



Improving CSO Operations during 7CPA

1. Recommendation

Community Service Obligation (CSO) requirements should be revised to ensure tax-payer funds are being used to optimise consumer access through community pharmacies of medicines and products subsidised under the Pharmaceutical Benefits Scheme (PBS), Repatriation Pharmaceutical Benefits Scheme (RPBS) and the National Diabetes Services Scheme (NDSS), irrespective of where people live. This will involve introducing higher CSO standards for the delivery of all PBS, RPBS and NDSS items and directing CSO funds to specifically cover the less commercially-viable aspects of delivery services.

2. Background

While the Pharmacy Guild of Australia (Guild) believes that there should be standard obligations associated with the listing of any pharmaceutical benefit to guarantee patient access via their preferred community pharmacy (see *Attachment A*), the CSO is currently the main means to enforce distribution and delivery standards for PBS medicines and NDSS items.

To date, the CSO has covered the storage and distribution of Section 85 medicines listed on the PBS to be delivered to almost any community pharmacy in Australia:

- within one working day for low-volume PBS medicines
- within 3 working days for 'high-volume' PBS medicines
- at the approved Price to Pharmacist (PTP)¹ for PBS medicines

The Sixth Community Pharmacy Agreement (6CPA) also saw the CSO covering the delivery of NDSS items to community pharmacies at no cost for NDSS items ordered via the NDSS administration platform (NDSS Connect).

CSO Distributors (CSODs) submit regular reports to the CSO Administrator to demonstrate they meet the criteria for delivering a fair portion of items with higher distribution costs (low cost items, low volume items and to regional and remote locations). Reports also include details of PBS or NDSS deliveries that did not meet the CSO standards. Subject to the CSODs remaining compliant with CSO standards, payments from the CSO funds are paid according to the volume of eligible PBS and NDSS items delivered within the payment period

3. 7CPA Wholesaler Funding Package

In addition to the \$2.066 billion in wholesaler remuneration for the distribution of PBS medicines (of which \$1.746 billion is Commonwealth subsidisation), CSODs are eligible for \$1.083 billion in CSO funding over the 5 years of the 7CPA for the distribution of PBS and NDSS items. This is an additional \$267 million in PBS remuneration and \$92 million in CSO funding compared to the 6CPA.²

¹ PTP = Approved Ex-Manufacture Price + allocated PBS wholesaler mark-up;
<https://www.legislation.gov.au/Series/F2015L01077>

² As part of the 6CPA Compact in 2017, compensation was to be paid to community pharmacy and wholesalers for both the lower than expected prescription volumes and reduced remuneration as a result of measures from the strategic agreement with Medicines Australia.

4. CSO Objectives

With an allocation of almost \$1.1 billion over 5 years, in the interests of the Australian public, the Guild believes the CSO should be better targeted to achieve the following objectives for the distribution of subsidised pharmaceuticals:

1. Ensure the distribution of PBS, RPBS and NDSS items is consistent with the Guild's **Recommended conditions for the listing and distribution of pharmaceutical benefits** – see *Attachment A*
2. Ensure CSODs are adequately compensated for:
 - 2.1 Delivery to all regions of Australia (with agreed limited exclusions) within 24 hours of all PBS, RPBS and NDSS items, including:
 - 2.1.1 low-volume PBS medicines
 - 2.1.2 specialised (S100) medicines
 - 2.1.3 PBS medicines requiring special handling (Controlled Drugs, cold chain lines, cytotoxic and high cost medicines)
 - 2.1.4 weekend deliveries, particularly in rural and remote locations
 - 2.2 Guaranteeing:
 - 2.2.1 pharmacies receive all PBS and RPBS medicines (including S100 medicines) at no more than the PTP
 - 2.2.2 pharmacies can access any PBS brand not subject to exclusive supply within 24 hours
 - 2.2.3 pharmacies are not subject to any additional fees or surcharges for delivery of PBS stock (save allowable account arrangements e.g. late payment or credit card payment fees)
 - 2.2.4 reasonable arrangements are in place to enable pharmacies to return PBS medicines if not used so long as return of product is consistent with the Code of Good Wholesaling
 - 2.2.5 arrangements to manage the implementation of statutory price reductions by passing on early price reduction arrangements negotiated with manufacturers (to minimise the potential for disruption of supply to patients)
 - 2.2.6 each warehouse keeping adequate stock for the supply of PBS, RPBS and NDSS products to ensure reasonable and timely access to those products by consumers where the demand is, or should reasonably have been, anticipated by the relevant CSOD warehouse
 - 2.2.7 order cut-off timing and delivery schedules to ensure any community pharmacy can effectively manage urgent, unanticipated medicine requirements for their patients
 - 2.3 Supporting:
 - 2.3.1 stewardship schemes for PBS, RPBS and NDSS items, such as return of unwanted medicines or publicly funded sharps disposal schemes

Importantly, the Guild regards the CSO as the means to guarantee timely and reliable consumer access to PBS medicines and not as a means for CSODs to cross-subsidise wholesaler discount arrangements for pharmacy chains.

5. CSO Problems

There are a number of problems with the CSO in its current setup that prevent it from meeting the objectives described above, including:

- the delivery of high volume medicines to pharmacies in high density metropolitan areas attracts the same amount of CSO funding (per unit) as deliveries to non-metro areas. This is inappropriate use of CSO funding and goes directly against the primary objectives of the CSO.

- dilution of service standards during the 6CPA that can affect a pharmacy's efficiency and flexibility to meet patient needs, such as:
 - an increase from 24 hours to 72 hours for guaranteed delivery of high volume items
 - minimum order quantities for high volume items
 - ability to impose surcharges that cannot be passed on to pharmacy customers if early delivery or smaller ordering volume is desired by the pharmacy
- the distinction between 'high-volume' and 'low-volume' is obscure and problematic if CSODs have the discretion to apply fees for non-compliant orders for 'high-volume' lines
 - discretionary fees are based on non-published shelf-packs agreed between the Department and CSODs and pharmacists are unaware of the basis for discretionary fees
 - shelf-pack quantities can be significantly in excess of average monthly usage for some items, thereby hindering pharmacy efficiency if forced to purchase in shelf packs
 - it is unclear how often the high and low volume lists are reviewed, noting the current list is from 2018³ and there is no efficient system that fits within a pharmacy's workflow arrangements for pharmacists to easily identify whether a product is high or low volume
- limitations in coverage
 - the CSO and any remediation in response to CSODs not meeting CSO standards is limited to eligible CSODs operating under a deed with the Commonwealth which reflects the CSO standards
 - there are no quality controls or oversight for the distribution and delivery of PBS medicines through non-CSO distributors
 - the CSO standards do not apply to non-dual listed S100 medicines or RPBS items
- variation in service standards for first-line and second-line accounts
- ability for CSODs to unilaterally adjust order cut-off times and delivery schedules that affects a pharmacy's ordering ability and capability of meeting unanticipated prescription needs late in the day and/or week – members report of wholesalers implementing earlier order cut-off times, cancelling Monday deliveries, having Saturday deliveries offered only with a first-line account

Under the *National Health Pharmaceutical Benefits) Regulations 2017*, 'an approved pharmacist commits an offence if he or she does not, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits'. It is reasonable to expect CSODs must also keep adequate stock in all warehouses to meet anticipated demand, and to have arrangements in place to urgently respond to unanticipated requirements. This is particularly pertinent in the lead up to a price disclosure cycle when members report it is not uncommon to experience stock shortages that may compromise patient care.

While pharmacies maintain stock levels to meet the anticipated demand of their local community, this is determined by a pharmacy's dispensing history and knowledge of the pharmacy's patients and local prescribers. The ability for a pharmacy to easily meet unanticipated demand (e.g. new medicine; prescription from a different GP/specialist; travelling patients) is determined by:

- the cut-off times for placing orders to enable next day delivery for medicines not routinely kept by the pharmacy

³ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

- suitable delivery schedules for orders placed on Friday, including regular Saturday and Monday deliveries to minimise delays in patient access over the weekend
- unrestricted ordering capabilities i.e. no order limits such as minimum order quantities or dollar values

The patient impact and health risks associated with any changes to ordering cut-off times or delivery schedules can be significant and particularly for pharmacies in rural, remote and one-pharmacy locations. In saying this, the impact on patients in larger regional or metropolitan cities should not be discounted and particularly for patients who have mobility or transport issues or who prefer using the one pharmacy for service and care continuity e.g. DAA patients. Members report that the impact on the pharmacy from the CSOD service changes, all of which have time and cost implications, includes:

- holding more stock to meet unanticipated demand, which has other business implications such as stock going out of date
- borrowing from other pharmacies or hospitals
- contacting prescribers to change the medicine

Likewise, there must not be order restrictions on pharmacies that hinder pharmacists from readily meeting the individual needs of its patients. CSODs should not have an option of charging additional fees for pharmacists needing to order a single pack of a 'high volume' PBS medicine to meet unanticipated needs of a patient. Not only are pharmacists unable to pass on such business costs, but the CSO provides the subsidisation to CSODs to compensate for these exceptional delivery requirements. The Guild supports greater efficiencies with ordering and delivery of subsidised pharmaceuticals, but not through punitive fees for pharmacy.

In addition, there should be no variation in service standards for first-line and second-line accounts. The majority of community pharmacies have second-line CSOD accounts, primarily as a supply backup should the first-line account be out of stock. In some instances, certain PBS medicines are only available from select CSODs and therefore pharmacies must also have an account if they have patients using these medicines. COVID-19 demonstrated issues that community pharmacies had when CSODs reduced their services for second-line accounts. The disruptions to medicine supplies occurring at both manufacturer and CSOD level resulted in pharmacies relying more and more on second-line CSOD accounts as backup and patient care was compromised when this service was reduced. CSODs receive CSO funding for eligible supplies to all accounts and therefore service standards for first-line and second-line accounts should be equitable and there should be no minimum order requirements for any PBS line.

6. Proposed CSO Improvements

Following the 6CPA Remuneration and Regulation Review, in early 2018, the Department of Health commenced a review of the obligations for CSODs. Subsequently, on 30 November 2018, the Department released an invitation to apply for CSO funding with revised guidelines for CSO obligations. Successful CSODs entered into new deeds with the Commonwealth from March 2019 until June 2020, with an option of extending until June 2022, and a further option of extending until June 2024 in 12 month increments. It is expected that CSODs will enter new deeds with the Department to reflect changes to 7CPA wholesaler remuneration coming into effect from 1 January 2021. This provides an opportune time to revise and improve the CSO standards to meet the objectives described above.

To address the issue that the distribution of CSO funding currently bears no relationship to its objectives, the Guild proposes the following amendments to the CSO as part of the 7CPA as a means of focusing

CSO funding on its prime purpose of covering the less commercially viable aspects associated with the distribution of PBS medicines, including recognising the additional distribution costs for:

- More difficult-to-reach pharmacies in regional, rural and remote locations
- low volume medicines
- medicines requiring special handling (cold chain, Controlled Drugs, cytotoxics)
- S100 medicines
- weekend deliveries, particularly to rural and remote locations

CSO funding be distributed amongst compliant CSODs based on the volumes of:

- All PBS medicines and RPBS and NDSS items distributed to pharmacies in regional, rural or remote areas (appropriately defined under the Modified Monash Model)
- PBS/RPBS low-volume medicines (all regions including metro)
- PBS/RPBS Controlled Drugs (all regions including metro)
- PBS/RPBS cytotoxic medicines (all regions including metro)
- PBS/RPBS cold chain items (all regions including metro)
- PBS/RPBS high cost medicines e.g. approved ex-manufacturer price > \$2,000 (all regions including metro)
- PBS/RPBS S100 medicines (all regions including metro)

Recognising the additional costs for weekend deliveries in rural and remote locations, an order subsidy can also be applied for Saturday deliveries that include PBS medicines or RPBS or NDSS items to pharmacies in regional, rural or remote areas (appropriately defined under the Modified Monash Model).

Other requirements to be incorporated into the CSO standards:

- Delivery of all PBS medicines and RPBS and NDSS items within 24 hours
- Monday to Friday deliveries, excluding public holidays
- Saturday deliveries to any pharmacy unless the pharmacy opts out
- Order cut off times no earlier than 4.30pm local pharmacy time
- Cost to pharmacy should be no more than the PTP, inclusive of all supply related fees (for clarity, this includes no additional fee for the delivery of special handling items, including Dangerous Drugs)
- Ensuring continuity of medicine supplies by managing statutory price reductions for community pharmacy by passing on negotiated reductions at an agreed, suitable time ahead of the change
- All warehouses holding adequate PBS, RPBS and NDSS stock to adequately meet anticipated demand

Note: As part of revising standards to meet the above requirements, arrangements would need to be in place to manage any routing. As an example, deliveries would have to be to a pharmacy address and not to a pharmacy group's warehouse in a regional location.

Exclusions to these requirements should be negotiated and subject to review and should not be a unilateral decision by a CSOD.

7. Transparency and Awareness

There is a general lack of awareness of CSO arrangements, including with consumers. Pharmacists in particular lack awareness of how complaints can be raised. The CSO administrator could work more with pharmacy and consumer organisations to raise awareness of the CSO and how to lodge a complaint. The Guild and its members would also like to see greater transparency with the CSO and its management, including with how funds have been distributed as well as the management of complaints. This could be managed by providing annual reports of national and state level aggregated information on the breakdown of volumes and funding allocation similar to that in the annual PBS Expenditure and Prescriptions Report⁴ e.g. according to the CSO categories under section 6 above (rural and remote supplies; low volume supplies; special handling).

Annual aggregate information on complaints management would also improve transparency and increase awareness of the governance and processes with the CSO.

⁴ <https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions> (Example Table 4; 2018-19 Report)

Attachment A: Recommended conditions for listing And distribution of pharmaceutical benefits

Noting that Approved Pharmacists must comply with conditions specified in section 92A of the *National Health Act 1953*, it would be reasonable to enforce conditions on all elements of the supply chain to better guarantee patient access to pharmaceutical benefits by implementing an approval process for sponsors and distributors. Below are the Guild's recommended conditions for the listing and distribution of pharmaceutical benefits which would apply to all responsible persons (sponsors) and distributors and would also address the issues associated with exclusive supply. CSO funding would complement these conditions to subsidise the distribution of items with higher distribution costs.

Recommended Conditions for Approved Responsible Persons

As part of the process to be an Approved Responsible Person that can have medicines listed on the PBS, the Guild proposes that Responsible Persons must meet the following conditions:

The Responsible Person must guarantee:

- compliance with the most current version of the Australian *Guide to good manufacturing of medicinal products*⁵
- ongoing supply of their medicine listed on the PBS to meet reasonable expected demand
- notification within two business days to the PBS Administrator of any issues which will disrupt supply of their PBS product, either nationally or locally and inclusive of both full and partial supply issues.
- that any Approved Pharmacist or Hospital can access any reasonable quantity of their PBS medicines within 24 hours of ordering, save for any exemptions supported by an independent PBS Supply Advisory Group¹
- their PBS medicine will be available to any Approved Pharmacist or Hospital from any full-line CSO compliant wholesaler, save for any exemptions supported by an independent PBS Supply Advisory Group¹
- where an exemption applies, details of the exemption and /or supply arrangements must be publicly available to any Approved Pharmacist or Hospital
- any PBS listed medicine (regardless of type of listing) is available to an Approved Pharmacist or Hospital at no more than the price on which remuneration is based (inclusive of all supply-related fees²)
- arrangements are in place to manage statutory price changes to ensure an Approved Distributor, Pharmacist or Hospital is able to hold adequate stock of their PBS listed medicines to meet demand without incurring financial losses
- ongoing stewardship of their medicines listed on the PBS, including disposal of expired or unwanted medicines and any waste associated with use of the medicine (e.g. sharps) as well as urgent safety related matters (e.g. recalls) with recompense for the supply chain
- a quality assurance process is in place to ensure that the above conditions continue to be met

⁵ <https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products>

Attachment A: Recommended conditions for listing And distribution of pharmaceutical benefits

In the event that an Approved Responsible Person breaches these conditions, there should be a similar range of compliance actions that can be undertaken as with Approved Pharmacists.

Recommended Conditions for Approved Distributors

As part of the process to be an Approved Distributor of PBS medicines, wholesalers and other distributors must meet the following conditions which reflect the Conditions for Approved Responsible Persons and which would also be reflected in CSO obligations for accessing CSO funding for CSO compliant full-line wholesalers:

- Approved Distributors must comply with the most current version of the *Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8*⁶
- Approved Distributors will carry sufficient stock of all PBS medicines to meet the demands of its pharmacy clientele, including:
 - at least one brand of every PBS medicine
 - for multi-branded PBS medicines, at least one innovator brand and one additional brand which is benchmark priced
- Any Approved Pharmacist or Hospital can access any reasonable quantity of their PBS medicines within 24 hours of ordering, save for exemptions recommended by an independent PBS Supply Advisory Group¹
- Any PBS listed medicine is available to an Approved Pharmacist or Hospital at no more than the price on which remuneration is based (inclusive of all supply-related fees²)
- Arrangements are in place to manage statutory price changes to ensure an Approved Pharmacist or Hospital is able to hold adequate stock of their PBS listed medicines to meet demand without incurring financial losses
- Arrangements are in place to support any stewardship schemes for PBS listed medicines, including disposal schemes for expired or unwanted medicines and associated waste as well as urgent safety related matters
- If the Approved Distributor uses delivery services other than direct employees, they must ensure that the contracted distributor also meets all of the above conditions
- A quality assurance program is in place to ensure that the above conditions continue to be met

In the event that an Approved Distributor breaches these conditions, there should be a similar range of compliance actions that can be undertaken as with Approved Pharmacists.

⁶ <https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8>

Attachment A: Recommended conditions for listing And distribution of pharmaceutical benefits

¹ An independent PBS Supply Advisory Group must be in place comprising of representatives from community pharmacy, prescribers, consumers, pharmaceutical distributors and medicines companies.

² Supply related fees are associated with the medicine or order e.g. a DD fee, cold-chain fee, order service fee, delivery fee. This is in contrast to additional account related fees such as a dishonour fee, overdue account fee or credit card payment fee.