed consultations by the appropriate means and communications were accessible and effective. For example, a centralised inbox was used to streamline communications between the department and stakeholders and improve accessibility.

4. **Not burdensome**

Consultation was conducted as early as possible and while the policy objectives and different policy approaches were still under consideration. However, there were time pressures put on to the consultation process to allow for a formal negotiation process to commence shortly after. Allowing for a longer time period of consultation would likely have relieved some burden from stakeholders that were required to provide input at short notice and may have improved the quality of input as stakeholders would have had more time to gather data and information.

5. **Transparent**

The department effectively and transparently conveyed the purpose of the consultation and the context in which the consultation was being conducted. This ensured stakeholders' expectations were realistic.

6. **Consistent and flexible**

The consultation was largely consistent with previous forms of consultation the department has conducted with sector stakeholders. Limited constraints were placed on stakeholders regarding the consultation, allowing stakeholders to comment freely and in a flexible way on any aspect of the CPA.

7. **Subject to evaluation and review**

The department continues to evaluate its consultation processes and regularly seeks feedback from stakeholders.

8. **Not rushed**

As noted above, consultation was time limited. It is unclear what impact, if at all, this had on the quality and quantity of consultation that was undertaken. However, with more time, more frequent meetings with stakeholders could have been held. The department was only able to meet with some stakeholders once. This challenge could be overcome in future by allowing more time for consultation and negotiations.

9. **A means rather than an end**

The department's consultation was indeed used as a way of improving decisions, not as a substitute to making decisions. This is evident by government's decision to negotiate a separate wholesaler agreement with the NPSA, following the 8CPA negotiation process where this view was clearly articulated to government as an area of reform.

Summary of stakeholder views

While there were a range of views presented about the role of the CPA, this IA will consider only those stakeholders that expressed views relevant to the wholesaler sector. The [REDACTED] presented specific input on how the CSO could be restructured to better reflect the current and future needs of the Australian public.

Some stakeholders were in favour of the current arrangements and were supportive of higher levels of remuneration for existing activities. Other stakeholders argued the existing arrangements were not supporting the intended aims of the policy and should be reviewed.

[REDACTED]-proposed five options with different levels of reform of the CSO funding pool arrangements. Each option focused on driving efficiencies from existing CSO funding arrangements. The options present a mix of funding to either single or multiple CSO distributors, either restricting or skewing CSO funding pool payments towards regional, rural and remote pharmacy deliveries.

The [REDACTED]-proposal is based on the view that PBS distribution in metropolitan areas is over-compensated with wholesalers using the current CSO funding pool to cross subsidise both PBS and

non-PBS product distribution to metropolitan pharmacies at the expense of timely access to rural and remote areas.

The views put forward by **[REDACTED]** informed the development of this IA and will be further considered through future approach-to-market processes.

[REDACTED] noted it has many concerns about the CSO and its ability to support a sustainable supply chain that delivers equitable, timely and affordable medicine access for patients in rural and remote areas.

[REDACTED] claimed it had become aware of suggestions circulating within industry that CSO funds may, allegedly, be used to underwrite incentives and inducements (such as rebates, discounted trading terms, funding for shop refits, etc.) to larger pharmacies, franchises, groups and chains which are overwhelmingly located in metro areas.

[REDACTED] also claimed preference deals are being made by CSO wholesalers. During COVID-19, certain large industry players were allegedly able to place excessively large orders, while smaller rural pharmacies were unable to secure medicines for their patients. It was unclear to **[REDACTED]** what measures have been in put in place to ensure this form of preventable, first in best dressed, situation does not occur again.

[REDACTED] also claimed practices where CSO wholesalers are able to deny applications from rural and remote pharmacies located in MMM4-7 or negotiate waivers with these pharmacies in exchange for a reduced level of service. These pharmacies, often unaligned with banner pharmacy groups, have less market options for wholesalers compared with metro wholesalers and can be forced into signing waivers in exchange for some level of supply.

In its discussions with **[REDACTED]**, the department was unable to substantiate its claims and asked that any potential breaches of the CSO be immediately reported to the CSO Administration Agency for further investigation.

As outlined in option 2, NPSA submitted a detailed proposal to government as part of 8CPA consultations. A key part of this proposal was the establishment of a dedicated wholesaler agreement, which has shaped the development of this IA and its options.

Areas of agreement and disagreement

All stakeholders agreed that the requirements the CSO places on wholesalers in terms of timely and reliable access play an important role in supporting Australia's health system and the objectives of the National Medicines Policy. However, there is significant disagreement between stakeholders as to the level of funding for these activities, how government investment could be better managed, and the extent to which the CSO was supporting access to medicines in regional, rural and remote locations.

[REDACTED] maintain that the level of funding for CSO wholesalers is inadequate and not keeping up with the increasing scale and complexity of the PBS (which the CSO requires wholesalers to support). [REDACTED] have indicated CSO funding should be diverted to support rural and regional distribution only, contesting that distribution to pharmacies in urban areas is self-sustaining and does not require government funding to support. In contrast, [REDACTED] noted the cost of distribution to regional and remote areas is far greater than urban areas due to higher costs of fuel, labour and other handling costs.

[REDACTED] argued CSO wholesalers were using their market power to preference more profitable pharmacy clients located in urban areas, leaving rural and remote pharmacies with limited market options to provide supply of PBS medicines. For example, [REDACTED] referenced wholesalers growing use of waivers to avoid meeting the CSO service standards in exchange for guarantees of supply. These issues were not raised by either DHL or NPSA, nor could the department independently verify them.

Negotiations with NPSA

The department commenced formal negotiations with the NPSA on a fortnightly basis from 7 March 2024. NPSA had already provided the government with a detailed proposal with general terms for a dedicated PWA, as part of the early 8CPA consultations. Additional negotiation meetings were dedicated to unpacking the various points and details within the NPSA proposal to stress-test and reconcile the proposal's assumptions with the department's own data.

Ongoing consultations

The department will continue to work with community organisations, consumer organisations, wholesalers and pharmacy stakeholders to review and consider the wholesaling arrangements. This includes the design of data collection and development of an evaluation framework for the CSO.

Any data that is collected through the evaluation frameworks would then be implemented as soon

as possible or be used to deliver changes in the next round of negotiations for a 2PWA, should government wish to enter a new agreement.

Influence of stakeholder views on this IA

Stakeholder views have had a significant impact in informing and shaping this IA and the four policy options. The clearest example of this is government's decision to negotiate a dedicated wholesaler agreement. Option 2 of this IA presents the views of the NPSA in their entirety as a genuine policy option for government. This is a clear demonstration of how consultation with stakeholders has led to the identification of policy options for government.

Many aspects of the NPSA's proposal (which were expressed through the consultation process) have been adopted in options 3A and 3B, including reforms to wholesale mark-up.

Other stakeholder views have informed the IA's presentation of options and evaluation of reforms.

6. What is the best option from those you have considered and how will it be implemented?

Preferred option

The preferred option is the option which would provide the greatest net benefit and achieve equitable, timely, safe, and reliable access to medicines and pharmacy services at a cost that individuals and the community can afford (i.e. in line with the NMP). Table M outlines the net benefit of each option and identifies option 3B as the preferred approach (91.7% net benefit).

Decision making process

The decision-making process to determine the preferred option considered information that has been discussed throughout this IA, primarily including the net benefit analysis calculations and the regulatory burden estimates for each option.

In relation to net benefit, option 3B provided for the highest net benefit score of each of the four options (91.7%).

Net benefit and Regulatory Burden Estimate (RBE) Comparison

	Option 1	Option 2	Option 3A	Option 3B
Weighted Average (%)	38.9%	72.2%	77.8%	91.7%
Regulatory Burden Estimate	$0	$19,088,568.70	$17,640,677.70	$17,040,677.70

Option 1 represents the lowest regulatory burden of each of the options, being the status quo. However, the net benefit outcome for this option (38.9%) is lower than option 3B.

Option 3B includes a slightly lower regulatory burden estimate than option 2 and option 3A, due to the absence of changes required to adjust systems for demand-driven CSO changes. The main contributor to these other costs are the ongoing additional compliance costs associated with

integrating section 100 medicines into the CSO. These include monthly reporting, compliance with audits and ongoing communication with and monitoring by the CSO Administration Agency. However, these costs are mitigated by the overwhelming patient benefits for including section 100 medicines in the CSO as well as the additional remuneration wholesalers would receive in return for providing these services.

Implementation

Implementation of option 3B will require negotiation and signing of the 1PWA with the NPSA. This is the next decision point for government. If an agreement can be reached, the department would be required to conduct a joint assessment with the Guild as to whether the terms of the 1PWA are likely to lead to a reduction in the estimated total pharmacy remuneration as set out in table 2 of the 8CPA. This is the preferred option's first key milestone.

Where that assessment concludes there is likely to be a reduction in estimated total pharmacy remuneration, government is required to adjust pharmacy dispensary remuneration such that the estimated total pharmacy dispensary remuneration to Approved Pharmacists under the 8CPA is received. This is the next key milestone.

There is a small risk the Guild does not support these changes. However, this risk is mitigated through clauses 3.2.6 and 3.2.7 of the 8CPA which provide a clear pathway for compensation.

Once the 1PWA is signed, the next milestone is for the department to, as soon as practicable, draft the necessary amendments to the components of the Commonwealth price. To operationalise the changes to WMU agreed with NPSA, Services Australia will commence IT upgrades to support the change. The department would also commence a tender process for a new CSO Administration Agency, outlining the agreed terms of the CSO (as per 1PWA) in that tender process.

Establish new CSO Deeds

The current Deeds between the Commonwealth and each CSO wholesaler have a five-year lifespan. These Deeds are the contractual arrangements between each CSO wholesaler and the Commonwealth. The Deeds outline the remuneration wholesalers would receive in exchange for upholding the CSO compliance requirements and service standards.

The existing CSO Deeds were set to expire on 30 June 2024. The department negotiated a 12-month extension to the Deeds (which wholesalers agreed to) to allow for the finalisation of a 1PWA

which would outline a remuneration framework for which the new Deeds would be based on.

No further extensions of the Deeds are possible under the Commonwealth Procurement Rules (CPRs). A variation to the Deed could be agreed to extend the current terms and allow for the finalisation of negotiations towards new arrangements, although this would require agreement from the CSO wholesalers.

To ensure there is no gap in service delivery following the expiry of the current Deeds on 1 July 2025, new Deeds must be established before this time. Assuming option 3B can be negotiated with the NPSA, the department would commence preparation of the new Deeds immediately. This is the next key milestone.

Implementation roadmap

Key Milestone	Date	Action	Governance	Risk-management
Enact clauses 3.2.6 and 3.2.7 of the 8CPA	On signing of 1PWA	Write to Executive Director of the Pharmacy Guild of Australia noting proposed changes to Commonwealth Price and compensation	Department of Health & Aged Care	Modelling estimates to be shared and agreed with the Guild
Commence drafting of two-year CSO wholesaler Deed extension (25-26 to 27-28)	On signing of 1PWA	Department's to commence work	Department of Health & Aged Care and existing CSO wholesaler legal representatives	As negotiated under 1PWA
Establish 1PWA Oversight Committee membership	On signing of 1PWA	Department to elect 1PWA Oversight Committee Chair. Department and NPSA to nominate representatives in accordance with Chair's direction. Committee to meet at least once before FY26-27 and at least 1 meeting in years after.	Department of Health & Aged Care and the NPSA	As negotiated under 1PWA
CSO Administration Agency to commence additional CSO payments for FY24-25	On signing of 1PWA	CSO Administration Agency to commence additional CSO payments for FY24-25.	1PWA Oversight Committee	As negotiated under 1PWA and monitored under 1PWA Oversight Committee

Commercial-in-confidence Commence preparation for CSO distributors ATM in FY2026-27	1 January 2026	Undertake open tender process.	Department of Health & Aged Care	Department of Finance Procurement and tender rules and guidelines
Commence DoH IT upgrades for WMU changes	1 January 2025	Department of Health & Aged Care to commence internal IT changes to facilitate WMU changes.	Department of Health & Aged Care	Timeframe to complete work is sufficient to allow for unexpected delays.
Commence system changes to wholesale mark-up tiers and calculations	1 July 2026	WMU tier and calculation changes go live.	1PWA Oversight Committee	As negotiated under 1PWA and monitored under 1PWA Oversight Committee. Requests with SA lodged prior to 1PWA signing.
Provide additional compensation payment to Approved Pharmacists (if required)	1 July 2026	Department of Health & Aged Care to work with Services Australia to ensure pharmacies receive remuneration as agreed under 8CPA.	Department of Health & Aged Care Pharmacy Guild of Australia	8CPA Oversight Forum

Calculate the Estimated Government Savings from WMU changes for FY26-27 (to be added to the CSO pool)	1 April 2026	For review (not agreement) by 1PWA Oversight Committee prior to 1 July 2026 (when payments would commence)	1PWA Oversight Committee	1PWA Oversight Committee

Communications

Due to the significance of reforms in the preferred option, the department would seek to communicate the agreed changes and the associated impact on relevant stakeholders. This would likely include consultation meetings with stakeholders and potentially a small communication campaign.

Relevant stakeholders include, but are not limited to, the community pharmacy sector, non-NPSA wholesalers, pharmacy professional organisations, other health professionals and consumers.

7. How will you evaluate your chosen option against the success metrics?

At the outset of this IA, the following policy problems were identified:

1. Guaranteeing access to medicines through community pharmacy
2. Aligning government investment in the wholesaler sector with the refreshed National Medicines Policy
3. Industry sustainability
4. Aligning wholesaler remuneration with business costs
5. Keeping the cost of medicines down
6. Improving stakeholder engagement

To address these policy problems, the following objectives for government intervention were determined:

1. Evaluate current pharmaceutical wholesaler remuneration arrangements in line with the objectives of the refreshed NMP
2. Determine an appropriate level of investment and associated policy measures in line with the NMP
3. Finalise arrangements that advance the objectives of the NMP, potentially through the establishment of a dedicated agreement with CSO wholesalers.

Following implementation of the preferred option, the department will evaluate the extent to which the objectives above have or have not been met. This evaluation will monitor the performance of the policy during and after implementation. The evaluation will take place in two distinct phases. The first is the ongoing monitoring and evaluation during policy implementation. This phase will monitor risks and provide mitigation strategies should unforeseen circumstances arise. A significant part of this evaluation will be informed by regular stakeholder engagement with affected parties.

The second phase of the evaluation will commence at the beginning of 2027, six months after the introduction of WMU reforms on 1 July 2026. At least six months is required after the commencement of these reforms to allow for sufficient data collection through Services Australia to inform an evaluation of the reforms. This evaluation must conclude within 6 months to allow for sufficient consideration of any findings and results prior to a government decision in late 2028 as to the future of wholesaler funding arrangements (i.e. whether to negotiate a second PWA, to move wholesaler arrangement back into the CPA, or other options).

Evaluation framework

To support both evaluations, the department will use an evaluation framework. The framework has been developed using the principles-based evaluation approach for the conduct of evaluations across the Commonwealth, as set out in the Commonwealth Evaluation Policy[35]. The Policy identifies five key principles that should guide evaluation across the Commonwealth:

1. Fit for purpose
2. Useful
3. Robust, ethical and culturally appropriate
4. Credible
5. Transparent where appropriate.

With these five principles in mind, the following critical questions have been identified to guide both evaluations:

1. How, if at all, has the policy improved the lives of Australians?
2. Was the policy effective in supporting the NMP's objectives?
3. Was the policy a worthwhile investment (i.e. did it achieve its outcomes, while delivering value)?

The first evaluation phase will be heavily reliant on stakeholder consultation to identify unintended impacts or risks that may arise. The department proposes to establish an Agreement Oversight Committee (AOC) to facilitate regular discussions between signatories of the agreement, meeting at least once in the first 1.5 financial years of the agreement and then at least once in later years to monitor implementation of the Agreement. It is proposed the AOC will include representatives from the NPSA and officials from the Department of Health & Aged Care on behalf of the Australian Government.

As soon as practicable after the minutes of a meeting of the AOC have been settled, the signatories will ensure communication to enable public scrutiny of the agreement's implementation. This will improve the evaluation's transparency and accountability.

Data gathering will be critical to the AOC's success. The department will bring forward data gathered by Services Australia and collected by the CSO Administration Agency to ensure there is sufficient consideration of up-to-date information and data.

The second phase of evaluation will particularly consider the reforms introduced as part of the preferred option which would result in significant change to the operation of the CSO and WMU arrangements. An evaluation of these changes, their effect on industry sustainability and any

[35] https://evaluation.treasury.gov.au/about/commonwealth-evaluation-policy

unintended impacts on other stakeholders, including patients, pharmacies, and manufacturers will support better policy making decisions in future and inform future government decisions on wholesaler funding arrangements.

Access to data will also be critical to conducting this evaluation. As part of the open tender process for a new CSO Administration Agency provider due by mid-2025, the department will work with respondents to identify potential data gaps which would better support the second evaluation phase.

The CSO Administration Agency collects data in accordance with CSO delivery performance against the CSO service standards. This includes:

- Sales and payments
- Market share and supply trends
- Rural and remote sales performance
- Low volume sales performance
- Timely supply performance
- Stocking performance
- Audits and complaints
- Non-performance and sanctions.

While the data currently available provides an accurate view of performance against the CSO delivery standards, it does not provide a clear view of the cost-effectiveness of government investment to support the industry's ongoing viability. Further improvements could be made to develop a stronger evidence-base for policy making decisions by developing and implementing approaches to monitor and evaluate the cost-effectiveness of government subsidy in the sector. Including these considerations for improvement as part of the 1PWA will support facilitation from necessary stakeholders to inform the development of additional data collection processes.

Monitoring stakeholder impacts

In addition to undertaking an evaluation of reforms introduced as part of 1PWA, the department is committed to evaluating the impacts of the proposal's implementation on all affected stakeholders. The department is also committed to ongoing consultations with key stakeholders including consumers, consumer-organisations, the NPSA, non-NPSA wholesalers, the pharmacy sector, and other commercial entities involved in the distribution of medicines to community pharmacy.

Consumers

Impacts on consumer's access to medicines will be monitored through the department's ongoing collection and monitoring of PBS medicine data. The department will continue publishing data on

PBS medicine trends, including through the annual PBS Expenditure and Prescriptions reports. Data on individual CSO performance against the service standards is commercially-sensitive, but will be considered as part of the second evaluation phase during the 1PWA term. This consultation will seek to include the views of consumers and consumer organisations through thorough consultation.

Wholesalers

The department will monitor wholesaler impacts through existing mechanisms, including with financial data provided by the CSO Administration Agency and Services Australia. Wholesaler viability and performance will be monitored to ensure there are no unintended effects on supply to consumers and pharmacies in regional, rural and remote Australia as a result of proposed 1PWA reforms.

Regular meetings with the NPSA will continue over the life of the 1PWA to monitor and consider any unforeseen impacts on the sector.

Community pharmacy sector

The department will continue to monitor the impact on the community pharmacy sector of 1PWA, including by monitoring remuneration for dispensing PBS medicines through existing mechanisms. Actual expenditure data are supplied by Services Australia and tracked on an annual basis. The department will also continue to monitor the number and distribution of pharmacies to ensure businesses continue to be viable and able to service patients across Australia, as is consistent with monitoring activities through the 8CPA.

The department currently receives monthly statistics on the number of pharmacy applications to move, change owners, open a new premises or close an existing pharmacy. The department then tracks this data with reference to population data to ensure access to PBS dispensing services through community pharmacy remains a consistent or improved level. The department also uses this data to ensure rural and remote Australians are not adversely effected by proposed closures.

The department will utilise this information to monitor and investigate any unintended impacts on the pharmacy sector that may be caused as a result of 1PWA reforms.

Appendix A

Redacted due to commercial-in-confidence material

Appendix B – Miscellaneous tables

Table R – Wholesale Mark-Up Tier Comparison

Components of the Commonwealth Price (8CPA vs PWA)
***(based on table 3 of 8CPA)**

Payment type	8CPA Value of payment (current)		PWA Value of payment (NPSA Proposal)	
wholesale mark-up (for Ready-Prepared Pharmaceutical Benefits)[1]	Where the Ex- Manufacturer Price is up to and including $5.50	$0.41 per dispense	Where the Ex-Manufacturer Price is up to and including $5.50	$0.24 per dispense
	Where the Ex- Manufacturer Price is over $5.50 and up to and including $720	7.52% of the Ex-Manufacturer Price per dispense	Where the Ex- Manufacturer Price is over $5.50 and up to and including $1,000	4.3% of the Ex-Manufacturer Price per dispense
	Where the Ex- Manufacturer Price is over $720	$54.14 per dispense	Where the Ex- Manufacturer Price is over $1,000 and up to and including $10,000	$43.00 plus 2% for every dollar the Ex-Manufacturer Price exceeds $1,000 per dispense
			Where the Ex-Manufacturer Price is over $10,000	$223.00 per dispense

^ The WMU for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.

^ The WMU for a Pack Quantity of a Listed Brand is no longer calculated using the Relevant Quantity. Instead the WMU is calculated with reference to the pack quantity and ex-manufacturer price for the pack quantity dispensed.

Table S – Components of the Commonwealth Price (AHI only)[36]

Payment type			Value of payment
Administration, Handling and Infrastructure Fee[52]	Tier One AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than $100	$4.79 per dispense of Maximum Quantity
	Tier Two AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity from $100 and up to and including $2,000	Tier One AHI Fee plus 5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds $100, per dispense of Maximum Quantity
	Tier Three AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity over $2,000	Tier One AHI Fee and $95 per dispense of Maximum Quantity

[36] Eighth Community Pharmacy Agreement (health.gov.au). Page 10-11

Table T: Forecasted wholesaler remuneration under 8CPA policy settings [REDACTED]



Table **U: PWA Option Comparison, Financial Impact** (as modelled by the Department of Health & Aged Care)

	Option 1 – No PWA. Maintain existing wholesaler arrangements negotiated through 7CPA (status quo)	**Option 2** – Establish PWA and accept NPSA proposal in-full	**Option 3A*/ 3B** – Establish PWA, implement structural policy reforms (including/ not including CSO demand-driven reforms) and align remuneration with wholesaler costs
Total funding package	$3.58 billion	$5.19 billion	$4.20 billion
Additional government investment (commercial in-confidence)	Nil	$1.22 billion	$632.1 million
Total patient saving	Nil	$36.5million	$28 million
Additional pharmacy remuneration (over PWA term) (commercial in-confidence)	Nil	-$13.9 million	-$11.7 million

Note: all cost forecasts are over five years, via community pharmacy distribution commencing 1 July 2024.

** Due to uncertainty associated with an uncapped CSO arrangement in option 3A, actual funding is likely to be far higher than what is forecast under current volume forecasts.*

Appendix C.1

Methods and assumptions made in calculating the Regulatory Burden Estimates

Estimates are presented to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on several assumptions detailed below.

1. No regulatory burden is created for community organisations or individuals as a result of structural changes to the CSO funding pool. The effort required to comply with the relevant obligations remains the same irrespective of whether CSO payments are made through a fixed funding pool or via a volume-based mechanism.
2. Maintaining existing wholesale mark-up arrangements would not create additional regulatory burden. There is no additional regulatory impact on business to continue meeting the obligations under the CSO.
3. The regulatory burden considerations are limited to those impacts which will result from each of the options presented for the remuneration of the supply of subsidised PBS medicines. This does not extend to the potential subsequent impacts that may occur as a result of future negotiations or considerations.
4. The below estimates were derived within the department from knowledge of previous negotiations processes with stakeholders in the pharmacy sector.
    a. Wholesaler remuneration is linked to the Commonwealth price, via the WMU. The WMU can be viewed as a "pass-on" cost by pharmacies, as it is remuneration that is paid to wholesalers by the Commonwealth, through pharmacies. Changes to wholesaler remuneration would be negotiated with the peak body representative of wholesalers, the NPSA.
    b. Assume a negotiation period of 12 meetings, including weekly meetings with a total duration of 5 hours, including 1.5 hours for the meeting itself and 3.5 hours to account for occasional travel to department offices in Canberra, ACT and preparatory work.
    c. The default hourly cost has been calculated using the average weekly earnings published by the Australian Bureau of Statistics but adjusted to include income tax. This provides an economy-wide value for employees of $48.67 per hour. This value needs to be scaled up using a multiplier of 1.75 to account for the non-wage labour on-costs (for example payroll tax and superannuation) and overhead costs (for example, rent, telephone, electricity and IT expenses). This results in a scaled-up rate of $85.17 per hour ($48.67 multiplied by 1.75).

d. Some substantive compliance costs are not fully known. Costs estimates represent desk-top research into similar/ comparable work.

Cost specific assumptions

Cost	Stakeholder Affected	Assumptions
System changes for CSO payments from a fixed pool to a volume-based structure.	Business	An estimated one-off cost of $100,000 is estimated for each CSO wholesaler to adjust their IT systems to allow for changes to CSO payments from a fixed pool to a volume-based model. It is assumed all six CSO wholesalers would be required to undertake this investment. A total number of six CSO wholesalers is assumed for the duration of the PWA.
System changes for WMU quantity definitions changes.	Business	An estimated one-off cost of $100,000 is estimated for each CSO wholesaler to adjust their IT systems to allow for changes to WMU quantity definition changes. It is assumed all six CSO wholesalers would be required to undertake this investment. A total number of six CSO wholesalers is assumed for the duration of the PWA.
System changes to integrate section 100 medicines under the WMU and CSO	Business	An estimated one-off cost of $500,000 is estimated for each CSO wholesaler to adjust their IT systems to integrate section 100 medicines under the CSO and WMU. It is expected this to represent a greater cost for wholesalers than other system changes due to the need to add additional systems to facilitate section 100 distribution through the CSO and WMU. It is assumed all six CSO wholesalers would be required to undertake this investment. A total number of six CSO wholesalers is assumed for the duration of the PWA.
Negotiation of a pharmaceutical wholesaler agreement	Business	There are two elements to this cost. The first is the development of a submission to government. The submission outlines the NPSA's proposal and includes detailed modelling of proposed changes. An average time burden of 20 hours is assumed to

		cover research and liaison work with NPSA members. The NPSA would be the only organisation involved with a total of 10 staff involved, including 2 in-house NPSA staff, 4 external consultants, and 1 staff from each NPSA member company (4 in total). The second is the negotiation process with the Department of Health and Aged Care, itself. An average time burden of five hours has been assumed for each meeting to account for meeting duration (1.5hrs) as well as preparatory and ad hoc travel to in-person meetings at the department's Canberra offices. A total of 12 meetings has been assumed. Six staff from NPSA are assumed to be involved in each meeting.
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Business	All CSO wholesalers are required to undertake standard monthly reporting processes with the CSO Admin Agency. There are also other compliance activities, including on-site auditing, compliance with breach investigations and other ad hoc communications with the CSO Admin Agency. These are expected in increase with the addition of section 100 medicines under the CSO. Calculations will vary depending on the size and scale of the CSO wholesaler's operations. Calculations have been completed for CSO wholesalers that operate in all states and territories (national) or otherwise (state-based). 10 hours is the time requirement assumed to complete each monthly report with 5 staff assumed in each state and territory, except for NSW and VIC (due to their size), where 10 staff are assumed. 1 hour is the time requirement assumed to complete each 'other compliance' activity. 50 occasions are assumed each year, for each CSO wholesaler The same

		staff members assumed for monthly reporting engaged in these activities also.

Appendix C.2 – RBE Calculations Breakdown by Option

Administrative costs are calculated as a labour cost using the following formula as per the Office of Impact Analysis Regulatory Burden Framework
Labour Cost = Price x Quantity
= (time required x labour cost) x (times performed x number of businesses or organisations x number of staff)

Option 2 - Total Regulatory Burden Costs

Cost	Nature (start-up or ongoing)	Category	Relevant population
System changes for CSO payments from a fixed pool to a volume-based structure.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
System changes for WMU quantity definition changes	Start-up	Substantive compliance	Businesses (CSO wholesalers)
System changes to integrate section 100 medicines under the WMU and CSO.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
Negotiation of a pharmaceutical wholesaler agreement.	Start-up	Administrative	Businesses (NPSA and its members)
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Ongoing	Administrative	Businesses (CSO wholesalers)

Option 2 - Start-up Cost Calculations

Cost	Category	Calculations
System changes for CSO payments from a fixed pool to a volume-based structure.	Substantive compliance	= ($100,000) x (1 occasion x 6 CSO wholesalers) = $600,000.00
System changes for WMU quantity definitions changes.	Substantive compliance	= ($100,000) x (1 occasion x 6 CSO wholesalers) = $600,000.00
System changes to integrate section 100 medicines under the WMU and CSO	Substantive compliance	= ($500,000) x (1 occasion x 6 CSO wholesalers) = $3,000,000.00
Negotiation of a pharmaceutical wholesaler agreement[37]	Administrative costs	Submission development & adjustment = (20hrs x $85.17) x (1 occasion x 1 organisation x 10 staff) = $17,034.00 Meeting timeline = (5hrs x $85.17) x (12 meetings x 1 organisation x 6 staff) = $30,661.20 Total = $47,695.20
Total		= $4,247,695.20

Substantive compliance costs are normally calculated as purchase costs using the following formula as per the Office of Impact Analysis Regulatory Burden Framework
Purchase cost = Price x Quantity
= (purchase cost) x (time performed x number of businesses or community organisations)
= (time required x labour cost) x (times performed x number of businesses or organisations x number of staff)

[37] Based off 12 meetings, with average duration of 5hrs to include travel and preparation time

Option 2 - Ongoing Cost Calculations

Cost	Category	Calculations
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Administrative	**National CSO Wholesalers** Monthly reporting = (10hrs x $85.17per hr) x (12 occasions x 5 years)[38] x (4 business x 40 staff[39]) = $8,176,320.00 Other compliance = (1hrs x $85.17 per hr) x (50 occasions x 5 years) x (4 businesses x 40 staff) = $3,406,800.00 **State-based CSO wholesalers** Monthly reporting = (10hrs x $85.17 per hr) x (12 occasions x 5 years) x [(2 businesses x 10 staff) + (5 business x 5 staff)] = $ 2,299,590.00 Other compliance = (1hr x $85.17 per hr) x (50 occasions x 5 years) x [(2 businesses x 10 staff) + (5 business x 5 staff)] = $958,162.50
Total		$14,840,872.50

[38] Monthly reporting over 5 year agreement length.

[39] 5 staff members are assumed in each state and territory for the four national CSO wholesalers (API, Sigma, Symbion, CH2), with ten staff in NSW and VIC. State based CSO wholesalers Barretts (VIC only) is assumed 10 staff and NPD (VIC and SA) is assumed 15 staff (10 in VIC and 5 in SA), as per same allocation for other national CSO wholesalers.

Option 3A – Total Regulatory Burden Costs

Cost	Nature (start-up or ongoing)	Category	Relevant population
System changes for CSO payments from a fixed pool to a volume-based structure.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
System changes for WMU quantity definitions changes.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
System changes to integrate section 100 medicines under the WMU and CSO.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
Negotiation of a pharmaceutical wholesaler agreement.	Start-up	Administrative	Businesses (NPSA and its members)
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Ongoing	Administrative	Businesses (CSO wholesalers)

Option 3A - Start-up Cost Calculations

Cost	Category	Calculations
System changes for CSO payments from a fixed pool to a volume-based structure.	Substantive compliance	= ($100,000) x (1 occasion x 6 CSO wholesalers) = $600,000.00
System changes for WMU quantity definitions changes.	Substantive compliance	= ($100,000) x (1 occasion x 6 CSO wholesalers) = $600,000.00
System changes to integrate section 100 medicines under the WMU and CSO	Substantive compliance	= ($500,000) x (1 occasion x 6 CSO wholesalers) = $3,000,000.00
Negotiation of a pharmaceutical wholesaler agreement[40]	Administrative costs	Submission development & adjustment = (20hrs x $85.17) x (1 occasion x 1 organisation x 10 staff) = $17,034.00 Meeting timeline = (5hrs x $85.17 per hr) x (12 meetings x 1 organisation x 6 staff) = $30,661.20 Total = $47,695.20
Total		= $4,247,695.20

[40] Based off 12 meetings, with average duration of 5hrs to include travel and preparation time

Option 3A - Ongoing Cost Calculations

Cost	Category	Calculations
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Administrative	**National CSO Wholesalers** Monthly reporting = (10hrs x $85.17per hr) x (12 occasions x 5 years)[41] x (4 business x 40 staff[42]) = $8,176,320.00 Other compliance = (1hrs x $85.17 per hr) x (50 occasions x 5 years) x (4 businesses x 40 staff) = $3,406,800.00 **State-based CSO wholesalers** Monthly reporting = (10hrs x $85.17 per hr) x (12 occasions x 5 years) x [(1 business x 10 staff) + (1 business x 15 staff)] = $1,277,550.00 Other compliance = (1hr x $85.17 per hr) x (50 occasions x 5 years) x [(1 business x 10 staff) + (1 business x 15 staff))] = $532,312.50
Total		= $13,392,982.50

[41] Monthly reporting over 5 year agreement length.

[42] 5 staff members are assumed in each state and territory for the four national CSO wholesalers (API, Sigma, Symbion, CH2), with ten staff in NSW and VIC. State based CSO wholesalers Barretts (VIC only) is assumed 10 staff and NPD (VIC and SA) is assumed 15 staff (10 in VIC and 5 in SA), as per same allocation for other national CSO wholesalers.

Option 3B – Total Regulatory Burden Costs

Cost	Nature (start-up or ongoing)	Category	Relevant population
System changes for WMU quantity definitions changes.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
System changes to integrate section 100 medicines under the WMU and CSO.	Start-up	Substantive compliance	Businesses (CSO wholesalers)
Negotiation of a pharmaceutical wholesaler agreement.	Start-up	Administrative	Businesses (NPSA and its members)
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Ongoing	Administrative	Businesses (CSO wholesalers)

Option 3B - Start-up Cost Calculations

Cost	Category	Calculations
System changes for WMU quantity definitions changes.	Substantive compliance	= ($100,000) x (1 occasion x 6 CSO wholesalers) = $600,000.00
System changes to integrate section 100 medicines under the WMU and CSO	Substantive compliance	= ($500,000) x (1 occasion x 6 CSO wholesalers) = $3,000,000.00
Negotiation of a pharmaceutical wholesaler agreement[43]	Administrative costs	Submission development & adjustment = (20hrs x $85.17) x (1 occasion x 1 organisation x 10 staff) = $17,034.00 Meeting timeline = (5hrs x $85.17 per hr) x (12 meetings x 1 organisation x 6 staff) = $30,661.20 Total = $47,695.20
Total		= $3,647,695.20

[43] Based off 12 meetings, with average duration of 5hrs to include travel and preparation time

Option 3B - Ongoing Cost Calculations

Cost	Category	Calculations
Additional CSO compliance activities for section 100 medicines, including monthly reporting, auditing, and ongoing communication with the CSO Administration Agency.	Administrative	**National CSO Wholesalers** Monthly reporting = (10hrs x $85.17per hr) x (12 occasions x 5 years)[44] x (4 business x 40 staff[45]) = $8,176,320.00 Other compliance = (1hrs x $85.17 per hr) x (50 occasions x 5 years) x (4 businesses x 40 staff) = $3,406,800.00 **State-based CSO wholesalers** Monthly reporting = (10hrs x $85.17 per hr) x (12 occasions x 5 years) x [(1 business x 10 staff) + (1 business x 15 staff)] = $1,277,550.00 Other compliance = (1hr x $85.17 per hr) x (50 occasions x 5 years) x [(1 business x 10 staff) + (1 business x 15 staff))] = $532,312.50
Total		= $13,392,982.50

[44] Monthly reporting over 5 year agreement length.

[45] 5 staff members are assumed in each state and territory for the four national CSO wholesalers (API, Sigma, Symbion, CH2), with ten staff in NSW and VIC. State based CSO wholesalers Barretts (VIC only) is assumed 10 staff and NPD (VIC and SA) is assumed 15 staff (10 in VIC and 5 in SA), as per same allocation for other national CSO wholesalers.

Appendix D - Proposed consultation plan (submitted at early assessment stage)

- **Explanation of the purpose and objectives of consultation**

Purpose: to understand the range of views amongst impacted stakeholders to inform government considerations for the negotiation of the PWA.

Objectives:

1. Support well-designed and evidence-based policymaking.
2. Understand the range of views and potential impacts of policy changes on stakeholders.
3. Inform the development of evaluation frameworks for policy changes.

- **A plan for conducting consultation**

As negotiations for a PWA have already commenced and consultation was already conducted as part of 8CPA, a plan to conduct consultations is not relevant in this circumstance.

- **Explanation of who should be consulted—and who does not need to be consulted**

The NPSA as the peak body for the majority of PBS wholesalers were consulted. NPSA will be a signatory to the PWA, along with the Australian Government.
Sensitivity (not for publication) begins…Additionally, the department met with the Remote and Isolated Pharmacist Association of Australia to understand issues regarding access to medicines in remote parts of Australia…. *Sensitivity ends.*

- **A strategy for the most efficient and meaningful consultation**

NPSA have already provided government with a detailed proposal for a dedicated PWA. This was submitted as part of the 8CPA consultations. Several negotiation meetings have been dedicated to stress-testing and reconciling the NPSA's proposal with the department's own data for accuracy. This has allowed NPSA to make updates to its proposal following data sharing with the department.

- A summary of the major topics to be covered and what issues might be raised

Key topics to be covered include: wholesaler remuneration levels, scope of medicines included under the CSO, changes to the CSO compliance requirements and service standards, and medicines shortage initiatives.