EXPLANATORY STATEMENT

National Health Act 1953

National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023

PB 57 of 2023

Purpose

The purpose of the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (PB 57 of 2023) (**Instrument**) is twofold.

Firstly, it amends the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (**HSD Special Arrangement**) to include pharmaceutical benefits used for the treatment of opioid dependence (**ODT medicines**) as a Section 100 Highly Specialised Drugs (**HSD**) Program (Community Access) listing. ODT medicines are already listed on the Pharmaceutical Benefits Scheme (**PBS**), but are not currently supplied under the HSD Special Arrangement.

The overarching intent is for existing Section 100 HSD Program community access arrangements to apply to ODT medicines. This means ODT medicines will be supplied in the same way as other community access Section 100 HSD Program medicines from PBS approved suppliers. These are approved community pharmacies, approved medical practitioners, and approved hospital authorities (public and private). For the purposes of the HSD Special Arrangement, certain 'HSD hospital authorities' that would not ordinarily be approved hospital authorities are taken to be approved hospital authorities and thus are PBS approved suppliers (of HSD medicines).

This implements a recommendation made by the Pharmaceutical Benefits Advisory Committee (**PBAC**) out-of-session in March 2023. The recommendation arose following the PBAC's consideration of the Interim Report for the Post-market Review (**PMR**) of Opioid Dependence Treatment Program medicines. The Interim Report is available at www.pbs.gov.au/info/reviews/post-market-review-of-opiate-dependence-treatment-program.The inclusion of ODT medicines under the HSD Special Arrangement is intended to address the core issues of patient affordability and equitable access to ODT medicines through the PBS, such that access to PBS subsidised ODT medicines aligns with usual PBS arrangements including the PBS co-payment and safety net arrangements.

Secondly, it amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to increase the maximum dispensed quantity (**MDQ**) for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS.

These changes will commence on 1 September 2023, as the first of three stages of implementation of the MDQ measure. Stage 1 includes some medicines for chronic conditions such as cardiovascular disease, Crohn disease, gout, heart failure, high cholesterol, hypertension, osteoporosis, and ulcerative colitis.

Authority

Amendments to the HSD Special Arrangement

Subsection 100(1) of the Act enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to certain persons:

- living in isolated areas or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment;
- where the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(2) of the Act provides that the Minister may vary or revoke an arrangement made under subsection 100(1) of the Act.

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect, subject to a special arrangement made under subsection 100(1).

Amendments to the Main Listing Instrument

Section 84AF of the Act enables the Minister to determine the responsible person for a brand of a pharmaceutical item. The responsible person is to be the person who has notified the Minister they are, or will be, the person who is, or will be, the supplier of a particular brand of a pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand.

Section 84AK of the Act enables the Minister to determine the pack quantity for a brand of a pharmaceutical item.

Section 85 of the Act enables the Minister to:

- declare drugs and medicinal preparations to be drugs or medicinal preparations to which Part VII applies (subsection 85(2)). A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug';
- determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3));
- determine the manner of administration of a form of a listed drug (subsection 85(4));
- determine a brand of a pharmaceutical item (subsection 85(6));

- determine that a brand of a pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items, for the purposes of paragraph 103(2A)(b) of the Act (subsection 85(6A)); and
- determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit (subsection 85(7)).

Section 85A of the Act enables the Minister to:

- determine the maximum quantity or number of units of a pharmaceutical item in a pharmaceutical benefit that may, in one prescription, be directed to be supplied to a patient on one occasion (paragraph 85A(2)(a));
- determine the maximum number of occasions on which the supply of a pharmaceutical benefit may, in one prescription, be directed to be repeated (paragraph 85A(2)(b)); and
- determine that particular conditions must be satisfied when writing a prescription for the maximum quantities and repeats (subsection 85A(2A)).

Section 88 of the Act enables the Minister to determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)) and authorised nurse practitioners (subsection 88(1E)).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Background – Opioid Dependence Treatment

ODT medicines currently listed on the PBS include methadone oral liquid, buprenorphine sublingual tablets, buprenorphine with naloxone sublingual films and long-acting injectable buprenorphine.

State and territory governments operate individual ODT programs in their respective jurisdictions. These programs include patient eligibility criteria, take-away dosing policies, as well as the approval or authorisation of participating prescribers (medical practitioners and nurse practitioners) and dispensing (dosing) points for participation in individual jurisdictional programs. The operation of state and territory ODT programs are currently and will continue to be governed by the respective policies, guidelines and regulations within each jurisdiction. The provision of ODT medicines under the PBS is intended to operate in parallel with jurisdictional ODT programs.

ODT medicines are listed as controlled drugs in Schedule 8 of the Poisons Standard (*Therapeutic Goods (Poisons Standard-June 2023) Instrument 2023*, available at www.legislation.gov.au), and therefore have specific requirements for handling, storage, prescribing and dispensing which are given effect through the relevant state and territory legislation. Prescribers and suppliers such as pharmacies must comply

with the provisions of state and territory regulations for controlled drugs when prescribing and dispensing medicines for the treatment of opioid dependence.

Section 100 HSD Program community access arrangements

The Section 100 HSD Program, implemented through the HSD Special Arrangement, is a well-established program that provides access to specialised PBS medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied. The addition of ODT medicines does not change the broader Section 100 HSD Program policy.

Section 100 HSD Program community access arrangements, established in 2015, allow authorised community-based practitioners to prescribe certain HSD medicines on the PBS without the need to be affiliated with a hospital. Community pharmacists are able to dispense these medicines regardless of where the medicine is prescribed, in other words there is not a requirement that the patient be receiving treatment in, at, or from a public or private hospital.

Under the Section 100 HSD Program, PBS-eligible patients pay the PBS co-payment for the supply of their ODT medicines (usually for up to 28 days' supply per pharmaceutical benefit prescribed) and payments contribute towards their PBS Safety Net threshold. This includes eligible patients receiving treatment at, or from public hospitals as a day admitted patient, non-admitted patient or patient on discharge. PBS approved suppliers cannot charge patients additional private dispensing or dosing fees for the supply of their ODT medicine under the PBS.

Arrangements for supply of ODT medicines under the Section 100 HSD program

Arrangements for supply of ODT medicines under the HSD Special Arrangement will be similar to arrangements for other Section 100 HSD Program community access pharmaceutical benefits:

- PBS approved suppliers such as approved pharmacists will purchase stock of ODT medicines from their usual pharmaceutical distributor/wholesaler and submit claims for Commonwealth payment to Services Australia for supply of ODT medicines;
- prescriptions for supply of ODT medicines under the HSD Special Arrangement must be written by eligible prescribers (medical practitioners and PBS approved authorised nurse practitioners);
- PBS approved suppliers will receive the applicable dispensing fee, dangerous drug fee and Section 100 mark-up in addition to the approved ex-manufacturer price (**AEMP**) or proportional ex-manufacturer price (**PEMP**) for the pharmaceutical benefit.

Buprenorphine-containing ODT medicines will be prescribed and dispensed up to the maximum quantity, like the prescribing of other PBS medicines. This means if different strengths are prescribed and supplied, each strength will attract one PBS co-payment.

Methadone liquid will be prescribed and dispensed on a maximum millilitre (mL) basis per prescription (that is, a total quantity in mL for up to 28 days of the daily

dose amount). This means pharmacists and other approved suppliers will be able to continue to share a bottle of methadone between multiple patients in the process of administering a particular patient their full supply over the month, if necessary, given it is impractical for pharmacies to store a bottle per patient in a safe.

Up to 2 repeats will be able to be prescribed for ODT medicines (that is, 3 months total supply when including the original).

Similar to other PBS medicines, patients will be able to receive early supply of ODT medicines in some circumstances. If the minimum interval of 20 days has passed since the previous supply, the PBS co-payment amount will contribute to the patient's safety net threshold.

Prescribers are encouraged to prescribe only the quantities and repeats that are suitable for the patient's clinical needs (including during medication initiation) until their next review (to a maximum of 3 months). Where necessary, prescribers may prescribe different quantities (up to the maximum quantity) and strengths of ODT medicines to meet the patient's dosing requirements as clinically determined by the prescriber, particularly during initiation.

Similar to other Section 100 HSD Program community access medicines, prescriptions for ODT medicines will require a Streamlined Authority Code up to the listed maximum quantity. Approval for increased quantities may be sought through Services Australia for oral and sublingual formulations of ODT medicines in line with the PBAC recommendation. Prescribers can request approval for increased quantities through Services Australia either by calling telephone number 1800 888 333 or applying online at www.servicesaustralia.gov.au/hpos?context=22786.

Prescribers are also encouraged to continue to provide clear daily dosing instructions including dose variations and take away arrangements to the PBS approved supplier, to support the dose administration (staged supply) of these medicines to patients.

Arrangements for prisoner access to other pharmaceutical benefits supplied under the Section 100 HSD program have been in place for many years. The same arrangements will apply for ODT medicines. The HSD Special Arrangement expressly allows for PBS-subsidised ODT medicines to be supplied by approved pharmacists and approved hospital authorities through an 'agent', i.e., the site of administration, such as a correctional facility, medical practice, or clinic to make it abundantly clear that those PBS approved suppliers are not required to supply ODT medicines to patients directly.

Given the strict rules under state and territory legislation for the storage and supply of ODT medicines, where a PBS approved supplier wishes to supply an ODT medicine through an agent, the agent must be authorised by the relevant jurisdiction to supply ODT medicines. Therefore, authorised GP and other clinics can continue to offer treatment with ODT medicines, including long-acting injectable opiate substitution therapy (buprenorphine) by obtaining supplies through PBS approved suppliers. Commonwealth payment for supply of the ODT medicine will continue to be made to the approved supplier.

The amendments to the HSD Special Arrangement made by the Instrument will not affect the capacity of existing ODT clinics, authorised by state and territory governments to participate in ODT programs, to treat and provide clinical services to patients including Medicare-rebatable consultations or treatments. Medical practitioners and authorised nurse practitioners who are PBS prescribers will be able to prescribe ODT medicines for the purposes of the HSD Special Arrangement. However, authorised nurse practitioners will not be able to supply these medicines under the HSD Special Arrangement and a medical practitioner will only be able to supply an ODT medicine if they are also a PBS approved medical practitioner.

Transitional arrangements for ODT medicine prescriptions written before 1 July 2023
It will be impractical for all ODT patients to see their prescriber and obtain a new prescription on 1 July 2023 for supply on the same day without placing significant pressure on patients and prescribers. The Instrument therefore includes arrangements that will allow PBS approved suppliers to continue to supply patients their ODT medicines using their existing prescriptions, for a transitional period. Further information regarding transitional arrangements is available on the ODT medicine website at www.pbs.gov.au/browse/section100-md.

A transition period for prescriptions importantly ensures a patient can, from the day they first present on or after 1 July 2023, pay the relevant PBS co-payment, have the amount contribute to their PBS safety-net, and cease paying private fees for the staged supply of their medicines when accessed from a PBS approved supplier. A transition period will ensure patients continue to receive their doses without any disruption to their dosing schedule, allowing time for the patient to return to their prescriber for a PBS prescription. Prescriptions will maintain the original period of validity and duration which was prescribed (to a maximum of 3 months).

Electronic prescriptions written before 1 July 2023 will be dispensed differently during the transition period. This is because administrative systems do not support suppliers submitting claims for electronic ODT prescriptions written prior to 1 July 2023 in the usual way. While the patient's electronic prescription will remain valid (and should not be cancelled), for the purposes of suppliers submitting their PBS claim for payment, suppliers can submit their claim as if they had dispensed from a paper-based prescription. Alternatively, prescribers could temporarily consider using paper-based prescriptions for the transition period to avoid patients needing a new PBS electronic prescription on 1 July 2023. Prescribers will be able to provide new, PBS electronic prescriptions for ODT medicines from 1 July 2023.

In transitioning existing prescriptions to align with PBS claiming, pharmacists and other approved suppliers will calculate (as required) the maximum quantity (and any applicable repeats) remaining on the existing prescription in line with this Instrument. See Attachment B for further detail on transitional arrangements. Factsheets are available at www.pbs.gov.au/browse/section100-md.

Noting not all existing prescriptions eligible for transition arrangements may meet specific PBS requirements for dispensing and claiming systems, such as Authority Prescription Numbers and Authority Approval Numbers, these numbers have been provided in this amendment instrument to be used for the purposes of submitting claims for pre-commencement prescriptions written before 1 July 2023.

ODT Community Pharmacy Program

In addition to the movement of PBS supply of ODT medicines to the HSD Special Arrangement from 1 July 2023, funding of $377.3 million over 4 years from 2023-24 (and $98.4 million ongoing) was announced in the 2023-24 Budget to improve access to and affordability of ODT within the community pharmacy sector, by supporting the delivery of pharmacy services for people in treatment programs for opioid dependence. A new ODT Community Pharmacy Program will take effect from 1 July 2023 and will be administered by the Pharmacy Programs Administrator (**PPA**). The ODT Community Pharmacy Program will complement, but is not part of, PBS arrangements for the supply of ODT medicines.

Pharmacists will separately be able to submit claims for payment through the PPA website (www.ppaonline.com.au) for activities relating to in-house and take-away dosing.

Background – Maximum Dispensed Quantity

The MDQ is the maximum number or quantity of units of a pharmaceutical benefit that can be prescribed for a particular purpose for supply to a patient on the one occasion under the PBS. Currently, the MDQ for many PBS medicines used in the treatment of chronic medical conditions equates to one month's supply.

In December 2022, the PBAC considered and provided advice to the Minister for Health and Aged Care on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased quantity for selected PBS medicines - two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) of the PBS listed for use in treatment of chronic conditions for suitability for the proposal. Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that over 300 medicines were acceptable for listing with increased MDQ. The PBAC also agreed on standard restriction wording for all medicines included in this proposal, to ensure the higher MDQ items are only prescribed to patients whose condition is stable.

New PBS items with the increased MDQ will be included in the Schedule of Pharmaceutical Benefits in addition to the medicine's current PBS items that provide for one month's supply and five repeats (in general). This will facilitate prescribing of smaller quantities than the new MDQ for patients as clinically appropriate, to avoid medicine wastage and support closer clinical monitoring of patients where required.

The PBAC considered this proposal would allow clinicians to exercise greater choice to prescribe the increased MDQ if clinically appropriate and provide patients with both financial and convenience benefits. The PBAC also considered allowing either two or three months' supply for dispensing on the one occasion was safe for the list of recommended medicines and considered that the implementation of increased MDQ allowing two or three months' supply was a decision for the Australian Government.

The Minister for Health and Aged Care, announced the Government's intention to implement the two-month MDQ proposal on 26 April 2023 as part of the 2023-24 Budget. The PBAC's advice from December 2022, including a full list of the PBS items considered by PBAC as suitable for an increased MDQ, was published on the same day.

The Minister, in announcing the measure, highlighted the reforms would deliver important and immediate cost of living relief to Australians with chronic health conditions. The Minister announced the Government's decision to implement the policy in three stages, with increased MDQ applied to the first set of medicines from 1 September 2023, to the second set of medicines from March 2024 and to the remaining set of medicines from 1 September 2024. Phased introduction of MDQ will allow the pharmacy sector additional time to adjust to the new practices required to implement these changes.

Implementation of the first stage of MDQ has been designed to maximise the financial and convenience benefits for the greatest number of patients and to deliver these benefits at the earliest possible opportunity. The medicines in stage 1 include many high-volume PBS items for high blood pressure and high cholesterol, chronic medical conditions that affect many Australians.

An increase in the MDQ for certain medicines used in treating chronic conditions will improve access to and affordability of PBS medicines and build on the recent PBS General Patient Co-Payment reduction to $30 on 1 January 2023. It will also mean that patients with chronic, stable medical conditions will need to make less visits to a pharmacy and their prescriber for some common PBS medicines. It will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people. Recent public representations and discussion have indicated broad support from prescribers and consumers for the policy.

Evaluation of MDQ and stakeholder impacts

The Department has committed to developing a comprehensive evaluation framework that will monitor risks and provide mitigation strategies over the course of implementation. This will utilise existing data sources (including PBS claims data) to analyse uptake rates of increased MDQ items, medicine shortages, pharmacovigilance and medicine wastage.

Lower health care costs for patients and Government and maintenance of patient safety will be evaluated by reviewing the PBS statistics for MDQ PBS items. Once sufficient PBS data is available, the utilisation of the new MDQ PBS items and the quantity of medicine dispensed will be monitored and the savings for consumers will be quantified through research conducted by the PBS Post-Market Review program. These utilisation reviews would be considered by the Drug Utilisation Sub-Committee (**DUSC**) of the PBAC, and any concerns referred to the PBAC.

The Department's planned evaluation framework will utilise existing well-developed processes within the Therapeutic Goods Administration (**TGA**) and the PBS program to assess outcomes of the implementation of MDQ on patient safety, optimal use of medicines and to identify/evaluate any previously unreported adverse reactions to

MDQ medicines (pharmacovigilance). The TGA will continue to monitor all spontaneous reports of adverse medicine events and will inform the Department and the PBAC of any emerging trends in adverse reactions or medicine misuse associated with these medicines.

The Department has committed to evaluating the impacts of MDQ on all affected stakeholders through existing mechanisms. The impact on the community pharmacy sector remuneration and continued participation in community pharmacy programs will be monitored through the existing Seventh Community Pharmacy Agreement (**7CPA**). The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 7CPA. Evaluation of financial impacts will be dependent on affected stakeholders providing necessary financial information at a granular level. The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

Commencement

Sections 1 to 4 and Schedule 1 of the Instrument commence on 1 July 2023. Schedule 1 of the Instrument includes amendments to the HSD Special Arrangement to enable ODT medicines to be supplied as a community access medication under the Special Arrangement.

Schedule 2 commences on 1 September 2023. Schedule 2 amends the Main Listing Instrument to implement the first stage of the MDQ measure.

Consultation – Opioid Dependence Treatment

The amendments made by this Instrument to the HSD Special Arrangement accord with recommendations made by the PBAC.

The PMR, and the Interim Report from which the PBAC recommendation arose included multiple opportunities for consultation with stakeholders regarding the existing arrangements for ODT medicines. This included public consultation on the draft Terms of Reference (28 May – 30 June 2021), submissions to the review (17 August – 1 October 2021), a stakeholder forum (held 24 February 2022) and targeted consultation with patients participating in ODT programs (throughout November 2022). Consultation included written submissions to the PMR, a live stakeholder forum webinar as well as focus groups and individual interviews with consumers.

Consultation, including meetings and written correspondence, on the implementation of reform to ODT medicines and its move to supply under the HSD Special Arrangement occurred with key stakeholders including pharmacy organisations, prescriber organisations, consumer organisations, state and territory governments and pharmaceutical sponsors of ODT medicines. Specific organisations include the Pharmacy Guild of Australia (**Guild**), Pharmaceutical Society of Australia (**PSA**), the Society of Hospital Pharmacists of Australia (**SHPA**), Royal Australian College of General Practitioners (**RACGP**), National Aboriginal Community Controlled Health Organisation (**NACCHO**), Australian Injecting & Illicit Drug Users League and Harm Reduction Australia.

The Commonwealth has also been engaging regularly with jurisdictions on how to best support the transition to usual PBS arrangements and ensure continuity of care for patients, while allowing patients to access PBS support as quickly as possible to remove financial barriers to treatment.

Specific consultation on the Instrument as it relates to ODT medicines was held 5 – 9 June 2023 with jurisdictions and the key stakeholders mentioned above.

Overall, stakeholders are supportive of reforms to ODT medicines as this will bring ODT medicines in line with other medicines on the PBS and ensure affordable access to treatment for patients. Throughout the process of implementing reforms to ODT access, the most significant concerns were raised by various stakeholders regarding the implementation timeframe, communication and potential implications for state and territory dosing sites who are not PBS approved suppliers.

However, commencement of this amendment instrument from 1 July 2023 will benefit patients sooner so patients are no longer required to pay private dispensing fees to access ODT medicines. In addition, the current section 100 special arrangement for ODT medicines is not registered on the Federal Register of Legislation. On 1 July, the Act will be amended to expressly provide that section 100 special arrangements must be made by legislative instrument. The amendments made by the Instrument to transition arrangements for the PBS supply of ODT medicines to the HSD Special Arrangement will also mean that all special arrangements will be registered by 1 July 2023.

Communication activities, including website updates, supporting documents, meetings and correspondence with stakeholders, are ongoing and updated regularly to ensure the sector is prepared for the commencement of the reform on 1 July 2023.

In response to concerns regarding continuity of care for patients receiving treatment at non-PBS dosing sites, the Commonwealth is preparing a separate, time-limited Section 100 special arrangement to take effect from 1 July 2023 that will enable the Commonwealth to continue to pay for the cost of ODT medicines to pharmaceutical companies for supplies of ODT medicines to private clinics, non-PBS approved pharmacies and other non-PBS dosing sites for a transition period until 30 November 2023.

These transition arrangements will ensure patients can still access ODT medicines from their current non-PBS dosing sites while the states and territory governments transition patients to a PBS approved supplier. These transition arrangements will not apply to approved pharmacies, approved hospital authorities or approved medical practitioners who can start to supply ODT medicines to their patients under the HSD Special Arrangement from 1 July 2023.

Consultation – Maximum Dispensed Quantity

The PBAC is an independent expert body established under section 100A of the Act. The PBAC makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits and shall advise the Minister upon any other matter concerning the operation of the PBS referred to it by the Minister. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. An industry nominee was appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015.

In August 2018, the PBAC considered a proposal for prescribers to be given the choice to prescribe larger medicine quantities (two months' supply) for some patients who have chronic, stable medical conditions, for particular medicines listed on the PBS. The PBAC outcome statement related to this proposal was published by the Department in April 2019. The Department held discussions with the Pharmacy Guild of Australia (**Guild**) on the increased MDQ proposal as part of negotiations towards the 7CPA in 2018/19 and 2019/20. The Guild strongly opposed the proposal, which would reduce income for pharmacy owners. In March 2019, the Guild undertook an advertising campaign warning against any measures in the 2019/20 Budget that might disadvantage its members. The Government chose not to proceed with changes to the quantities for PBS medicines at that time.

Stakeholder views on the proposal have been well known to the Department since publication of the 2018 PBAC recommendation. Several stakeholders communicated publicly that they encouraged the Government to reconsider and implement this option, including the AMA and the RACGP.

In December 2022, the PBAC considered an updated list of general schedule PBS medicines indicated for the treatment of chronic medical conditions for their suitability for listing with increased MDQs up to two or three months' supply per dispensing.

The Minister for Health and Aged Care and the Department met with the Guild in March and April 2023 to discuss the changes.

The Department commenced implementation consultations with other affected stakeholders at the earliest opportunity following the Minister for Health and Aged Care's 26 April 2023 announcement and the publication of the December 2022 PBAC recommendations on the same day (Pharmaceutical Benefits Scheme (PBS) | Recommendations made by the PBAC – December 2022 Intracycle meeting).

Throughout May the Department met with the following stakeholders to discuss the increased MDQ package of measures:

- PSA;

- SHPA;
- PBS Online Software Developer Forum (which includes the Medicine Software Industry Association);
- Medicines Australia and separately with Generic Biosimilar Medicines Australia, both of whom represent medicines sponsors;
- Community Pharmacy Consultation Committee (Guild representatives only);
- Pharmacy Stakeholder Consultation Committee (made up of representatives from the Guild, PSA, NACCHO and Consumers Health Forum of Australia);
- National Pharmaceutical Services Association;
- Wholesale medicines distributors, Wesfarmers Health and DHL.

Recognising the concerns relating to the loss of remuneration from dispensing, the Government committed to reinvesting all savings accruing to government from the measure back into community pharmacy programs as part of the 2023-24 Budget. The Government is continuing to work with stakeholders including the Guild on ways to support the sector during the transition period for increased MDQ.

The Government has also committed to growing the role of community pharmacy in primary healthcare. Investment in expanded pharmacy programs will ensure consumers have greater and easier access to critical health services through their local community pharmacy. It will also advance the pharmacy profession to work at the top of their scope of practice.

Medicines in shortage have been a feature of the supply chain for a number of years. Medicine sponsors (manufacturers) must inform the TGA if there is not enough medicine to supply normal demand in Australia within the next six months. Since the 2019 introduction of mandatory reporting by medicine sponsors to the TGA, the number of new medicine shortages appearing each month on the TGA Medicine Shortage Reports Database has consistently averaged around 120 notifications.

The overall number of patients and volume of medicines prescribed will not change significantly due to an increase in the maximum quantity that can be supplied on a single occasion. For example, an eligible patient who would have received 12 months' supply of a medicine in 12 supplies each sufficient for one month's treatment, will now receive the same total amount of medicine in 6 supplies each sufficient for 2 months' treatment.

On 4 May 2023 in response to public concerns about the measure exacerbating shortages, Minister Butler wrote to Professor Andrew Wilson AO, Chair of the PBAC, requesting the Committee's advice whether the proposed MDQ changes would materially exacerbate medicine supply shortages that would impact on the ability for patients to access effective PBS treatments for their clinical conditions. On 8 May 2023, Professor Wilson responded of behalf of the PBAC, that the PBAC believes the concerns raised publicly present no reason to change its previous advice regarding increased maximum quantities for a range of medicines used to treat stable conditions. The PBAC considered the change can be safely implemented and will benefit people with stable medical conditions requiring long term use of the included

medicines. The PBAC noted that the number of patients and volume of medicines prescribed will not change significantly due to the policy, and that any shortages were likely to be short-term as the system adjusts to a new phased model of supply. The PBAC also noted that community pharmacists have already proven they are able to manage medicine shortages to ensure patients are able to remain on an equivalent medicine without impact on their care.

The former PBAC Chair Emeritus Professor Lloyd Sansom AO has also stated that he does not consider medicine supply shortages will be impacted by changes to the increased maximum dispensing quantity of certain medicines to treat stable chronic conditions. Professor Sansom commented that the staged introduction of the PBS changes and cooperation with medicine peak bodies Medicines Australia and the Generic and Biosimilar Medicines Association, will help ameliorate any demand concerns during early implementation.

In addition, the Government has taken steps to ensure on-shore stock holdings for many commonly used medicines for some of the most prevalent health conditions in the Australian community. From 1 July 2023, amendments made by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021* give effect to the commitments in the new Strategic Agreements with the medicines industry, which includes the Minimum Stockholding Requirements. The Minimum Stockholding Requirements are designed to help protect Australian patients, pharmacists, and prescribers from the impact of global medicines shortages. Medicine sponsors will be required to hold a minimum of either 4 or 6 months' of stock in Australia for certain PBS listed medicines, referred to as 'designated brands'. While these measures will not prevent shortages that are outside of the control of Australian companies, they will help to ensure that Australian medicine sponsors are better placed to continue supply when global disruptions occur. Greater buffers will allow time for supply disruptions to be resolved and ensure better continuity of supply for Australians, including through identifying alternative sources of supply (where possible). The investment by the medicines industry in managing supply chain risks through the minimum stockholding requirements has been supported through one-off price increases on 1 October 2022 and floor price protections for low-cost medicines.

The government has considered current shortages in determining the medicines included in Stage 1.

Medicines have been considered suitable for implementation of the increased MDQ measure on 1 September 2023, if they have premium-free alternative brands of the same form that are substitutable by the pharmacist (based on the shortages reported to TGA in one, or more, brands, of one, or more, forms at 14 June 2023).

A full list of the medicines and PBS item codes for which an increased MDQ will be implemented for all brands of pharmaceutical item listed on the PBS on 1 September 2023, is provided at Table 1 at Attachment B. The medicines and PBS item codes included in Table 1 have all been recommended by the PBAC for inclusion in the increased MDQ measure.

A small number of medicines recommended by the PBAC in December 2022 will not have increased MDQ listings implemented as they have been, or are in the process of

being, removed from the PBS by their sponsor companies. Some medicines recommended by the PBAC as suitable for an increased MDQ have a listing that allows prescribers, in certain circumstances, to prescribe one month's supply with 11 repeats, or similar (**12 month repeat listing**), rather than the standard one month's supply with 5 repeats. PBAC recommended that if the medicine was included in the MDQ measure, the 12 month repeat listing could be removed from the PBS (or amended to an increased MDQ listing). The medicine listings that currently give effect to the 12 month repeat measure will be amended to increased MDQ listings in two steps. In the first step, a new increased MDQ listing will be applied to each medicine alongside its existing listings. In the second step, the 12 month repeat listing will be made 'supply only' ahead of its eventual removal from the PBS (meaning supplies can continue to be made on existing prescriptions but new prescriptions under the 12 month repeat listing cannot be written). This stepwise approach ensures patients with 12 month repeat prescriptions valid beyond 1 September 2023 can continue to fill these prescriptions. The legislative changes needed to give effect to the second step will be brought forward in a later legislative instrument.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of the consultation process the Department and Services Australia have collaborated on required information technology system changes, including to ensure that software vendors receive data outputs with sufficient time to ensure prescribing and dispensing software can be updated for the 1 September 2023 commencement of the increased MDQ measure.

Regulation Impact Analysis

A Regulation Impact Analysis *Lowering the cost of medicines through changes to maximum dispensing quantities* (OIA ID: 22-03771) in relation to the MDQ measure was prepared by the Department and is at Attachment A.

The Office of Impact Analysis advised that a Regulation Impact Analysis was not required to be prepared in relation to the amendment to the HSD Special Arrangement to include supply of ODT medicines (OIA ID: 23-051100).

Incorporation by reference

The Instrument incorporates be reference the following legislative instruments, or provisions of the following legislative instruments:

- *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020;*
- *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017;*
- *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022;*
- *National Health (Listing of Pharmaceutical Benefits) Instrument 2012;*
- *National Health (Pharmaceutical Benefits) Regulations 2017.*

These instruments or relevant provisions of the instruments are all incorporated as in force from time to time and the instruments can be accessed free of charge on the Federal Register of Legislation at www.legislation.gov.au.

The Instrument also incorporates by reference the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance) (**Risk Calculator**) as part of eight 'circumstances codes' and 'purposes codes' in Schedule 4 of the Main Listing Instrument. These codes setting out the purposes for which and circumstances in which prescriptions for two months' supply of certain PBS items containing ezetimibe, ezetimibe and rosuvastatin, ezetimibe with atorvastatin and ezetimibe with simvastatin, respectively, can be written. The Risk Calculator can be used to find out a person's absolute 'heart and stroke' risk score and chance of getting heart, stroke and blood vessel disease in the next five years. The Instrument specifies that the Risk Calculator is incorporated as in force on 1 April 2018. The Risk Calculator can be accessed free of charge at https://www.cvdcheck.org.au/calculator. The reference to the Risk Calculator already appears in circumstances codes for one month's supply of these benefits.

Details of the Instrument are at Attachment B.

The human rights statement of compatibility is at Attachment C. The statement of compatibility concludes the Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

ATTACHMENT A

IMPACT ANALYSIS

LOWERING THE COSTS OF MEDICINES THROUGH CHANGES TO MAXIMUM DISPENSING QUANTITIES

OFFICE OF IMPACT ANALYSIS ID: 22-03771

Contents

Executive Summary

This proposal will enable consumers to have an increased maximum dispensed quantity (MDQ) of certain Pharmaceutical Benefits Scheme (PBS) medicines, used for many common and chronic diseases as recommended by the independent Pharmaceutical Benefits Advisory Committee (PBAC).

There are three options for consideration:

i. Make no change to MDQ of one month's supply;

ii. Increase the MDQ to two months' supply; or

iii. Increase the MDQ to three months' supply.

The Impact Analysis contained in this document was prepared in line with the *Australian Government Guide to Policy Impact Analysis*[1] to inform consideration of the proposal in the 2023-24 Budget. Financial estimates in this Impact Analysis assume that Option 2 or Option 3 would be implemented on a single date in 2023-24.

The Hon Mark Butler MP, Minister for Health and Aged Care, announced the Government's decision to implement this proposal on 26 April 2023.[2] The Minister announced the Government's decision to implement this policy in three stages, with the first operating from 1 September 2023, the second from March 2024 and the third stage from 1 September 2024.[3]

An increase in MDQ for certain medicines treating chronic conditions will improve access to and affordability of PBS medicines and build on the recent PBS General Patient Co-Payment reduction to $30 on 1 January 2023. An increase to the MDQ will mean that consumers with chronic, stable medical conditions will need to make less visits to a pharmacy to fill their prescriptions for some common PBS medicines. This will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people.

For example, under the **two month** maximum dispensing quantity option:

i. Concessional beneficiaries (non-Safety Net) currently pay $14.60 for two months' supply for medicines requiring a monthly prescription (two co-payments of $7.30). If this proposal is accepted they will only pay $7.30 for two months' supply of the same medicines. For a patient who needs 12 months' supply of medicine every year and does not reach the PBS concessional Safety Net, after the MDQ changes they will save up to $43.80 per year per medicine.

[1] https://oia.pmc.gov.au/sites/default/files/2023-02/oia-impact-analysis-guide-nov-22.pdf

[2] https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/cheaper-medicines-to-ease-cost-of-living?language=en

[3] https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-26-april-2023?language=en

ii. General beneficiaries (non-Safety Net) currently pay up to $30 per prescription for their PBS medicines. Some medicines are priced below the general PBS co-payment, however for those medicines that require 12 prescriptions per year and where the dispensed price of the medicine exceeds $30, general beneficiaries could save up to $180 per year per medicine.

This proposal, if adopted by clinicians and consumers, will reduce the volume of PBS dispensing by pharmacies. Pharmacy owners will receive significantly less PBS income due to the decrease in the volume of dispensing related remuneration resulting from the proposed PBS changes. This includes less dispensing payments from the Government and fewer co-payments by patients. However, pharmacy remuneration for all other medicines and from other sources (e.g. commercial sales) will continue.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. The Government's decision to implement this proposal in three stages may lessen the immediate financial impact on individual pharmacies and allow time for businesses to adjust to changes in revenue. The estimated average impact per pharmacy in the first year of implementation based on the Government's decision to implement this proposal in three stages may be up to $49,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 6% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be $775,000 in the first year). For the two month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to $158,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be $867,000 in the fourth year). For the three month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to $210,000 reduction in Government remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be $867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, but is the focus of the financial analysis presented.

This proposal supports consumers to access medicines at lower prices, addressing cost of living pressures. In total, it is estimated that patients who are prescribed prescriptions that allow 2 months' supply per dispense will save around $540 million in PBS patient contributions in 2026-27, and approximately $1.8 billion between 2023-24 and 2026-27. For the 3 month option, the total estimated save to patients is $740 million in PBS patient contributions in 2026-27, and approximately $2.5 billion between 2023-24 and 2026-27. These financial estimates assume a single implementation date of all MDQ changes in 2023-24 and the Government's decision to implement this proposal in three stages may lessen the immediate savings to

patients. Once fully implemented, some patients using MDQ medicines (approximately 1.8 million per year) may avoid visits to a general practitioner (GP) or other prescriber solely for the purpose of obtaining repeat prescriptions for medicines covered under the proposal.

It will also provide savings to Government to reinvest in other priorities by reducing dispensing related remuneration paid to pharmacy owners, which will help to keep the costs of the PBS sustainable.

The Government intends to reinvest savings from the proposal to support the development of new, and expansion of existing programs and services by community pharmacy. This will also help to practically expand the scope of practice for community pharmacists, as well as supporting more clinical services for patients in pharmacy. This includes proposals that seek to increase funding to pharmacy programs over the term of the Seventh Community Pharmacy Agreement (7CPA), fund community pharmacies for the administration of vaccines under the National Immunisation Program (NIP) and provide additional support to remote and regional pharmacies.

Background

1.1 The PBS

The PBS is a national, Government-funded scheme that subsidises the cost of a wide range of medicines for all Australians to help them afford effective treatments. The PBS lists all the medicinal products available under the scheme and explains the conditions for which they can be subsidised.[4]

The PBS is a key program supporting delivery of the Government's National Medicines Policy (NMP)[5] which aims to "focus on achieving positive health results that matter to people and their communities and make sure all Australians have timely, safe and reliable access to effective, high-quality medicines." The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement are also eligible to access the Scheme.

The operation of the PBS is established by the *National Health Act 1953* (the Act). This Act establishes the responsibility of the statutory independent expert advisory committee, the PBAC, in its primary role of recommending, to the Minister for Health and Aged Care, which medicines and medicinal preparations should be subsidised under the PBS and which vaccines are subsidised under the National Immunisation Program.

Under the PBS, the Australian Government subsidises the cost of medicine for most medical conditions. Most PBS medicines are dispensed by community pharmacies and used by patients at home. These are known as 'General Schedule' or 'section 85' medicines because **section 85** of the Act establishes the ability for the Minister for Health and Aged Care to list medicines on the PBS and for the Commonwealth to supply the pharmaceutical benefit.

In addition to the medicines and medicinal preparations available under normal PBS arrangements (section 85), a number of medicines are also available as pharmaceutical benefits but are distributed under alternative arrangements. Section 100 of the Act provides for alternative ways of providing a medicine when the usual supply through community pharmacies is unsuitable. There are several programs funded under this provision including the Highly Specialised Drugs Program; the Botulinum Toxin Program; the Human Growth Hormone Program; and the IVF program.

[4] https://www.health.gov.au/sites/default/files/documents/2019/10/department-of-health-annual-report-2018-19_0.pdf
[5] National Medicines Policy | Australian Government Department of Health and Aged Care

The Government pays pharmacists to procure, supply and dispense all PBS medicines to consumers throughout Australia. A dispensing fee paid to pharmacists is set by the Government and forms part of the total price paid for a PBS medicine. The dispensing fee is adjusted on the first of July each year.

The cost of a medicine is negotiated between the government and the supplier of the medicine. The agreed price becomes the basis of the dispensed price of the medicine. Pharmacists purchase PBS-listed medicines from the wholesaler or supplier. The price of the medicine to pharmacy includes the wholesaler's mark-up. The Dispensed Price for Maximum Quantity (DPMQ) listed on the PBS website is the price for dispensing the maximum quantity of a product under a given prescribing rule. The DPMQ incorporates the approved ex-manufacturer price (AEMP) and all relevant dispensing fees and mark-ups (wholesale and pharmacy). Pharmacists claim the difference between the dispensed price and the patient co-payment contribution from Services Australia.

The PBS Schedule lists all of the medicines available to be prescribed and dispensed to patients at a Government-subsidised price. The Schedule is part of the wider PBS managed by the Department of Health and Aged Care and administered by Services Australia. This schedule is published online and updated on a monthly basis. The online searchable version contains:

- all of the medicines listed on the PBS
- the form, strength, quantity of medicines supplied and number of prescription repeats allowed
- information on the conditions of use for the prescribing of PBS medicines
- detailed consumer information for medicines that have been prescribed by their doctor or dentist
- what consumers can expect to pay for medicines.

1.2 The role of the PBAC

The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives. When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments.

A new medicine cannot be listed on the PBS unless the PBAC makes a positive recommendation for its listing. Under **section 101** the Act, the PBAC must take into account both the cost and clinical effectiveness of the medicine when compared

with other treatments for the same condition. The PBAC recommends maximum quantities and repeats of a pharmaceutical benefit or pharmaceutical item. Under Part VII, Division 1, of the Act, the maximum quantity (MQ) is the 'quantity or number of units of that pharmaceutical benefit or pharmaceutical item that is determined by the Minister, under paragraph 85A(2)(a), to be the maximum quantity, or the maximum number of units, of that pharmaceutical benefit or pharmaceutical item that may, in one prescription, be directed to be supplied on any one occasion.[6]

1.3 Which medicines does the government subsidise?

The Government subsidises medicines that are necessary to maintain the health of the community in a way that is cost-effective. This is achieved by carefully assessing the therapeutic benefits and costs of medicines, including comparisons with other treatments where appropriate. If a medicine is found to be acceptably cost-effective, then government negotiates its price with the supplier.

The PBAC[7] has a broad statutory function under the Act, to advise the Minister for Health and Aged Care on any matters concerning the operation of the PBS, which includes making further recommendations regarding the safety, effectiveness, and cost-effectiveness of medicines after they have been listed.

The PBAC is responsible for evaluating the clinical and cost-effectiveness of medicines in order to make recommendations relating to listing on the PBS. Recommendations for new listings are informed by evidence of a medicine's clinical effectiveness (how well it works), safety, and cost-effectiveness ('value for money') compared with other treatments for a particular group of patients with a health condition, including but not limited to other medicines to treat those patients for that condition.

The PBS covers life-saving and life-changing medicines across a broad range of conditions, from asthma and arthritis to diabetes and cancer. The PBAC takes into account if the medicine will affect the use of other healthcare and related resources (e.g. reduced GP visits, shorter or no hospitalisation, improved quality of life etc.). A cost-effective and clinically-effective PBS medicine may reduce expenditure in other areas of the healthcare system.

1.4 What are the current patient fees and charges?

To help meet the cost of the scheme, patients pay a 'co-payment' for PBS medicines and the Government pays the remainder of the listed cost. Many PBS medicines cost significantly more than the co-payment amount. From 1 January 2023, the general

[6] https://www.legislation.gov.au/Details/C2020C00062

[7] Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee, Version 5.0 (pbs.gov.au)

beneficiary patient co-payment was reduced from $42.50 to $30.00. Also from 1 January 2023, medicines for general patients with a dispensed price between $30.00 and $45.60 may be discounted to any price (including a price below $30.00). Patients may pay up to $30.00 for most PBS medicines or $7.30 if they are a concession card holder. Co-payment amounts are adjusted in line with indexation on 1 January each year.

Since 1 January 2016, pharmacists may choose to discount the PBS patient co-payment by up to $1.00. This is not mandatory and it is the pharmacist's choice whether or not to provide a discount.

1.5 The PBS Safety Net supports patients with high medicine costs

The PBS Safety Net protects patients and their families requiring a large number of PBS or Repatriation PBS (RPBS) medicines. The Safety Net threshold is reached by accumulating eligible patient contributions for PBS or RPBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient and their family reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the remainder of that calendar year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

As at 1 January 2023, the Safety Net thresholds were $262.80 (for concession card holders) and $1,563.50 (for all general beneficiary patients). After reaching the Safety Net threshold, general patients pay for subsequent PBS prescriptions at the concessional co-payment rate and concession card holders are not charged the PBS co-payment for medicines dispensed over the remainder of that calendar year.

1.6 Seventh Community Pharmacy Agreement (7CPA)[8]

The Seventh Community Pharmacy Agreement (7CPA) is an agreement between the Commonwealth of Australia, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. It supports consumer access to PBS subsidised medicines through community pharmacies across Australia.

The 7CPA has an overall funding envelope of $18.35 billion, comprising:

- $16.00 billion in estimated pharmacy remuneration for dispensing PBS subsidised medicines
- $1.20 billion for professional pharmacy programs

- $1.15 billion for the Community Service Obligation and National Diabetes Services Scheme product distribution arrangements.

The 7CPA commenced 1 July 2020 and will be in place until 30 June 2025.

The 7CPA[9] recognises that community pharmacy is an integral part of the Australian health care system through its role in supporting the PBS, and can provide a broader range of clinical services to the community beyond medicine dispensing services. To further support Australians' access to PBS and RPBS medicines and appropriately remunerating community pharmacy for services, the signatories to the agreement are committed to:

1. Ensuring Australians have access to patient focused, outcome oriented professional pharmacy services and programs that support the safe and quality use of medicines

2. Predictable remuneration for community pharmacies to support their viability and allow for an efficient and effective network of approved pharmacies and pharmacists across Australia, while ensuring the proper use of public resources

3. Ensuring that out of pocket expenses for PBS and pharmacy programs are transparent and appropriate

4. Maintaining a co-operative relationship between the signatories and a broader more inclusive set of key stakeholders, to ensure that Australian patients receive the best possible outcomes from the PBS and associated community pharmacy programs.

The delivery of professional pharmacy programs is forecast to expend more than the agreed $1.2 billion. This proposal is part of a package of measures seeking to re-invest savings realised by implementation of changes in maximum dispensing quantities for medicines, as recommended by the PBAC, back into the community pharmacy to support the delivery of new and expanded services by pharmacy. This includes proposals that seek to increase funding for pharmacy programs over the term of the 7CPA, fund the administration of vaccines under the National Immunisation Program (NIP) by pharmacies and provide additional support to remote and regional pharmacies.

1.7 Current PBS fees, co-payment and safety net arrangements

The co-payment arrangements help to ensure that medicines remain affordable and are valued by patients, improving sustainability of the PBS. The full cost of medicines is shown on pbs.gov.au. The full cost is also shown on the dispensing label. The

[9] 7CPA-signed-Agreement.pdf (pbs.gov.au)

following fees, patient contributions and Safety Net thresholds apply as at 1 January 2023 are included, where applicable, in prices published in the Schedule.

Table 1.1 PBS Fees, Patient Contributions and Safety Net Thresholds 1 January 2023

Dispensing Fees:	Ready-prepared	$7.82
	Dangerous drug fee	$4.84
	Extemporaneously-prepared	$9.86
	Allowable additional patient charge*	$3.29
Administration, Handling and Infrastructure Fee (AHI Fee):	Tier One: For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than $100	$4.32 per dispense of Maximum Quantity
	Tier Two: 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: 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.
Additional Fees (for Safety Net prices):	Ready-prepared	$1.31
	Extemporaneously-prepared	$1.68
Wholesale Mark-Up:	When 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
Patient Co-payments:	General (maximum)	$30.00
	Concessional	$7.30
Safety Net Thresholds:	General	$1,563.50
	Concessional	$262.80
Safety Net Card Issue Fee:		$11.42

Source: http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment amount. The pharmacist may charge general patients the allowable

additional fee but the fee cannot take the cost of the prescription above the general patient co-payment amount for the medicine.

1.8 PBAC Recommendation

In August 2018, the PBAC considered a proposal for doctors to be given the choice to prescribe larger medicine quantities (two months' supply) for some patients who have chronic stable medical conditions, for particular medicines listed on the PBS. The PBAC outcome statement related to this proposal was published by the Department of Health.[10] The Government did not proceed with changes to the quantities for PBS medicines at that time.

In December 2022, the PBAC considered and provided advice on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased dispensed quantity for selected PBS medicines; two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) listed for use in chronic conditions for suitability for the proposal. Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that some 300 plus medicines were acceptable for listing with increased maximum quantities. The PBAC also agreed on a criterion and standard restriction wording for all medicines included in this proposal, to ensure the higher maximum dispensed quantity items are only prescribed to patients whose condition is stable. The PBS items with the increased maximum dispensed quantities would be in addition to the medicine's corresponding current PBS items that provide one month's supply and five repeats. Prescriptions for smaller quantities could still be prescribed for patients as clinically appropriate, avoiding medicine wastage and supporting closer clinical monitoring of patients where required.

The PBAC considered that this proposal would allow clinicians to exercise greater choice and provide patients both financial and convenience benefits through choosing to prescribe the increased maximum quantity if clinically appropriate. The PBAC also considered that allowing two or three months' supply per dispensing was safe for the list of recommended medicines and that the implementation of increased maximum quantities allowing two or three months' supply was a decision for Government. The PBAC did not express a preference for either option and considered that allowing two or three months' supply per dispensing was safe for the list of recommended medicines.

The list of medicines recommended by the PBAC as suitable for increased maximum dispensed quantities includes medicines for asthma, cardiovascular disease, chronic

[10] http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2018-08/Outcome-Statement-August-2018-Increased-MDQ.pdf

obstructive pulmonary disease (COPD), constipation, chronic renal failure, Crohn disease, depression, diabetes, epilepsy, eye drops for glaucoma and dry eyes, gout, heart failure, high cholesterol, hormonal replacement and modulation therapy, hypertension, osteoporosis, Parkinson disease and ulcerative colitis. There are some medicines for conditions that require frequent clinical monitoring or dose titration that are not considered by PBAC as safe and suitable for dispensing in higher quantities.

The PBAC outcome statement from December 2022[11] and list of medicines recommended by the PBAC for an increase in MDQ[12] was published at pbs.gov.au.

[11] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2022-12/december-2022-pbac-web-outcomes-other-matters.pdf
[12] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2022-12/Increased-Dispensing-Quantities-List-of-Medicines.pdf

Impact Analysis

1. What is the problem this proposal will solve?

Cost of living pressures

The PBS, funded by the Australian Government, subsidises the cost of most prescription medicines for all eligible Australians. Consumers pay a PBS co-payment to the pharmacist for each dispensing of their medicine. Following changes introduced on 1 January 2023, the PBS co-payment is $7.30 for concessional patients and $30 for general patients per dispensing.

Researchers[13] [14] and consumers have raised concerns regarding the monthly cost of PBS medicines. In November 2019, the Consumers Health Forum of Australia stated that reducing the requirement for consumers on routine medication to visit a pharmacy each month would improve accessibility, convenience and affordability for consumers.[15]

Research suggests that 1 in 5 Australians aged 18-64 find prescription medicines to be unaffordable and that more than 900,000 Australians delayed or did not fill their prescriptions due to cost in 2019-2020.[16] The Australian Bureau of Statistics Report, *Patient Experiences* (2021-22)[17] found over 771,000 Australians did not fill their prescriptions or delayed having their prescribed medicine dispensed due to cost. The proportion of people who delayed or did not get prescription medication when needed due to cost increased to 5.6% in 2021-22, from 4.4% in 2020-21. In addition, those Australians with a long-term health condition were more likely to delay or not get prescription medication dispensed due to cost than those without a long term health condition (6.4% compared to 3.8%).

The Australian Patient's Association (APA) 2022 Australian Healthcare Index Report[18] showed that of people taking prescription medicine, 24% disagreed when asked whether medicine was affordable to them, increased from 19% in the previous survey (October 2021)[19]. The medicines affordability issue is a concern for both the non-concessional (largely under 65) population and the older population, with 29%

[13] https://www.yourlifechoices.com.au/health/news/paying-too-much-for-meds
[14] Not so universal: How to reduce out-of-pocket healthcare payments - Grattan Institute
[15] https://chf.org.au/media-releases/open-pharmacy-agreement-give-consumers-better-deal
[16] https://www.patients.org.au/affordable-medicines-now/
[17] Australian Bureau of Statistics (2021-22), Patient Experiences, ABS Website, accessed 18 January 2023.
[18] https://australianhealthcareindex.com.au/australian-healthcare-index-june-2022-report/
[19] Australian-Healthcare-Index-Report-2-October-2021.pdf (australianhealthcareindex.com.au)

of people aged 50 to 64 disagreeing that medicines were affordable, along with 13% of people aged 65 or over.

People with chronic health conditions have an ongoing burden of health care costs. If they do not take their medicines because they cannot afford to fill a prescription their condition is likely to deteriorate, which impacts not only the individual through a change in clinical outcomes, quality of life, and the ability to earn an income, but also on the taxpayers and the broader economy. When people are unwell they need more health services and cannot contribute productively to the economy.

Access and convenience

Patients in the community, who have chronic medical conditions and are prescribed medicines listed on the PBS, obtain their medication through community pharmacies. A valid PBS prescription for a chronic condition usually provides six months of medication supply, dispensed monthly by the pharmacist. This means patients with a chronic stable condition are required to visit their doctor every six months to obtain a new prescription.

While there are some exemptions to reduce the burden on consumers to return to the pharmacy to access prescription medicines, these are limited in scope. Under current PBS regulations, original prescriptions and the maximum number of repeat supplies allowed of pharmaceutical benefits can only be supplied at the one time if a prescriber is satisfied that the maximum dispensing quantity is insufficient for the patient's treatment; the patient has a chronic illness and lives in a remote area where access to PBS supplies is limited; or the patient would suffer great hardship trying to get the pharmaceutical benefit on separate occasions. A co-payment is still required for each original and repeat supply of the PBS medicine. For example, a single month’s supply of simvastatin 10 mg tablets would cost a concessional patient one co-payment of $7.30. If the patient filled five repeat prescriptions on separate occasions, six months’ supply of the medicine would cost 6 x $7.30 = $43.80. If the pharmacy applied the optional $1 discount at each dispensing, the cost reduces to $37.80. If the same patient satisfies the conditions above and receives the same medicine and has the original prescription and five repeats dispensed at the one time, the cost would still be 6 x $7.30 = $43.80 or $37.80 if the $1 discount per dispensing is applied.

Through the MBS Review[20], the CHF raised consumer concerns about patient access to repeat prescriptions for continuing medications and that the current PBS restrictions limited flexibility with regard to prescriptions for medicines to treat many chronic conditions.

[20] https://www1.health.gov.au/internet/main/publishing.nsf/Content/MBSR-about
https://www1.health.gov.au/internet/main/publishing.nsf/Content/MBSR-about

Sustainability of the PBS

The cost of the PBS is expected to continue to grow, and this will put increased pressure on the health budget.[21] Total PBS Government expense for the supply of medicines for the 2021-22 financial year was $14.7 billion (excluding revenue from rebates paid to Government for medicines with special pricing arrangements and/or risk sharing arrangements), compared with $13.8 billion for the previous year. This is an increase of 6.7%.[22] To ensure the ongoing sustainability of the PBS, both the medicines subsidised and the programs through which medicines are supplied and accessed are reviewed regularly by Government.

[21] https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/Impact%20of%20PBS%20Reform%20Report%203.pdf

[22] https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-1-july-2021-to-30-june-2022#:~:text=Summary%20of%20Pharmaceutical%20Benefits%20Scheme%202021-22%20Total%20Pharmaceutical,compared%20with%20%2413.8%20billion%20for%20the%20previous%20year

2. Why is government action needed?

The central pillars of the refreshed 2022 National Medicines Policy[23] are:

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

The intended outcome of the first pillar is that medicines and medicine 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. Ensuring equity of access to medicines and medicine-related services for all Australians involves considering effectiveness, safety, affordability and the health, social and economic benefits. The Australian Government provides subsidised access to medicines and vaccines through the PBS, the RPBS and the NIP. Medicines are also accessed through public and private hospitals, clinical trials, compassionate access programs, or privately purchased (including non-prescription medicines). This is supported by access arrangements between federal, state and territory governments for certain technologies.

The Australian Government is solely responsible for the administration and management of the PBS, to provide timely, reliable and affordable access to necessary medicines for Australians at a cost the community can afford. The Government takes advice from medical experts, including those on the PBAC, on all medical and medicine matters related to the PBS, and makes the final decision on the implementation and timing of PBAC recommendations.
The Government is committed to:

- Convenient and affordable access for consumers to PBS medicines for many chronic conditions
- Lower healthcare costs for consumers and Government without compromising patient safety
- Improvements to the PBS to provide more choice for doctors and consumers
- Consistently implementing the recommendations of the independent PBAC
- Maintaining the sustainability of the PBS.

[23] National Medicines Policy | Australian Government Department of Health and Aged Care

There are some constraints to the Government taking action. There is a risk that the proposal will raise concerns for pharmacy stakeholders. However, based on recent public representations and discussion, the proposal has support from prescribers and consumers and will reduce the out of pocket costs of PBS medicines for millions of Australians. A comprehensive public education campaign will be required to clearly explain how the changes will work for patients and how these PBS changes will interact with other PBS policy and legislation, including the PBS safety net. This will also explain the expanded role for pharmacies in the delivery of clinical services and programs, which will also support the viability of this important part of the health care system. Consumers with chronic conditions will need to be informed and encouraged to raise this opportunity to be considered for a prescription for an increased MDQ for their medicine with their prescriber.

Prescribing and dispensing software vendors will be consulted prior to implementation of the proposal to ensure the new arrangements will be reflected in the software update from the start date. Inclusion of the large volume of PBS Schedule changes (new PBS items and amended PBS items) into one monthly software update may mean that other PBS changes may not be progressed in that specific PBS listing month. This will allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

3. What policy options are you considering?

The Government is considering the advice provided by the PBAC to increase the maximum dispensed quantities of certain PBS medicines.

The options being considered in this Impact Analysis are:

- Option 1 - maintain the status quo
- Option 2 - Implement MDQ changes for medicines - 2 months' supply
- Option 3 - Implement MDQ changes for medicines - 3 months' supply

Option 1: Status quo

- In general, one month's supply of PBS medicine per dispense by a pharmacist.
- Each prescription provides six months' supply of medicine, there will be six dispense events per prescription.

Stakeholder roles and responsibilities

Consumers

- Under the status quo, there is no change to existing process. Consumers will visit a pharmacy each month to have their prescription dispensed and visit the GP or other prescriber for a new prescription every six months, depending on the medicines they take and the stability of their medical conditions.
- Reduced access to pharmacy programs to cut program expenditure on programs such as Dose Administration Aids and Medication Management Reviews to the level agreed in the 7CPA.

Pharmacies

- Pharmaceutical benefits are mainly supplied by approved pharmacists, who are approved to dispense medicines from particular pharmacy premises. All approved pharmacists are subject to certain conditions under the Act related to pricing, record keeping, supply and advertising. The roles of the prescriber and dispensing pharmacist are complementary and these health care professionals work together to improve patient outcomes.[24]
- Under the status quo, there is no change to existing process. Pharmacies will receive a dispensing fee ($7.82)[25] plus an Administration, Handling and Infrastructure (AHI) fee per dispense of a month's supply of medicine. The AHI fee ranges from Tier One: $4.32 to Tier Three: $4.32 + $95 per dispense of

[24] Collaboration between doctors and pharmacists in the community - Australian Prescriber (nps.org.au)
[25] As at 1 January 2023 pbs.gov.au

Maximum Quantity (the tier dependent on the price of the medicine to pharmacy).[26]

- There is no expected change in prescription volumes dispensed.
- No redirection of dispensing cost savings to support expanded scope of practice and the delivery of new and expanded services and programs in community pharmacy. The current level of programs being delivered under the 7CPA will need to be reduced to fit within the $1.2 billion envelope available under the 7CPA.

Prescribers[27]

- Pharmaceutical benefits can only be prescribed by doctors, dentists, optometrists, midwives and nurse practitioners who are approved under the Act. The roles of the prescriber and dispensing pharmacist are complementary and these health care professionals work together to improve patient outcomes.
- Under the status quo, there is no change to existing process. Prescribers can prescribe one month's supply per dispensing and up to six months' supply of a medicine per prescription (in general) for medicines to treat chronic stable conditions.

Government

- There is no change to existing process and no change in PBS or 7CPA expenditure. The Government continues to pay pharmacies handling fees for monthly dispensing of PBS medicines. No change to the numbers of consumers reaching the PBS Safety Net threshold in a calendar year.

Software vendors

- There is no change to the business as usual monthly prescribing and dispensing software updates.

Services Australia and the Department of Health and Aged Care

- There is no change to business as usual monthly listing processes. Changes and additions to the PBS can be progressed as usual.

[27] The PBS items subject to the MDQ changes can be prescribed by medical practitioners, nurse practitioners and optometrists, the permitted prescriber for each PBS item is noted in the PBS Schedule.

Medicine sponsors

- A sponsor[28] is a person or company who does one or more of the following: exports therapeutic goods (medicines) from Australia, imports therapeutic goods into Australia, manufactures therapeutic goods for supply in Australia or elsewhere, arranges for another party to import, export or manufacture therapeutic goods. The sponsor is responsible for applying to the Therapeutic Goods Administration (TGA) to have their medicine included on the Australian Register of Therapeutic Goods (ARTG) and for making an application to the PBAC to list their medicine on the PBS.
- Sponsors will not be required to change Australian on shore stock for certain PBS medicines.

Pharmacy wholesalers[29]

- Pharmaceutical wholesalers maintain distribution facilities for medicines and are the link between sponsors of medicines and community pharmacies where the medicines are dispensed to patients.
- Pharmaceutical wholesalers will not be required to change current stock levels or experience reductions in remuneration through legislated wholesaler mark ups.

Option 2: Implement MDQ changes for medicines – 2 months' supply

- If a patient's condition is stable and suitable for the increased MDQ, a prescriber may provide a prescription for 2 months' supply of some PBS medicines per dispense.
- Each prescription with the increased MDQ will supply approximately 12 months' medicine - as there will be six dispense events, each providing 2 months' of medicine supply per prescription.
- New and amended items will be listed on the PBS schedule with an increased MDQ sufficient to last the patient approximately 2 months, and in most cases the prescription will have the same number of repeats i.e. one original and 5 repeats.
- It is necessary to list new PBS items as the PBAC has explicitly recommended that the increased MDQ listing for medicines in the proposal are in addition

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28 Role of the sponsor | Therapeutic Goods Administration (TGA)

29 www.npsa.org.au/#:~:text=The%20Pharmaceutical%20Wholesale%20Industry%20is%20a%20vital%20part,–%20pharmacies%20where%20they%20are%20dispensed%20to%20patients

to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.

- These changes to the PBS will be made to the Schedule at the same time.
- The savings to Government made possible by Option 2 will support programs and services provided to patients under the 7CPA, including higher volume of existing programs, higher payments under the Regional Pharmacy Maintenance Allowance and new programs, including funding for administration of NIP vaccines to eligible patients in community pharmacies.

Stakeholders and roles and responsibilities

Consumers

- Consumers will experience lower costs for accessing medicines they need to manage their chronic conditions. This is because patients will pay fewer co-payments (approximately half for each medicine with increased MDQ) or if the medicine is priced under the co-payment, one dispensing and AHI fee for two months' supply instead of one months' supply as currently occurs under Option 1.
- Some consumers would need to visit a pharmacy every second month instead of each month to have their prescription dispensed and may reduce their GP visits depending on the medicines they take and the stability of their medical conditions.
- Consumers who only take medicines subject to the MDQ changes may only be required to visit their GP once a year for a new prescription instead of the current situation where they need to obtain a new prescription every 6 months.
- Consumers will continue to benefit from services and programs provided by community pharmacies, including services such as Dose Administration Aids, Medication Reviews and vaccine administration under the NIP, due to re-investment of some of the Government save into these Programs.

Pharmacies

- Pharmacies will receive a dispensing fee ($7.82)[30] plus an Administration, Handling and Infrastructure (AHI) fee per dispense of two months' supply of a PBS medicine (Range: Tier One: $4.32 to Tier Three: $4.32 + $95 per dispense of the maximum quantity). The tier is dependent on the price of the medicine to pharmacy.[31]
- Business as usual monthly dispensing software update will incorporate new and amended PBS medicine items.
- Increased level of stocks my need to be held to fulfil increased maximum quantity prescriptions.
- Pharmacies may experience temporary changes to cash flow to purchase an increased stock level during the initial implementation phase.
- Pharmacies will be able to offer more professional services under Government-funded programs, including more patient services under existing 7CPA programs and under new programs which will expand the

[30] As at 1 January 2023 pbs.gov.au
[31] As at 1 January 2023 pbs.gov.au

scope of practice of pharmacists in community pharmacy, for the administration of NIP vaccines.

Prescribers

- Prescribers will have the option to consider prescribing higher quantities of all medicines included in the proposal to patients with chronic, stable conditions if clinically appropriate.
- Prescribers will still have discretion to prescribe one month's supply per dispensing and up to six months' supply of a medicine per prescription, avoiding medicine wastage and supporting closer clinical monitoring of patients where required.
- Many patients with chronic conditions that require ongoing medication will no longer be required to attend a doctor's consultation at least twice a year to obtain their prescriptions for these medicines. Prescribers may have the opportunity to use these appointments to spend time with patients on more complex health issues and consultations, rather than writing repeat prescriptions for medicines to treat patients with chronic stable conditions.

Software vendors

- Software vendors will have a high volume of new and amended PBS items to add to prescribing and dispensing software through business as usual processes.
- Other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month to allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

Services Australia and the Department of Health and Aged care

- A high volume of new and amended PBS items will be added to business systems and databases.
- The volume of PBS items to be added/amended exceeds usual monthly changes. Other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month to allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

Medicine sponsors

- Initially, medicine sponsors may be required to increase Australian onshore stock in the short term for certain PBS medicines. Total amount of medicine supplied will not increase overall.

Pharmacy wholesalers

- Wholesalers may be required to temporarily increase stock levels depending on the uptake of the changes in the initial implementation phase.
- Remuneration for wholesalers may be reduced because of the way remuneration is calculated. Wholesaler mark-ups are derived according to legislative requirements. Wholesale mark-ups apply in three tiers, a flat fee for tiers one and three (low and high cost medicines) and a percentage mark-up for tier two. The changes will only impact medicines with prices that fall in tier one or tier three either for the single quantity item or the increased maximum dispensed quantity item.

Option 3: Implement MDQ changes for medicines – 3 months' supply

- If a patient's condition is stable and suitable for the increased MDQ item, a prescriber may provide a prescription that allows 3 months' supply of some PBS medicines per dispense.
- Each prescription will provide approximately 12 months' supply of medicine because there will be a maximum of four dispense events i.e. an original and 3 repeats per prescription. A PBS prescription is only valid for 12 months[32] from the time it is written. Therefore, if the 3 month MDQ option is implemented the number of repeats per prescription will need to be adjusted to allow a maximum of 12 months' supply of medication.
- New and amended items will be listed on the PBS schedule with an increased MDQ sufficient to last the patient approximately 3 months, and a reduced number of repeats to provide sufficient medication for a maximum of 12 months.
- It is necessary to list new PBS items as the PBAC has explicitly recommended that the increased MDQ listing for medicines in the proposal are in addition to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.
- These changes to the PBS will all be made to the Schedule at the same time.
- The savings to Government made possible by Option 3 will support programs and services provided to patients under the 7CPA, including higher volume of existing programs, higher payments under the Regional Pharmacy Maintenance Allowance and new programs, including funding for administration of NIP vaccines to eligible patients in community pharmacies.

[32] National Health (Pharmaceutical Benefits) Regulations 2017 (legislation.gov.au) Part 5 – Prescriptions and supply 44, 2 (b)

Stakeholders and roles and responsibilities

Consumers

- Some consumers would need to visit a pharmacy every third month instead of each month to have their prescription dispensed and may reduce their GP visits to once per twelve months depending on the medicines they take and the stability of their medical conditions.
- Consumers will pay a co-payment for every three months' quantity of medicine versus for every one month's quantity of medicine under the status quo.
- Consumers who only take medicines subject to the MDQ changes may only be required to visit their GP once a year for a prescription, if all their medicine prescriptions can be renewed at the same time.

Pharmacies

- Pharmacies will receive a dispensing fee ($7.82)[33] plus an Administration, Handling and Infrastructure (AHI) fee per dispense of three months' supply of medicine (Range: Tier One: $4.32 to Tier Three: $4.32 + $95 per dispense of maximum quantity). The tier is dependent on the price of the medicine to pharmacy[34].

All other stakeholder roles and responsibilities as for Option 2.

[33] As at 1 January 2023 pbs.gov.au
[34] As at 1 January 2023 pbs.gov.au

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

Option 1: Status quo

Access to all PBS medicines and the current quantity of medicines dispensed would remain unchanged. This would not address the cost barriers to access to medicines detailed above under 'Cost of Living pressures'. For the majority of PBS listed medicines used to treat chronic conditions, patients are required to consult their prescriber every six months to obtain a new prescription and to return to a pharmacy each month to have one month's supply of medication dispensed. The exceptions are:

- some commonly prescribed medicines are currently available on the PBS with increased maximum quantities that require higher than normal doses. For medicines such as corticosteroid creams for eczema and antibiotics for indications with a specific treatment course, there is no requirement to obtain prior Services Australia approval
- the oral contraceptive pill (unrestricted listing, four months' supply per dispensing with two repeats)
- medicines available under the 12 month repeat measure (implemented in 2008-09) which allows prescriptions for one month's supply and 11 repeats to be issued by a prescriber, a total of 12 months' supply.

Pharmacists would continue to receive a dispensing fee ($7.82)[35] plus an Administration, Handling and Infrastructure (AHI) fee (Range: Tier One: $4.32 to Tier Three: $4.32 + $95 per dispense of Maximum Quantity, tier dependent on the price of the medicine to pharmacy)[36] for each dispense. There will be six dispense events per prescription or twelve dispense events per year (once the patient has obtained a second prescription).

Option 2: Implement MDQ changes for medicines – 2 months' supply

When fully implemented, the proposed changes could benefit a significant proportion of the base number of 9.6 million patients (derived in the next section) when their prescriber's assessment is that the patient's chronic condition is stable and suitable for the higher maximum dispensed quantity item. These patients could benefit from a reduction in the number of individual PBS co-payments they would have to make for medicines included in the MDQ proposal, and visits to the doctor and pharmacy may be reduced. Implementing the two month supply option will

[35] As at 1 January 2023 pbs.gov.au
[36] As at 1 January 2023 pbs.gov.au

provide less savings to Government and consumers than Option 3, but the financial impact on pharmacies would also be less than for Option 3.

Consumers

Implementation of Option 2 will provide ongoing financial and convenience benefits for consumers. It will facilitate equitable access for consumers to higher quantities of PBS medicines, pending individual assessment of a patient's suitability by their prescriber.

This option will reduce the financial barrier to accessing medicines experienced by low income, elderly and other vulnerable patients[37], and patients taking multiple medications. The risk of patients missing medication dosages at the end of each month when their prescription runs out may be reduced.
Some patients will effectively reduce their out of pocket medicines costs by up to half for Option 2. For example:

- Concessional ordinary (non-Safety Net) patients currently pay $14.60 for two months' supply for medicines requiring a monthly prescription (two co-payments of $7.30), under this proposal they will only pay $7.30. For a patient who needs 12 months' supply every year and is in a family that does not reach the PBS concessional Safety Net after the MDQ changes that is a saving of $43.80 per year for each medicine included in the proposal.
- General ordinary (non-Safety Net) patients currently pay up to $30 per prescription for their PBS medicines. Some medicines are priced below the general PBS co-payment, however for those medicines that require 12 prescriptions per year and where the dispensed price of the medicine exceeds $30, general patients could save up to $180 per year.

In total, it is estimated that patients who are prescribed prescriptions that allow two months' supply per dispense will save around $540 million in PBS patient contributions in 2026-27, and approximately $1.8 billion between 2023-24 and 2026-27. Once fully implemented, this represents a significant reduction in out of pocket costs for patients accessing PBS medicines. The extent to which an individual patient is impacted is dependent on a number of contributing factors which include:

- The prescriber assessing the patient's chronic condition as stable and suitable for the higher maximum dispensed quantity item
- The number of medicines affected by the proposal that a patient is prescribed
- Whether patient has a concession card for accessing PBS medicines

[37] Kemp Anna, Preen David B., Glover John, Semmens James, Roughead Elizabeth E. (2011) How much do we spend on prescription medicines? Out-of-pocket costs for patients in Australia and other OECD countries. *Australian Health Review* 35, 341-349.https://doi.org/10.1071/AH10906 . https://doi.org/10.1071/AH10906

- Whether the patient, as part of a family or individually, reaches the PBS Safety Net
- For a general patient, the cost of the individual medicine the patient is prescribed, and how this price is impacted by the increased quantity listing.

The complex interaction of these factors has been considered in the detailed financial modelling and analysis supporting the proposal. To account for this complexity, the financial impact of the proposal has been modelled as the reduction in prescriptions for the single quantity items, the uptake of the increased quantity items and the patient types accessing these prescriptions.
The detailed prescription volume and pricing forecasts that underpin the model account for:

- The range of medicines impacted by the proposal
- The rate of uptake of prescribing the increased quantity items
- Whether the prescription is for a concessional or general patient
- Whether the prescription is for a patient who individually, or as part of a family, has reached the PBS Safety Net
- The setting in which the prescription is dispensed (across community pharmacy, private or public hospital)
- Assumptions about changes in the future price of medicines
- Changes in the policy environment and projected indexation of patient co-payments, the PBS Safety Net threshold, fees and mark-ups for wholesalers and pharmacies.
- Special Pricing Arrangements and Risk Sharing Arrangements with sponsors for certain medicines.

Considering each of these factors, the estimated financial impact on consumers takes into account the financial benefit to the patient each time a dispensing of two prescriptions for one month's supply are replaced by a single prescription for two months' supply.

Consumers taking only those medicines subject to the MDQ changes will visit a pharmacy every second month instead of each month to have their prescription dispensed and may reduce their doctor visits. Consumers may reach their applicable PBS Safety Net threshold later in the calendar year and co-payment costs may be spread more evenly across the calendar year, rather than concentrated in the first half of the calendar year. For medicines included in the MDQ proposal, consumers would pay a co-payment every second month to receive 12 months' supply in total of medicine per prescription. For the same medicine under the status quo, consumers pay a co-payment each month, or twelve per year. Comparing the two month option to the status quo, three co-payments would be required in the first six months of the year rather than six co-payments.

The base number of patients eligible for the proposal was derived from PBS data. Around 9.6 million consumers received two or more dispensing of medicines included in the proposal in 2022.[38] The rate that consumers are likely to take up this proposal is assumed to be gradual, increasing from a 45% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items in Year 1, 58% in Year 2, 63% in Year 3 to 63% in Year 4. The ceiling uptake rate of 63% in based on a study of a previous rollout of increased MDQ for some items. The consumer take up rate is assumed to be the same under Option 2 and Option 3 as the same group of PBS patients will have been assessed by their prescriber to have chronic medical conditions that are stable and therefore suitable for increased MDQ items.

Once the MDQ changes are fully implemented, it is expected that the aggregate impact on eligible prescription volumes for these patients across all MDQ items will be a 63% reduction in prescriptions for the single month's quantity item. Because two prescriptions for the single quantity item will become one prescription for the double quantity item, half the amount of prescriptions that were reduced for the single quantity items will be taken up for the double quantity items. Patients whose prescriptions are included in this reduction in aggregate prescription volumes could benefit through reduced numbers of individual PBS co-payments.

The subgroup of patients who receive **only** PBS medicines with increased MDQ items (approximately 1.89 million patients by 2026-27) have been estimated to save 35 minutes (consultation and travel time) attending a GP clinic annually and 90 minutes (6 visits x 15 minutes) attending the pharmacy annually. Consumers who live in rural or regional areas or who find it difficult to visit a pharmacy each month may experience added convenience.

The following table shows the Direct Regulatory Impact savings for consumers if the MDQ is increased to two months' supply for medicines included in the proposal. It is estimated around 1.8 million patients will benefit in 2023-24, with total reduction in regulatory burden of approximately $135 million. This increases to more than 1.89 million patients, with more than $141 million in reduced regulatory burden by 2026-27.

The following method and assumptions were used:

1. The base number of patients eligible was derived from PBS data. Around 9.6 million patients received two or more dispensing's of the PBS medicines in the list found suitable by the PBAC for increased MDQs in 2022. Of these, a subset of 1.77 million patients were only dispensed the increased MDQ medicines (and no other PBS medicines), therefore may benefit from fewer visits to the pharmacy and prescriber (GP).

[38] Department of Health and Aged Care April 2023

2. At a population level, the assumed growth rate of PBS patient numbers per year is 1.6% based on ABS population projections. In 2023-24, it is assumed that the number of unique patients that will be prescribed more than one prescription for an MDQ item (but no other PBS subsidised medicines) will be 1.8 million.
3. Number of person minutes saved is GP visit x 1.8 million patients x 35 minutes (GP visit[39] + travel time of 15 minutes) + 6 pharmacy visits x 1.8 million patients x 15 minutes (pharmacy visit only, travel not included[40]).
4. Consumer/person time saved per pharmacy visit does not include travel time. GP offices and pharmacies may be co-located.
5. The default value for an individual's leisure time is estimated at $36[41] per hour.
6. The estimated regulatory impact of the save is: (consumer/person minutes saved x $36), divided by 60.
7. The estimated regulatory impact assumes a single implementation date in 2023-24.

[39] Level B consultation Item 23 Medical Benefits Schedule

www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23

[40] Estimated by consultation with Department of Health and Aged Care practicing community pharmacists

[41] 2022 Regulatory Burden Measurement Framework | The Office of Impact Analysis (pmc.gov.au)

Table 4.1: Direct Regulatory Impact savings for consumers by increasing MDQ - two months' supply

Number of times per year each patient affected				
2023-24	2024-25	2025-26	2026-27	TOTAL
GP visits saved per year				
1	**1**	**1**	**1**	
Pharmacy visits saved per year				
6	**6**	**6**	**6**	
Number of patients affected				
1,800,000	**1,830,000**	**1,860,000**	**1,890,000**	
Number of person minutes saved (annual)				
2023-24	2024-25	2025-26	2026-27	
225,000,000	**228,750,000**	**232,500,000**	**236,250,000**	
Estimated Regulatory Impact value of patient save (annual)				
2023-24	2024-25	2025-26	2026-27	Total
$135,000,000	**$137,250,000**	**$139,500,000**	**$141,750,000**	**$553,500,000**

Source: 2023 Impact analysis costing- MDQ 2 month OIA22IA-03771
*Average annual patient save: $138,375,000

Pharmacies

The community pharmacy sector will be significantly impacted by this proposal. Owners of over 5,900 pharmacies will receive less dispensing income due to the decrease in the volume of dispensing and related remuneration resulting from the proposed changes. Some pharmacies may experience temporary changes to cash flow to purchase an increased stock level during the initial implementation phase, however this is likely to be mitigated by favourable terms of trade extended by suppliers to pharmacies, which is an established practice.

There will be little time for business owners to transition to other income sources, although the Government is providing increasing financial support for pharmacies to deliver patient services, including new vaccinations to eligible patients under the NIP to provide opportunities to ameliorate the business impact and diversify into other public-funded health programs.

The full impact of the reduction in dispensing volumes will not occur immediately. Financial modelling assumes that consumer uptake of the proposal will increase from a 45% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items to a 63% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items over the next four years. Many

consumers will still have valid prescriptions for their medicines at the time of implementation and may only choose to seek a prescription for an increased quantity of medicine at their next scheduled doctor's appointment. The availability of medical appointments will also limit the numbers of patients seeking a consultation for the sole purpose of obtaining a prescription for an increased quantity of their PBS medicines at the time of implementation.

Pharmacies will be paid one fee for dispensing two months' supply of a medicine on the one occasion, rather than one fee paid on two separate occasions for dispensing a month's supply of medicine over two separate months. The proposed changes will financially impact on pharmacy businesses, as pharmacists will receive less dispensing and handling fee income due to the decrease in dispensing volumes and associated fees received from Government.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. For the two month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to $158,000 reduction in remuneration, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy fees (estimated to be $867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis. The impact by individual pharmacy will vary considerably according to its operating model and factors such as:

- Dispensing volumes for impacted PBS items
- The types of medicines dispensed within this overall volume
- Take-up of increased quantity prescribing by doctors
- Other demographic and regional variations.

Pharmacists and other pharmacy employees will save time through reduced patient-pharmacist interactions due to fewer dispensings for some medicines. This time may be spent on other patient related health care activities, including public funded health programs and services delivered in pharmacies.
Pharmacies may experience the loss of other sales revenue, as a result of reduced foot traffic through the pharmacy. The volume of medicines distributed by pharmaceutical wholesalers may also change.

Smaller pharmacies and those in isolated/remote areas may be impacted more than larger pharmacies and those in metropolitan areas, as in addition to reduced dispensing related remuneration, there may be less foot traffic and therefore less opportunity for over the counter sales due to the smaller populations of serviced regions. Under the 7CPA, regional, rural and remote pharmacies receive additional

funding (Regional Pharmacy Maintenance Allowance (RPMA) program)[42] to support the supply of medicines and healthcare in the community, to ensure access for all Australians to the medicines and pharmacy services required.

Alongside this proposal, the Government is considering proposals designed to mitigate the financial impact of increasing the MDQ by reinvesting savings back into the community pharmacy sector. The reinvestment package includes a proposal aimed specifically at rural and remote pharmacies and seeks to increase remote pharmacies, doubling the overall budget of Community payments under the RPMA program. It also seeks to provide an increase to the overall public investment in community pharmacy programs to ensure dose administration aids, medication management and review, opioid dependency treatment services and vaccination services can be offered by community pharmacies, and for existing programs, at levels above those for the 2022 calendar year, and above the level funded in the 7CPA.

The following table shows the Direct Regulatory Impact savings for pharmacists by increasing the MDQ for medicines – two months' supply. It has been estimated that pharmacists, on average will save four and a half minutes per dispensing for over 66.8 million dispensings[43] by 2026-27. This will free pharmacists to participate in other patient health care related activities.
The following method and assumptions were used:

1. Pharmacists were estimated to save 4.5 minutes per dispensing avoided.[44]
2. The estimated time saved (minutes) by pharmacists is 4.5 minutes x the number of dispensings avoided.

Table 4.2: Estimated dispensing time saved for Pharmacists by increasing MDQ to two months' supply

Estimated dispensing time saved (minutes) by pharmacists				**Total**
2023-24	2024-25	2025-26	2026-27	
171,604,993	259,335,612	292,486,140	300,648,996	1,024,075,742

Source: 2023 Impact analysis costing-MDQ 2 month OIA22IA-03771

Prescribers

This proposal will give prescribers the option to consider prescribing higher quantities of some medicines to patients with chronic, stable conditions if appropriate.

[42] Government boosts funding for community pharmacies to support more rural and regional communities | Health Portfolio Ministers and Aged Care
[43] Number of dispensing's avoided based on forecasts 2023-03-24 TAAD Double MDQ costing, Department of Health and Aged Care
[44] Estimated by consultation with Department of Health and Aged Care with practising community pharmacists

When changes to the dispensing quantity were previously considered by the PBAC in 2018 it was publicly supported by medical stakeholders.[45,46] In February 2023, the RACGP and the AMA supported the proposal and requested that it be reconsidered. However, some medical professionals may be concerned due to a higher quantity of the prescribed medicine potentially compromising patient safety and quality use of medicines. This risk is mitigated by the independent PBAC having recommended only medicines for chronic conditions that are considered clinically safe and suitable for dispensing in the community in higher quantities.

Prescribers will also retain the choice of clinically appropriate prescribing. Prescribers will be able to prescribe one month's supply per dispensing and up to six months' supply of a medicine per prescription, supporting closer clinical monitoring of patients where clinically required.

Many patients with chronic conditions may no longer be required to attend a doctor's consultation at least twice a year to obtain their prescriptions for these medicines. These appointments will otherwise be taken up by other patients. It is anticipated prescribers will have the opportunity to use these appointments to spend time with patients on more complex health issues and consultations, rather than writing repeat prescriptions for medicines to treat patients with chronic stable conditions. Over time, with improved patient medication adherence, there may be less need for prescribers to manage escalating health issues in patients not taking their medication as prescribed.

Pharmaceutical wholesalers

There are six Community Service Obligation (CSO) wholesalers who supply a majority share of PBS medicines to community pharmacy and are likely to be affected.

However, there are a number of non-CSO wholesalers who do not have a specific arrangement with the Commonwealth but also supply some PBS medicines. As these additional suppliers are not regulated, it is not possible to estimate the total number of wholesalers that will be affected.

This proposal will result in the reduction of remuneration to wholesalers because of the way remuneration is calculated. Wholesaler mark-ups are derived according to legislative provisions.

The wholesaler mark-up for ready prepared pharmaceutical benefits is calculated as a percentage for medicines between the price of $5.50 and $720 (ex-manufacturer). For those products that fall outside this range it is applied as a flat fee for the

[45] https://www1.racgp.org.au/newsgp/racgp/government-backdown-on-dispensing-prioritises-prof
[46] https://www.smh.com.au/politics/federal/greg-hunt-shelves-plan-for-two-month-scripts-after-pharmacist-backlash-20190328-p518gw.html

maximum amount of medicine that can be dispensed. As a result, increasing the maximum dispensed amount in a PBS listing for any of these medicines, may reduce the amount of wholesaler mark-up paid by the Commonwealth overall. Approximately 220 pharmaceutical items (the drug, form and manner of administration set out in the PBS listing47) will have a reduced wholesale mark-up as a result of the listing of the increased quantity item for the two month supply option.

The number of impacted pharmaceutical codes may change over time as PBS ex-manufacturer prices are subject to PBS pricing mechanisms such as price disclosure, anniversary price reductions and first new brand reductions.

The following example illustrates the effect of the two month supply option on wholesale mark up and pharmacy for a specific medicine, rosuvastatin 10mg tablet, 30 pack.

Table 4.3 Primary impact – Two prescriptions for a one month supply become one prescription for a two month supply

Example – General beneficiary under two month MDQ option - medicine rosuvastatin 10 mg tablet, 30 pack.					
	Current arrangements		***2 months' MDQ***	***Financial Impact***	***Notes***
	1 month's supply	***2 x 1 month's supply***	***1 x 2 month's supply***		
Ex-manufacturer price	***$3.50***	***$7.00***	***$7.00***	***$0.00***	***No impact on ex-manufacturer price***
Wholesale mark-up	***$0.41***	***$0.82***	***$0.52***	***-$0.30***	***The wholesale mark-up will reduce by $0.30 across the two months of supply***
AHI Fee	***$4.32***	***$8.64***	***$4.32***	***-$4.32***	***One fewer AHI Tier 1 fee ($4.32) will be paid across the two months of supply.***

[47] https://www.pbs.gov.au/info/industry/listing/procedure-guidance/shortened-forms-and-definitions

Example – General beneficiary under two month MDQ option - medicine rosuvastatin 10 mg tablet, 30 pack.					
Dispensing Fee	*$7.82*	*$15.64*	*$7.82*	*-$7.82*	*One fewer ready prepared dispensing fee ($7.82) is paid across the two months of supply.*
Dispensed Price for Maximum Quantity	*$16.05*	*$32.10*	*$19.66*	*-$12.44*	*The overall dispensed price for 1 script of 2-month supply is $12.44 less than for 2 scripts of 1-month supply.*
Note: AHI = Administration, Handling and Infrastructure Fee					

Explanation: $12.44 is the saving to the PBS as a whole for 2 x one month's supply of the medicine becoming 1 x two months' supply of the medicine.
How the $12.44 saving is distributed between patients and the government depends on whether the patient holds a concession card or safety net card.

Table 4.4 Secondary impact - Flow-on to dispensed price of the existing PBS item code providing one month's supply

Secondary impact – Flow-on to dispensed price of the existing PBS item code providing one month's supply.			
	Current arrangements	*Proposed arrangements*	*Financial Impact on existing one month's supply item*
	1 month's supply	*1 month's supply*	
Ex-manufacturer price	*$3.50*	*$3.50*	*$0.00*
Wholesale mark-up	*$0.41*	*$0.26*	*-$0.15*
AHI Fee	*$4.32*	*$4.32*	*$0.00*
Dispensing Fee	*$7.82*	*$7.82*	*$0.00*
Dispensed Price for Maximum Quantity	*$16.05*	*$15.90*	*-$0.15*
Notes and Caveats: *Ex-manufacturer prices as at 1 April 2023.* *Fees and mark-ups are for the 2022-23 financial year (noting that fees will change on 1 July 2023 prior to the policy starting).* *The example is based on a single dispense of the maximum quantity.* *The example is for a specific medicine. The impact of this policy varies depending on the price of the medicine.* *This example accounts for components of the Commonwealth Price only, and does not account*			

Secondary impact – Flow-on to dispensed price of the existing PBS item code providing one month's supply.
for discounting by pharmacy, additional allowable charges by pharmacy or brand premium payments.

Medicine sponsors

Initially, medicine sponsors may be required to increase Australian onshore stock levels due to a short-term increase in demand for certain PBS medicines. However, overall the same amount of medicine is expected to be supplied to the Australian market annually. A small financial gain in PBS revenue/rebate payments is expected for sponsors of medicines with a special pricing arrangement and/or a risk sharing arrangement, due to the expected impact of the proposal in reducing Commonwealth expenditure.

Medical and Dispensing Software Providers, Services Australia and Department of Health and Aged Care

Under usual PBS listing processes, there are limits to the number of changes that can be made to the PBS schedule each month. Implementation of this proposal may result in a very high volume of changes, meaning some other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month. This is both to ensure that prescribing and pharmacy software vendors and Services Australia are able to implement the high number of new items in their respective databases, but also to ensure that no errors are created in the PBS data where other changes may affect the same medicines that are subject to the MDQ changes.

Government

The cost of the PBS is expected to continue to grow over time, and this will put increasing pressure on the health budget.[48] This proposal will reduce PBS expenditure through:

- reducing dispensing and handling fees paid to pharmacists, as fewer prescriptions will need to be processed, and
- consumers will reach their applicable PBS Safety Net threshold later in the calendar year, or no longer reach their applicable PBS Safety Net threshold, as they will incur fewer co-payments early in the calendar year, and
- reducing the Safety Net card issue fees paid to pharmacists due to a smaller number of patients and families spending enough on PBS and RPBS medicines to reach their applicable PBS Safety Net threshold and be issued a PBS Safety Net card, and

[48]https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/Impact%20of%20PBS%20Reform%20Report%203.pdf

- reducing the payments for the Electronic Prescription Fee for Prescription Exchange Services as the overall volume of PBS and RPBS prescriptions is reduced, and
- reducing wholesale mark-ups paid for those medicines which have prices where the wholesale mark-up calculation is impacted by the listing of the increased quantity items.

When two months' quantity of medicine is dispensed at one time there is a risk of increased wastage, potentially increasing the cost of medicines to the PBS. This will be mitigated by the PBS restriction for these higher quantity items containing the following wording: "Patient's condition must be stable and suitable for higher maximum dispensed quantity measure".

Implementing the two month supply option may reduce the amount of medicine wastage, as double rather than triple quantities (Option 3) would be supplied at one time.

Regulatory burden estimate (RBE) table – Option 2

Average annual regulatory costs				
Change in costs ($ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$138,375,000 (save)	$	$	$138,375,000 (save)

Option 3: Implement MDQ changes for medicines – 3 months' supply

This option will require a significant number of new and amended items to be listed on the PBS schedule.

When fully implemented, the proposed changes could benefit a significant proportion of the base number of 9.6 million patients, when their prescriber's assessment is that the patient's chronic condition is stable and suitable for the higher maximum dispensed quantity item, by reducing the number of individual PBS co-payments they would have to make for medicines included in the MDQ proposal, and visits to the doctor and pharmacy may be reduced.

This option will have a bigger reduction to PBS expenditure compared to Option 2, provide a greater reduction in regulatory impact and greater savings in medicine costs for consumers than Option 2. This option has a higher financial impact to pharmacies than Option 2.

Consumers

Under this option, consumers will visit a pharmacy every third month instead of each month to have their prescription dispensed and may reduce their doctor visits.
In total, it is estimated that patients who are prescribed prescriptions at the triple maximum quantity will save around $740 million in PBS patient contributions in 2026-27, and approximately $2.5 billion between 2023-24 and 2026-27. Once fully implemented, this represents a further reduction in out of pocket costs for patients accessing PBS medicines compared to Option 2. In a similar way to Option 2, the estimated financial impact on consumers takes into account the financial benefit to the patient each time a dispensing of three prescriptions for one month's supply are replaced by a single prescription for three months' supply.

The subgroup of patients who receive **only** PBS medicines with increased MDQ items (approximately 1.89 million patients by 2026-27) have been estimated to save 15 minutes travel time and 20 minutes[49] attending a GP clinic annually and 120 minutes (8 visits x 15 minutes) attending the pharmacy annually.
All other impacts as for Consumers under Option 2.

The following table shows the Direct Regulatory Impact savings for consumers if the MDQ is increased to three months' supply for medicines included in the proposal.

It is estimated around 1.8 million patients will benefit in 2023-24, with total reduction in regulatory burden of approximately $167 million. This increases to more than 1.89 million patients with more than $175 million in reduced regulatory burden by 2026-27.

The following method and assumptions were used:

1. The base number of patients eligible was derived from PBS data. Around 9.6 million patients received two or more dispensing's of the PBS medicines in the list found suitable by the PBAC for increased MDQs in 2022. Of these, a subset of 1.77 million patients were only dispensed the increased MDQ medicines (and no other PBS medicines), therefore may benefit from fewer visits to the pharmacy and prescriber (GP).
2. At a population level, the assumed growth rate of PBS patient numbers per year is 1.6% based on ABS population projections. In 2023-24, it is assumed that the number of unique patients that will be prescribed more than one prescription for an MDQ item (but no other PBS subsidised medicines) will be 1.8 million.

[49] Level B Consultation as 1/2/2023
http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23#:~:text=A%20Level%20B%20item%20will%20be%20used%20for,this%20should%20be%20reflected%20in%20the%20practitioner%27s%20record.

3. Number of person minutes saved is GP visit x 1.8 million patients x 35 minutes (GP visit + travel time of 15 minutes) + 8 pharmacy visits x 1.8 million patients x 15 minutes.
4. Consumer/person time saved per pharmacy visit does not include travel time. GP offices and pharmacies may be co-located.
5. The default value for an individual's leisure time is estimated at $36[50] per hour.
6. The estimated regulatory impact of the save is: (consumer/person minutes saved x $36), divided by 60.
7. The estimated regulatory impact assumes a single implementation date in 2023-24.

Table 4.5: Direct Regulatory Impact savings for consumers by increasing MDQ to three months' supply

Number of times per year each patient affected				
2023-24	2024-25	2025-26	2026-27	TOTAL
GP visits saved per year				
1	**1**	**1**	**1**	
Pharmacy visits saved per year				
8	**8**	**8**	**8**	
Number of patients affected				
1,800,000	**1,830,000**	**1,860,000**	**1,890,000**	
Number of person minutes saved (annual)				
2023-24	2024-25	2025-26	2026-27	
279,000,000	**283,650,000**	**288,300,000**	**292,950,000**	
Estimated Regulatory Impact value of patient save (annual)				
2023-24	2024-25	2025-26	2026-27	Total
$167,400,000	**$170,190,000**	**$172,980,000**	**$175,770,000**	**$686,340,000**

Source: 2023 Impact analysis costing- MDQMDQ 3 month OIA22IA-03771
*Average annual patient save: $171,585,000

Pharmacies

The community pharmacy sector will be highly impacted by this option. This option has a higher financial impact to pharmacies than Option 2.

Under three month supply option, pharmacies will be paid one fee for dispensing three months' supply of a medicine on the one occasion, rather than one fee paid on three separate occasions for dispensing a month's supply of medicine over three separate months.

[50] 2022 Regulatory Burden Measurement Framework | The Office of Impact Analysis (pmc.gov.au)

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. For the three month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to $210,000 reduction in remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be $867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis. The impact by individual pharmacy will vary considerably according to its operating model and factors such as:

- Dispensing volumes for impacted PBS items
- The types of medicines dispensed within this overall volume
- Take-up of increased quantity prescribing by doctors
- Other demographic and regional variations.

All other impacts as for Pharmacies under Option 2.

The following table shows the estimated dispensing time saved for pharmacists if the MDQ is increased to three months' supply for medicines included in the proposal.

It has been estimated that pharmacists, on average will save four and a half minutes per dispensing for over 89.1 million dispensings[51] by 2026-27. This will free pharmacists to participate in other patient health care related activities

The following method and assumptions were used:

1. Pharmacists were estimated to save 4.5 minutes[52] per dispensing avoided.
2. The estimated time saved (minutes) by pharmacists is 4.5 minutes x the number of dispensings avoided.

Table 4.6: Estimated dispensing time saved for pharmacists by increasing MDQ - three month option

Estimated dispensing time saved (minutes) by pharmacists				
2023-24	2024-25	2025-26	2026-27	TOTAL
228,726,540	345,764,277	390,009,505	400,899,510	1,365,399,833

Source: 2023 Impact analysis costing- MDQMDQ 3 month OIA22IA-03771

Prescribers

All impacts as for Prescribers under Option 2.

The impacts are the same as under Option 2 because under both options, each prescription with the increased MDQ will supply approximately 12 months' of medicine, an increase from 6 months under the status quo option. As such, under

[51] Number of dispensings avoided based on forecasts 2023-03-24 TAAD Triple MDQ costing Department of Health and Aged Care

[52] Estimated by consultation with Department of Health and Aged Care with practising community pharmacists

both Option 2 and Option 3, prescribers may see the same reduction in appointments from affected patients.

Pharmaceutical wholesalers

The impact on wholesaler remuneration may be greater under Option 3. The wholesaler mark-up for ready prepared pharmaceutical benefits is calculated as a percentage for medicines between the price of $5.50 and $720 (ex-manufacturer). For those medicines that fall outside this range it is applied as a flat fee for the maximum amount of medicine that can be dispensed. As Option 3 provides a greater MDQ, the impact of the triple increased maximum quantity item in scaling down the calculated wholesale mark-up for impacted medicines may be more significant, further reducing the amount of wholesaler mark-up paid by the Commonwealth overall.

Medicine sponsors

Initially, medicine sponsors may be required to increase Australian onshore stock levels due to a short-term increase in demand for certain PBS medicines, and it would be assumed the effect of Option 3 would be greater than Option 2 due to the higher MDQ involved. However overall, the same amount of medicine is expected to be supplied to the Australian market annually. A small financial gain in PBS revenue/rebate payments is expected for sponsors of medicines with a special pricing arrangement and/or a risk sharing arrangement, due to the expected impact of the proposal in reducing Commonwealth expenditure.

Medical and dispensing software providers, Services Australia and Department of Health and Aged Care

All other impacts as under Option 2.

Government

Implementing the three month supply option is forecast to provide greater savings to Government than the savings forecast for Option 2. This option may increase the amount of medicine wastage, as triple rather than double quantities would be supplied at one time.

All other impacts as for Government under Option 2.

Regulatory burden estimate (RBE) table – Option 3

Average annual regulatory costs				
Change in costs ($ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	$171,585,000	$	$	$171,585,000

(save)	(save)

5. Who will you consult about these options and how will you consult them?

Some consultation on increasing the maximum dispensed quantities (MDQ) occurred after the initial PBAC recommendation in 2018 to increase MDQ to two months. More recently a number of stakeholders have communicated publicly that they encourage the Government to reconsider this option, including the AMA and the RACGP.

As in 2018, the Pharmacy Guild of Australia (the Guild) remains unsupportive of the measure and argues that it would be preferable to increase the government subsidy on PBS medicines by further reducing the PBS general maximum co-payment (reduced on 1 January 2023 from $42.50 to $30) to $19 in the May 2023 Budget. The Guild also argues that current supply shortages create challenges for some pharmacies in providing patients with one month's supply of medication.[53]
On 10 April 2023[54], the Director of the Chemist Warehouse pharmacy chain supported the measure in principle but noted that “doubling the supply of common medicines may exacerbate medicine shortages”. He stated, “the measure could work well if there was a long lead time before the changes are made and the supply chain was right”.

The Government will hold consultations with key affected stakeholders in the pharmacy sector prior to the finalisation and/or announcement of these measures. Objectives of consultation for this proposal will be to educate, create awareness to expedite implementation and to inform evaluation.

PBAC

The PBAC provided advice on a similar proposal in 2018. The recommendations made by the PBAC were published on pbs.gov.au via its August 2018 Outcome Statement in April 2019. The PBAC provided advice and recommendations on the clinical safety and suitability of an extensive list of PBS items for inclusion in a proposal to increase the quantities per dispensing from one month’s supply to two months’ supply for patients with stable, chronic conditions.

In December 2022, the PBAC reconsidered its August 2018 advice around items on the PBS that could have increased maximum dispensed quantities of medicines for chronic conditions. The PBAC confirmed its 2018 recommendations, considered that a two or three month dispensed quantity would be clinically appropriate and

[53] https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab
[54] https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab

expanded the list of medicines that could be included in the proposal. The recommendations for PBS items with higher dispensed quantities are in addition to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.

The PBAC noted that the Government may choose to implement either the two or the three months' supply per dispensing and advised that the medicines recommended for inclusion in the proposal would be appropriate for either option. Consistent with PBAC advice, existing listings would be retained alongside the new MDQ items, and prescribers will retain the ability to prescribe lower quantities where this is clinically recommended (for instance, where a patient needs more frequent monitoring on the medication).

The Pharmacy Guild of Australia

When consulted on the PBAC's similar August 2018 proposal, the Guild strongly opposed this measure, which reduced income for pharmacy owners.

This proposal is part of a package of proposals being considered by Government to mitigate the financial impact of increasing the MDQ by reinvesting savings back into the community pharmacy sector. The reinvestment package includes a proposal aimed specifically at rural and remote pharmacies, and also seeks to increase public funding for clinical services and programs, other than dispensing activities, delivered by community pharmacies. This will provide opportunities for pharmacies to provide a broader range of funded health services to the community and expand pharmacist scope of practice in community pharmacy.

The Guild's 'Distribution and Delivery of Pharmaceutical Benefits' policy states it 'believes that all Australians should have timely and affordable access to the full range of pharmaceutical benefits through their community pharmacy to achieve better health outcomes, consistent with the objectives of Australia's National Medicines Policy. A reliable, efficient and effective pharmaceutical distribution system is essential to achieving this'.[55]

On 7 September 2022, the National President of the Pharmacy Guild expressed support for introduction of Commonwealth legislation to reduce the PBS General co-payment from 1 January 2023 to $30, citing the Guild's advocacy on behalf of patients for a reduction to the cost of medicines.[56] On 10 April 2023, the Guild called for a further reduction to the PBS general maximum co-payment (reduced on 1 January 2023 from $42.50 to $30) to $19 in the May 2023 Budget.[57]

[55] PBS medicines supply (guild.org.au)
[56] Cheaper medicines a step closer - Pharmacy Guild of Australia
[57] https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab

Royal Australian College of General Practitioners (RACGP)

In February 2023, the Royal Australian College of General Practitioners (RACGP) publicly stated[58] that the PBAC should revisit the 2018[59] recommendation to increase the maximum dispensed quantities on selected PBS items from one to two months' supply to reduce out-of-pocket costs, as well as the risk of patients missing medication dosages at the end of each month when their prescriptions run out.

The RACGP[60] continues to be highly supportive of the proposal, stating the May 2023 Budget is an opportunity for government to reduce cost of living pressures for Australians by acting on reforms. Reasons put forward by the RACGP include to:

- extend the length of prescriptions to save patients money and time
- allow a larger supply of medicines in one go – a 2-month supply would halve dispensing fees, which cost taxpayers $1.67 billion in 2021-22
- make prescribing faster and easier for GPs so they have more time for patient care by streamlining the PBS prescribing system, which is unnecessarily complex.

Australian Medical Association (AMA)

On 12 February 2023, the Australian Medical Association (AMA) called on the Government to implement the PBAC's recommendation to increase the maximum dispensed quantities on selected PBS medicine items from one month's supply to two months' supply, stating that patients could halve the costs of their medicines[61].

Prescriber and dispensing software providers

Consultation will be undertaken through business as usual software vendor forums.

[58] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2018-08/Outcome-Statement-August-2018-Increased-MDQ.pdf
[59] https://www1.racgp.org.au/newsgp/professional/gps-back-renewed-push-for-extended-dispensing-rule
[60] RACGP - Media releases
[61] https://www.ama.com.au/media/ama-calls-two-months-medicines-be-dispensed-single-script-0#:~:text=%E2%80%9CBy%20doing%20this%2C%20for%20these%20particular%20medicines%2C%20patients,repeat%20medications%2C%20it%20would%20effectively%20halve%20the%20cost .

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

Should the Government not implement either Option 2 or Option 3, there will be no additional benefits for consumers with chronic, stable medical conditions such as a reduced PBS co-payments, reduction in the number of visits to a pharmacy and reduced yearly out of pocket costs for some PBS medicines. Pharmacy owners will continue to dispense all PBS medicines for chronic conditions on a monthly basis, and receive similar revenue from dispensings and the associated fees and charges. In December 2022, the independent PBAC noted that the Government may choose to increase the MDQ to either two month (Option 2) or three month (Option 3) supply. The PBAC advised that the list of medicines recommended for inclusion in the proposal would be safe and appropriate for either option.

Options 2 and 3 will provide more affordable access to PBS medicines for consumers for many chronic conditions and provide significant savings to Government by reducing dispensing related remuneration paid to pharmacy owners. The overall reduction in the number of PBS dispensings means some patients will reach their applicable PBS Safety Net threshold later in the calendar year and prescriptions lasting 12 months may contribute to fewer doctor visits for the sole purpose of renewing a prescription every six months.

Options 2 and 3 will result in fewer patients reaching the PBS Safety Net threshold, however these patients will save overall, as they will pay fewer PBS patient co-payments over the course of a year, due to the lower number of prescriptions needed to receive the same amount of medicine. Options 2 and 3 may also improve patient compliance to effective medicines, resulting in improved health outcomes and less burden on the Australian health care system.

Under Option 2, a significant proportion of the 9.6 million patients using medicines included in the proposal will collectively save around $540 million in reduced PBS patient contributions in 2026-27, and approximately $1.8 billion between 2023-24 and 2026-27.

For Option 2, a subset of approximately 1.89 million of these patients who use only PBS medicines with increased MDQ items for stable and chronic conditions (and no other PBS medicines) may save 35 minutes (consultation and travel time) attending a GP clinic annually and 90 minutes (6 visits x 15 minutes) attending the pharmacy annually. Patients who live in rural or regional areas or who find it difficult to visit a pharmacy each month may experience added convenience. In 2026-27, the total reduced regulatory burden for these 1.89 million patients is estimated to be more than $141 million.

Under Option 3, a significant proportion of the 9.6 million patients using medicines included in the proposal will collectively save around $740 million in PBS patient contributions in 2026-27, and approximately $2.5 billion between 2023-24 and 2026-27.

For Option 3, a subset of approximately 1.89 million of these patients who use only PBS medicines with increased MDQ items for stable and chronic conditions (and no other PBS medicines) may save 35 minutes (consultation and travel time) attending a GP clinic annually and 120 minutes (8 visits x 15 minutes) attending the pharmacy annually. In 2026-27, the total reduced regulatory burden for these 1.89 million patients is estimated to be more than $175 million.

Options 2 and 3 will result in owners of pharmacies and pharmaceutical wholesalers receiving reduced revenue associated with the dispensing of PBS medicines. In 2018, the Pharmacy Guild strongly opposed the two month option due to the reduction in income for pharmacy business owners, of which there are more than 5,900 across Australia.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. Under Option 2, the estimated average impact per pharmacy in the fourth year following implementation may be up to a $158,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be $867,000 in the fourth year). For Option 3, the estimated average impact per pharmacy in the fourth year following implementation may be up to a $210,000 reduction in Government remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be $867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis.

Increasing the maximum dispensed amount for some of the included PBS medicines will also reduce the overall amount of wholesaler mark-up paid by the Government. There are six Community Service Obligation (CSO) wholesalers who supply a majority share of PBS medicines to community pharmacy and are likely to be affected. However, there are a number of non-CSO wholesalers who do not have a specific arrangement with the Commonwealth but also supply some PBS medicines. As these additional suppliers are not regulated, it is not possible to estimate the total number of wholesalers that will be affected.

Under Option 2, patients may save up to $180 per year (General Beneficiaries) and up to $43.80 per year (Concessional Beneficiaries) for each medicine prescribed for a chronic, stable medical condition. Option 2 out of pocket savings and regulatory savings for consumers are lower than those generated under Option 3 (for general patients up to $240 per year and for concessional patients up to $58.40 per year).

However, the financial impact to the community pharmacy sector of Option 2 is less than for Option 3, noting that mitigation measures are proposed as part of these reforms to offset some of this impact.

Preferred option

The preferred option is that the two month MDQ option (Option 2) is implemented. This option will deliver significant savings to both patients and the Government compared to current policy settings (Option 1) and will have a more moderate impact on pharmacy and wholesalers than the three month option.

Implementation of the two-month option would give the Government the ability to retain the PBAC's recommendation for the three month option for later consideration, providing the opportunity to assess the financial impact of the two months dispensing quantity reforms on the network of pharmacies in Australia before proceeding to implement further changes, such as three months dispensing quantity reforms. In general, PBAC recommendations remain valid for two years.

In addition, Option 2 has been widely shared publicly as a concept, with the proposal well supported by medical and consumer stakeholders when recommended by the PBAC in 2018. It is likely minimal consultation on Option 2 will be required, as only the number of medicines captured within the 2018 PBAC recommendation has been updated in the 2022 PBAC recommendation.

Implementation of Option 2 rather than Option 3 will result in the dispensing of less medicine quantity at one time (i.e. double rather than triple the current one month's supply). This may have two potential benefits:

1. allay the concerns expressed by some medical professionals in 2018 that the availability of large quantities of some medicines could compromise patient safety and quality use of medicines; and
2. potentially reduce the amount of medicine wastage and reduce any associated risk to Government of increased PBS costs.

Under Option 2 the risk of wastage is lower as only two months' supply of medicines is wasted instead of three months' supply if the patient develops a side effect or change in medical condition that means they do not continue taking the medicine. Implementation of Option 2 rather than Option 3 may lessen the initial impact on medicine sponsors to meet an increase in Australian on shore stock levels of medicines. The amount of medicine supplied will not increase overall, and the increase will be offset once consumer demand for increased dispensed quantity prescriptions stabilises. The two month option may also place less pressure on logistics and supply chains in the initial implementation phase compared with the three month option.

This Impact Analysis assumes that implementation of Option 2 or Option 3 would occur on a single implementation date in 2023-24, following consideration of the

proposal by the Government in the 2023-24 Budget. Delivering the recommended changes in a single instalment at the earliest opportunity would create the largest possible savings for both consumers and the Government. It would also minimise stakeholder and consumer confusion around medicine eligibility, given all changes would be available at the time of implementation.

Implementation

The Government will undertake consultation with key affected stakeholders in the pharmacy sector, including the Guild and other pharmacy stakeholders about the implementation of these proposals.

Consultation

The Government will conduct broader consultation with the community, including patient and prescriber groups following announcement. Objectives of consultation for this proposal will be to educate, create awareness to expedite implementation and to inform evaluation.

The Department of Health and Aged Care (Department) intends to undertake consultation and education of prescribers, all health professionals, consumers, medicine suppliers and software vendor representatives to expedite implementation and uptake as soon as any announcement is made.

Following a Government decision on the proposal, consultation will be undertaken by the Department with pharmacy representative groups, including the Guild, the National Pharmaceutical Services Association and the Pharmaceutical Society of Australia. Consultation with software stakeholders will also be undertaken by the Department, following a decision of Government. Consultation with other stakeholders (including the general public) will be undertaken by the Department following any announcement.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of implementation, the Department will consult and work collaboratively with Services Australia to ensure the significant volume of changes can be made and that systems can support the PBS Schedule changes. The Department and Services Australia have already collaborated to develop co-ordinated preliminary internal implementation plans to map the implementation process in preparation for a decision by Government. The Department is confident that the risk of unforeseen issues occurring during implementation is mitigated by this approach that encompasses a combination of consultation and well established business as usual processes.

Prescribing and dispensing software vendors will be consulted prior to implementation of the proposal through business as usual software vendor forums

to ensure the new arrangements will be reflected in the software update for the chosen implementation month. Inclusion of the large volume of PBS Schedule changes (new PBS items and amended PBS items) into one monthly software update may mean that other PBS changes may not be progressed in the same month. Essential changes only for maintenance and proper functioning will be made to the PBS Schedule for that month. This is to ensure that prescribing and pharmacy software vendors, the Department and Services Australia are able to implement the large number of new items in their respective databases. It will also minimise errors created in the PBS data where other changes may affect the same medicines that are subject to the MDQ changes. Again, the Department is confident that the risk of unforeseen issues occurring and consequently unsuccessful implementation is mitigated by this approach that encompasses a combination of consultation and well established business as usual processes.

This proposal may result in increased pressure on the availability of doctor's appointments as consumers seek to access prescriptions for greater quantities of medicines while they still possess valid monthly prescriptions for their medicines. The Department will consult with prescriber representative organisations such as the RACGP and AMA to formulate strategies to manage demand on GP appointments. This may include targeted communication campaigns by the Department to manage consumer expectations.

Communications

The Department has commenced preparation of communication materials that will inform stakeholders of the feasibility of the chosen option and anticipate, address and respond to stakeholders' concerns about implementation. Communications with consumers and prescribers will provide clear and factual information about the PBS changes and expected benefits to patients. It will also ensure that the community is provided factual information about the interaction between co-payments and the PBS Safety Net and to alert prescribers to the changes so that they can adapt their clinical practice.

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

The Department of Health and Aged Care will develop a comprehensive evaluation framework that will monitor risks and provide mitigation strategies should unforeseen circumstances arise. The framework will utilise existing PBS evaluation processes and existing data sources (e.g. PBS claims data) where possible, and implement specific evaluation processes as required.

Comprehensive evaluation framework

The comprehensive evaluation framework will align with the objectives underpinning this proposal and may include:

1. *Improved and more affordable access to PBS medicines for people treated for many chronic conditions*

   These objectives will be evaluated by reviewing the PBS statistics for the first quarter of implementation to establish baseline uptake of the proposal. Once 12 months of PBS data is available after the changes are implemented, the percentage of PBS prescriptions for medicines included in the proposal dispensed as MDQ items in the first year of implementation will be compared to the modelled estimates.

2. *Lower healthcare costs for consumers and Government without compromising patient safety*

   This objective will be evaluated through monitoring the utilisation of the new MDQ items, quantity of medicine dispensed and quantifying the savings for patients once sufficient PBS data is available. This activity can be undertaken through routine research conducted by the PBS Post-Market Review program. These utilisation reviews would be considered by the Drug Utilisation Sub-Committee (DUSC) of the PBAC, and any concerns referred to the PBAC.

3. *Maintaining the sustainability of the PBS*

   The cost of the PBS is expected to continue to grow over time, putting increased pressure on the health budget. To evaluate this objective, the total PBS Government expense for the supply of medicines for the 2023-24 financial year and following years will be monitored and compared with costs and annual percentage increases in previous years. To ensure the ongoing sustainability of the PBS, both the medicines subsidised and the programs

through which medicines are supplied and accessed are reviewed regularly by Government.

4. *Quality Use of Medicines - Wastage*

As a result of implementing of Option 2 there is the potential for increased medicine wastage and cost to the PBS for medicines included in this proposal. However, the risk of wastage is mitigated by prescribers choosing the PBS item for increased dispensed quantities only for patients with stable medical conditions. The PBS restriction for all items with increased quantities will include the following clinical criterion: *Patient's condition must be stable and suitable for the increased Maximum Dispensed Quantity measure.*

Any increase in the annual utilisation (quantity dispensed) of the medicines implemented with increased quantities may result inadvertently in more medicine wastage. Patients discontinue medicines for many reasons including a change in their condition or side effects meaning the additional quantities dispensed may be wasted. However, it will not be obvious if any increase in medicine utilisation is due to waste or increased adherence across the treated population taking these medicines.

Medicine wastage may be evaluated through the use of more complex drug utilisation research techniques using PBS unit record data. It is possible to determine the number of people initiating new treatment or discontinuing treatment early who have been prescribed two-month supply items. Assessment of adherence and persistence to treatment can also be measured based on PBS dispensing data. Such research can be requested and interpreted by the DUSC of the PBAC, should uptake and utilisation of the medicine items implemented in Option 2 be greater than expected.
The Return Unwanted Medicines (RUM) Project[62] is funded by the Commonwealth Government through the Department of Health and Aged Care to address the Quality Use of Medicines (QUM) in Australia. The project facilitates the collection and disposal of unwanted medicines from the community. The project operates nationally with the cooperation of the pharmaceutical wholesalers and community pharmacies. The initiative provides consumers with a free and convenient way to dispose of expired and unwanted medicines. Medicines can be returned to any community pharmacy anytime, for safe collection and disposal.

RUM collection data (in kilograms) has been available for comparison month by month by state since 2001.[63] To date, over 12 million kilograms of

[62] Return of Expired and Unwanted Medicine | Home (returnmed.com.au)
[63] Collection Results and Data | Return of Unwanted Medicine (returnmed.com.au)

unwanted medicines have been collected. Any increase in the amount of medicines collected through this program may serve as a broad indicator of increased wastage, particularly if the trend correlates with the timing of implementation of the PBS items with increased quantities. However, this measure is limited, as the RUM program covers all medicines including over the counter and non – PBS medicines are collected.

5. Quality Use of Medicines – Pharmacovigilance

The Department's planned evaluation framework will utilise existing well developed processes within the Therapeutic Goods Administration (TGA) and the PBS program to assess outcomes of the implementation of Option 2 on patient safety and pharmacovigilance.

The PBAC has provided advice and recommendations on the clinical safety and suitability of a list of PBS items for inclusion in the proposal for patients with stable, chronic medical conditions. The PBAC confirmed that only medicines or generics of medicines that have been PBS listed for five or more years are to be included in the policy, as severe but rare adverse effects frequently become evident during the first few years a drug is widely available.

Pharmacovigilance refers to monitoring the effects of medicines post TGA registration for use in Australia to identify and evaluate previously unreported adverse reactions. This is a 'business as usual' activity of the TGA, supporting the National Medicines Policy (NMP)[64] through ensuring medicines meet the required standards of quality, safety and efficacy.

The TGA has a pharmacovigilance program[65], which involves the assessment of adverse events that are reported to the TGA by consumers, health professionals, the pharmaceutical industry, international medicine regulators or by the medical and scientific experts on TGA advisory committees. There are strong linkages between the TGA and the PBAC. TGA representatives routinely attend PBAC meetings. Once the MDQ changes have been implemented, the Department will notify the TGA of the medicines included in the proposal. The TGA will continue to monitor all spontaneous reports of adverse medicine events submitted by healthcare professionals, patients or consumers and will inform the Department and the PBAC of any emerging trends in adverse reactions or medicine misuse associated with these medicines.

6. Quality Use of Medicines – Medicines shortages

[64] National Medicines Policy | Australian Government Department of Health and Aged Care
[65] TGA regulatory framework | Therapeutic Goods Administration (TGA)

Medicine shortages are routinely published on the TGA website.[66] Medicine sponsors inform the TGA if there is not enough medicine to supply normal demand in Australia within the next six months. The Department will monitor the Medicines Shortages website and liaise with the TGA to determine any impacts resulting from implementation of the proposal.

Monitoring stakeholder impacts

In addition to the development of a comprehensive evaluation framework to measure success and mitigate unforeseen issues, the Department is also committed to evaluating the impacts of implementation of the proposal all affected stakeholders through existing mechanisms.

Community pharmacy sector

The Department will continue to monitor the impact on the community pharmacy sector remuneration through existing 7CPA arrangements. The Department will monitor continued participation by community pharmacies in 7CPA programs, which are expected to continue at current levels with the reinvestment of Government savings from the proposal.

Evaluation of financial impacts will be dependent on affected stakeholders providing necessary financial information at a granular level to allow assessment of any variation in the impact on pharmacies in different settings (i.e. regional and remote). The Department will also monitor the number and distribution of pharmacies across Australia to ensure businesses continue to be viable and provide convenient and affordable access to medicines for all Australians.

Wholesalers

The ongoing annual impact on wholesalers will be monitored by the Department through the existing 7CPA arrangements. Evaluation will be dependent on affected stakeholders providing necessary financial information.

Software vendors

The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

[66] Medicine shortages: Information for consumers | Therapeutic Goods Administration (TGA)

ATTACHMENT B

Details of the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (**Instrument**). It may also be cited as PB 57 of 2023.

Section 2 – Commencement

Section 2 provides that the Instrument commences as follows:

- sections 1 to 4 and Schedule 1 of the instrument commence on 1 July 2023;
- Schedule 2 of the instrument commences on 1 September 2023.

Schedule 1 of the Instrument amends the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (**HSD Special Arrangement**). Schedule 2 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (**Main Listing Instrument**).

Section 3 – Authority

Section 3 provides that the instrument is made under sections 84AF, 84AK, 85, 85A, 88, 99 and 100 of the *National Health Act 1953* (**Act**).

Section 4 – Schedules

Section 4 provides that each instrument specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Schedule 1 amends the HSD Special Arrangement and Schedule 2 amends the Main Listing Instrument.

Schedule 1—Opioid Dependence Treatment

National Heath (Highly Specialised Drugs Program) Special Arrangement 2021

Item 1 – Section 6

Item 3 amends section 6 of the HSD Special Arrangement to include the following new definitions:

- **Approved Pharmacists Commonwealth Price Determination** means the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020*;

- **Approved Pharmacists Conditions Determination** means the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017*.

These definitions refer to the Approved Pharmacists Commonwealth Price Determination and Approved Pharmacists Conditions Determination as in force from time to time. Copies of both instruments are available free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Item 2 – Section 6 – after paragraph (b) of the definition of *community access medication*

Item 2 amends the definition of ***community access medication*** in section 6 of the HSD Special Arrangement to include a medication for the treatment of opioid dependence.

A medication for the treatment of opioid dependence is buprenorphine, buprenorphine with naloxone, and methadone (see item 3). The ODT pharmaceutical benefits to be covered by the HSD Special Arrangement that contain these drugs will be listed in Schedules 1 and 3 of the HSD Special Arrangement. They will be included in the Schedules by the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July) Instrument 2023* as part of the regular monthly updating of the HSD Special Arrangement for 1 July 2023.

Item 3 – Section 6

Item 3 amends section 6 of the HSD Special Arrangement to insert definitions that provide that ***dangerous drug*** and ***dangerous drug fee*** have the same meaning as in the Approved Pharmacists Commonwealth Price Determination.

Under the Approved Pharmacists Commonwealth Price Determination, a dangerous drug is either of:

- a pharmaceutical benefit mentioned in Schedule 3 to the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019*; or
- a pharmaceutical benefit that, under the law of a State or Territory, is classified as a dangerous drug.

The *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019* mentions buprenorphine and methadone as dangerous drugs.

The dangerous drug fee Approved Pharmacists Commonwealth Price Determination is, from 1 July 2023, $5.18.

The definitions of ***dangerous drug fee*** and ***dangerous drug*** are incorporated from the Approved Pharmacists Commonwealth Price Determination as in force from time to time. This means that any amendments to those definitions in the Approved Pharmacists Commonwealth Price Determination will automatically apply for the purposes of the HSD Special Arrangement.

Item 3 also inserts a definition of ***medication for the treatment of opioid dependence*** as meaning any of the following medicines:

- buprenorphine;
- buprenorphine with naloxone;
- methadone.

Buprenorphine is included on the PBS as tablets and modified release injections, buprenorphine with naloxone is included as a films and methadone as an oral liquid.

Item 3 also inserts a definition of an ODT pharmaceutical benefit, being an HSD pharmaceutical benefit that has a drug that is a medication for the treatment of opioid dependence.

Item 4 – Section 6 (definition of *shelf life*)

Item 4 repeals the definition of ***shelf life*** of a medicine. Following amendments to section 25 of the HSD Instrument that took effect on 1 June 2023, this definition is now redundant.

Item 5 – Section 6 – (definition of *special arrangement supply*)

Item 5 amends section 6 of the HSD Special Arrangement to include a definition of ***special arrangement supply*** that provides it has the meaning given by sections 13 and 44 of the HSD Special Arrangement.

This consequential amendment is required because of the addition of transitional arrangements providing for the supply of ODT medicines under the HSD Special Arrangement from 1 July 2023 under new Division 2 of the HSD Special Arrangement, where the prescription was written before 1 July 2023.

Items 6, 7 and 8 – Paragraph 7(4)(a), paragraph 7(4)(b), paragraph 7(4)(c)

Items 6, 7 and 8 make technical drafting improvements to subsection 7(4) of the HSD Special Arrangement by clarifying that:

- paragraph 7(4)(a) is referring to a pharmaceutical benefit with a drug that is a medication for the treatment of hepatitis C;
- paragraph 7(4)(b) is referring to a pharmaceutical benefit that is a medication that has the drug lanreotide;
- paragraph 7(4)(c) is referring to a pharmaceutical benefit that is a medication that has the drug octreotide.

These amendments do not affect the operation of subsection 7(4).

Item 9 – Subsection 7(5)

Subsection 7(5) specifies authorised prescribers for HSD pharmaceutical benefits for the treatment of hepatitis B, hepatitis C, HIV or AIDS and schizophrenia. Item 9 substitutes a new subsection 7(5) to improve drafting. It makes no substantive change to the operation of the section and no change has been made to the classes of authorised prescribers.

Item 10 – At the end of section 7

Item 10 inserts new subsection 7(6) at the end of section 7 of the HSD Special Arrangement.

Section 7 specifies the classes of authorised prescribers for different HSD pharmaceutical benefits. New subsection 7(6) specifies that for a medication for the treatment of opioid dependence, a medical practitioner or an authorised nurse practitioner is an authorised prescriber. To be an authorised nurse practitioner eligible to prescribe under the PBS, a nurse practitioner must be approved under section 84AAF of the Act.

Arrangements for the PBS supply of OTD medicines under the HSD Special Arrangement will continue to operate in conjunction with jurisdictional arrangements for the administration of opioid dependence treatment programs. This will include any restrictions imposed by jurisdictions on the medical practitioners and authorised nurse practitioners who can prescribe OTD medicines for the purpose of their jurisdictional programs.

Items 11 to 16 – Subsection 8(2), subsection 8(3), subsection 8(5), subsection 8(6) (heading), paragraph 8(6)(a) and paragraph 13(3)(a)

Items 11 to 16 amend section 8 of the HSD Special Arrangement, which deals with who is an ‘eligible patient’ for the HSD Special Arrangement, and also paragraph 13(3)(1). Items 11 to 16 make drafting improvements, to better reflect standard terminology under the Act that a pharmaceutical item ‘has a drug’ rather than ‘contains a drug’ and also describe HSD pharmaceutical benefits at the specific benefit level.

These amendments do not affect the operation of sections 8 or 13 of the HSD Special Arrangement.

Items 17 and 18 – Subsection 14(2) and at the end of section 14

Items 17 and 18 amend section 14 of the HSD Special Arrangement.

Section 14 of the HSD Special Arrangement is made for section 88 of the Act which, among other things, enables the Minister to authorise medical practitioners and authorised nurse practitioners to prescribe certain pharmaceutical benefits for the purposes of the PBS.

Medical practitioners and authorised nurse practitioners will generally rely on subsection 9(1A) and 9(4) respectively of the Main Listing Instrument for their authorisation under section 88 of the Act. However, section 14 of the HSD Special Arrangement provides a separate, more limited, authorisation for the purposes of prescribing pharmaceutical benefits under the special arrangement. This authorisation only extends to medical practitioners and authorised nurse practitioners who are an 'authorised prescriber' for the particular HSD pharmaceutical benefit.

Subsection 14(2) of the HSD Special Arrangement disapplies the broader authorisation to prescribe for medical practitioners in the Main Listing Instrument, except in the case of medications for the treatment of hepatitis C. Medications for the treatment of hepatitis C are listed under section 85 of the Act and can be prescribed and supplied outside the HSD Special Arrangement.

Item 17 substitutes a new subsection 14(2) that provides that the authorisation to prescribe in subsection 9(1A) of the Main Listing Instrument also continues to apply for methadone. Methadone can also be prescribed and supplied outside the HSD Special Arrangement in certain circumstances, such as in palliative care settings so the broader authorisation in the Main Listing Instrument needs to continue to apply.

Item 18 inserts new subsection 14(4) which provides that subsection 9(4) of the Main Listing Instrument, through which authorised nurse practitioners are authorised to write prescriptions for PBS purposes, does not apply to an HSD pharmaceutical benefit other than for a medication for the treatment of hepatitis C and methadone.

This corresponds to subsection 14(2) for medical practitioners and corrects a drafting oversight that omitted a provision that disapplied the broader authorisation in the Main Listing Instrument. This ensures it is clear that an authorised nurse practitioner can only rely on the authorisation in the HSD Special Arrangement for the purposes of prescribing HSD pharmaceutical benefits, except for medications for the treatment of hepatitis C and methadone.

Items 19 and 20 – Before subsection 20(5) and before subsection 21(5)

Items 19 and 20 insert the subheading 'Application of this section' before subsections 20(5) and 21(5), respectively, of the HSD Special Arrangement. These are technical amendments to improve the readability of sections 20 and 21 and do not affect the operation of the sections.

Items 21 and 22 – Section 23 (heading), subsection 23(1)

Items 21 and 22 makes technical amendments to the heading to section 23 and subsection 23(1) of the HSD Special Arrangement to improve drafting by changing reference to an HSD benefit that 'contains' the drug eculizumab to be a reference to an HSD benefit that 'has' the drug eculizumab. This reflects that the Act refers to pharmaceutical benefits 'having' a drug.

Item 23 – Sections 25 and 26

Item 23 repeals and replaces sections 25 and 26 of the HSD Special Arrangement.

Section 25

Section 25 of the Special Arrangement modifies the application of the Approved Pharmacists Conditions Determination for supplies of HSD pharmaceutical benefits. The approval of a pharmacist to supply pharmaceutical benefits at particular premises is subject to a number of conditions, including those in the Approved Pharmacists Conditions Determination.

Section 25 provided that the Approved Pharmacists Conditions Determination does not apply to the dispensing or supply of any HSD pharmaceutical benefit if all the following apply:

- the manner of administration for the benefit is injection or extracorporeal circulation;
- the benefit does not have a drug that is a community access medication; and
- the supply is made under the HSD Special Arrangement.

Previous section 25, with minor technical drafting improvements, is retained as new subsection 25(1).

New subsection 25(2) modifies the application of the Approved Pharmacists Conditions Determination to the dispensing or supply of an ODT pharmaceutical benefit, where the dispensing or supply is made by an approved pharmacist through an agent, for example a prison dispensary or other state and territory ODT dosing site (however authorised) that is not a PBS approved supplier. Agents must be authorised to supply medication for the treatment of opioid dependence in the relevant jurisdiction (see new section 26).

Enabling approved pharmacists (and also approved hospital authorities) to supply an ODT medicine through such an agent will assist to facilitate supplies to patient populations such as prisoners who cannot physically access a community pharmacy.

However, this means that not all steps in the dispensing and supply of the medicine will be carried out at the premises of the approved pharmacy. As a result, the following provisions of the Approved Pharmacists Conditions Determination that require certain dispensing actions to be taken at the approved premises or under the supervision of a pharmacist at the approved premises should not apply in these circumstances:

- paragraph 6(e) – relating to dispensing procedures;
- subsection 9(1) – relating to supply to people who are present at the approve premises when the supply is made;
- section 10 – relating to where dispensing steps must be carried out;
- paragraphs 14(a) and (b) – relating to use of approval numbers and where dispensing steps must be carried out;
- section 15 – relating to arrangements that would allow an approved pharmacist to supply to patients presenting at a different pharmacy business.

Where an approved pharmacist makes a supply of a medicine for the treatment of opioid dependence through an agent, the approved pharmacist must still comply with the remainder of the requirements in the Approved Pharmacists Conditions Determination including:

- complying with all legal requirements for the practice of pharmacy;
- treating patients with dignity regardless of manner of payment, race, sex, age, nationality, religion, disability or any other factor; and
- complying with the Pharmaceutical Society of Australia's Code of Ethics for Pharmacists 2017 and Professional Practice Standards (Version 5).

New subsection 25(3) modifies the application of the Approved Pharmacists Conditions Determination to the dispensing or supply of an ODT medicine by an approved pharmacist, where the dispensing or supply is not made through an agent. In these circumstances, the Approved Pharmacists Conditions Determination applies as if paragraph (c) of the definition of ***dispensing step*** in that Determination were omitted.

The Approved Pharmacists Conditions Determination requires each of the activities that make up the dispensing step to occur at the premises in respect of which the pharmacist is approved to supply pharmaceutical benefits. Paragraph (c) of the definition of dispensing steps deals with affixing a label to the packaging of the benefit that information including the name of the patient, name of the pharmacy and date of dispensing. Medicines for the treatment of opioid dependence will frequently be given to patients without traditional packaging, for example a daily dose of liquid methadone. It is impractical for approved pharmacists to label the dispensed PBS quantity in these circumstances.

Section 26

Subsection 26(1) provides that an HSD hospital authority may supply an HSD pharmaceutical benefit to a person under the HSD Special Arrangement through an agent, or other than directly to the person. This replicates existing section 26 of the HSD Special Arrangement.

New subsection 26(2) provides that an approved pharmacist or approved hospital authority supply of a medication for the treatment of opioid dependence to a person under the HSD Special Arrangement through a person or organisation that both:

- has premises in a State or Territory; and
- is authorised (however described) by an authority of the State or Territory for the purposes of supplying medication for the treatment of opioid dependence.

This ensures that an approved pharmacist or approved hospital authority can only make a supply through a person or organisation that is participating in the jurisdictional arrangements for the supply of medications for the treatment of opioid dependence.

New subsection 26(3) provides that section 26 applies in addition to section 94 of the Act, which relates to the approval of hospital authorities to supply pharmaceutical benefits to patients receiving treatment in or at the hospital. This replicates previous subsection 26(2).

Items 24 to 26 – At the end of subsection 28(1), at the end of subsection 30(2) and at the end of subsection 31(1)

Sections 28, 30 and 31 of the HSD Special Arrangement specify the rates of Commonwealth payment for the supply of a pharmaceutical benefit under the HSD Special Arrangement to approved hospital authorities for public hospitals (section 28), approved pharmacists and approved medical practitioners (section 30) and approved hospital authorities for private hospitals (section 31).

In each case the rate of payment is the amount (if any) by which the ***dispensed price*** for the supply exceeds the amount that the patient can be charged under section 87 of the Act.

Payments for the supply of ODT medicines under the HSD Special Arrangement will be consistent with these existing arrangements. However, items 24 to 26 insert a note to subsections 28(1), 30(1) and 31(1) making clear to readers that section 87 of the Act limits the amount that patients can be charged for the supply of a pharmaceutical benefit.

Under the new arrangements for the supply by approved suppliers of ODT medicines under the HSD Special Arrangement, patients must be charged consistently with general PBS arrangements.

Section 87 of the Act prevents an approved pharmacist, approved medical practitioner and approved hospital authority asking for or receiving a payment or other valuable consideration from a patient in respect of the supply of a pharmaceutical benefit, except as allowed under the section.

The main patient charge allowed by section 87 is commonly referred to as the patient co-payment. The concessional patient co-payment is currently $7.30. The general patient co-payment is currently $30.00.

ODT medicines are not subject to any special patient contribution (or brand price premium) that could be required to be paid in addition to the basic patient co-payment.

Accordingly, the only fees in addition to the patient co-payment that a patient can be asked to pay for the supply of an ODT medicine by an approved pharmacist, approved medical practitioner or approved hospital authority is an amount for supply outside of normal business hours, or a delivery fee. In accordance with subsection 87(4) of the Act and section 56 of the *National Health (Pharmaceutical Benefits) Regulations 2017*, the delivery fee cannot be more than an amount equal to the cost of the delivery.

Section 87 of the Act relates specifically to the supply of a pharmaceutical benefit and is does not affect charges that may be made in relation to, for example, Medicare services subsidised by the Australian Government.

Contribution to patient PBS safety-net

Amounts paid by a patient for a supply of an ODT medicine under the HSD Special Arrangement will contribute to their PBS safety net under the existing arrangements for other supplies made under the HSD Special Arrangement, found in section 37 of the HSD Special Arrangement.

Section 37 provides, in essence, that the value for safety net purposes for a person is the amount paid by the person (e.g. their patient co-payment) for the supply, minus any applicable special patient contribution. As mentioned, no special patient contribution applies for any of the ODT medicines able to be supplied under the HSD Special Arrangement.

Items 27 to 29 – at the end of paragraph 32(1)(a), at the end of paragraph 32(1)(b), at the end of subsection 32(1)

Items 27 to 29 include a dangerous drug fee in the calculation of the dispensed price for a supply of a pharmaceutical benefit under the HSD Special Arrangement (where relevant). The dangerous drug fee will only apply where the supply is made by a supplier who is not an approved hospital authority for a public hospital and the benefit is a ready-prepared pharmaceutical benefit.

This amendment is required because all of the pharmaceutical benefits, including methadone, buprenorphine and buprenorphine with naloxone, that can be supplied under the HSD Special Arrangement are dangerous drugs for the purposes of the Approved Pharmacists Commonwealth Price Determination, namely either:

- a pharmaceutical benefit mentioned in Schedule 3 to the *National Health (Commonwealth Price and Conditions for Commonwealth Payments for Supply of Pharmaceutical Benefits) Determination 2019*; or
- a pharmaceutical benefit that, under the law of a State or Territory, is classified as a dangerous drug.

The dangerous drug fee for the purposes of the HSD Special Arrangement is equal to the dangerous drug that applies under the Approved Pharmacists Commonwealth Price Determination for general PBS supplies ($5.18 from 1 July 2023).

New subparagraphs 32(1)(a)(iv), 32(1)(b)(iii) and 32(1)(c)(v) will result in a dangerous drug fee being included in the calculation of the dispensed price for the supply of a ready-prepared HSD pharmaceutical benefit that is a dangerous drug where the amount of the supply is equal to, less than or more than a multiple of a pack quantity of the benefit.

Item 30 and 31 – Subparagraph 34(1)(a)(i) and subparagraph 34(1)(a)(ii)

Item 30 and 31 amend subparagraphs 34(1)(a)(i) and 34(1)(a)(ii) of the HSD Special Arrangement to omit reference to the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020* (PB 66 of 2020) and insert reference to the Approved Pharmacists Commonwealth Price Determination. As noted for item 1, the Approved Pharmacists Commonwealth Price Determination is

incorporated by reference as in force from time to time and can be accessed for free on the Federal Register of Legislation.

This amendment is consequential to the inclusion of a definition of the term ***Approved Pharmacists Commonwealth Price Determination*** in section 6 of the HSD Special Arrangement (see item 1).

Item 32 – Paragraph 34(1)(b)

Item 32 amends section 34 of the HSD Special Arrangement to ensure that if a prescriber directs that instead of a patient receiving repeated supplies of an HSD pharmaceutical benefit, the patient should be supplied the full amount on the one occasion, only one dangerous drug fee will be applicable.

This is consistent with arrangements for the application of a dangerous drug fee under the Approved Pharmacists Commonwealth Price Determination.

Item 33 – Subsection 35(1)

Item 33 amends subsection 35(1) of the HSD Special Arrangement to omit reference to the *National Health (Claims and under co-payment data) Rules 2012 (PB 19 of 2012)*, which has been repealed, and insert reference to it replacement the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*.

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* is incorporated by reference as in force from time to time, and can be accessed free of charge on the Federal Register of Legislation.

Item 34 – Before subsection 37(3)

Item 34 inserts a subheading "Application of this section" before subsection 37(3) of the HSD Special Arrangement. This amendment is to improve drafting and does not affect the operation of section 37.

Item 35 - At the end of Part 6

Item 35 inserts new Division 2 of Part 6 into the HSD Special Arrangement.

Part 6 deals with application, savings and transitional provisions for the HSD Special Arrangement. Division 2 of Part 6 establishes transitional arrangements relating prescriptions written before 1 July 2023 for medications for the treatment of opioid dependence.

<u>Section 39 – Purpose of this Division</u>

New section 39 of the HSD Special Arrangement provides that the purpose of Division 2 is to make provision in relation to certain prescriptions written before

1 July 2023 for the purpose of the application of Part VII of the Act, and regulations and other instrument made for the purpose of Part VII, to those prescriptions.

The main purpose of the arrangements is to enable patients with a pre-commencement prescription (see new section 40) to continue to use that prescription to obtain PBS supplies under the HSD Special Arrangement on and after 1 July 2023, for a limited transitional period.

Section 40 – Definitions

New section 40 provides that a prescription will be a ***pre-commencement prescription*** if:

- the prescription was written before 1 July 2023, by an authorised nurse practitioner or a medical practitioner, for the supply of a drug that is a medication for the treatment of opioid dependence; and
- the prescription was written for the treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal; and
- immediately before 1 July 2023, a pre-commencement benefit could have been supplied to the person on the basis of the prescription (in other words, the prescription was still within its period of validity, had not been cancelled, and the patient had not already exhausted the full supply allowed under the prescription).

Section 40 also:

- defines ***Claims Rules*** as meaning the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*. This definition is relevant for section 49. The Claims Rules are incorporated as in force from time to time and are available for free on the Federal Register of Legislation; and
- points readers to section 50 for the meaning of ***pre-commencement benefit***.

Section 41 – Definition of ***special arrangement supply***

New section 41 of the HSD Special Arrangement establishes when a supply made on the basis of a pre-commencement prescription will be a ***special arrangement supply***.

A supply of an ODT pharmaceutical benefit to a person is a special arrangement supply under section 41 if:

- the benefit is supplied on or after 1 July 2023 to a person who is, or is to be treated as, an eligible person for the purposes of the *Health Insurance Act 1973* (in other words, the person is eligible for Medicare);
- the supply is made by a PBS approved supplier (which for the purposes of the HSD Special Arrangement includes an HSD hospital authority);

- the supply is made on the basis of a pre-commencement prescription and in accordance with Division 2 of Part 6.

Special arrangement supplies of medications for the treatment of opioid dependence under section 41 are subject to the usual rules in the Act and in Part 3 to 5 of the HSD Special Arrangement in relation to limited patient charging, a patient's co-payments contributing to their PBS safety-net, and payment of Commonwealth subsidy to approved suppliers.

Section 42 – Prescriptions directing supply for dispensing over time

From 1 July 2023, prescriptions for medications for the treatment of ODT medicines for supply under the PBS will include the quantity or number of units of the medication to be supplied, usually as a monthly supply. However, pre-commencement prescriptions written before 1 July 2023 may only provide for daily dosage to be dispensed to a patient over a period of time, for example over 3 months or valid until a specific date.

New section 42 of the HSD Special Arrangement establishes transitional arrangements for such pre-commencement prescriptions.

Subsection 42(1) provides that section 42 applies if a pre-commencement prescription directs the supply of a specified quantity or number of units, whether expressed as a total or as a dose, to be dispensed over a specified period of time. This period is known as the ***directed dispensing period***.

Subsection 42(2) covers situations where the quantity or number of units specified in the pre-commencement prescription, or the quantity or number of units required for the doses over the directed dispensing period in the prescription, is more than the maximum quantity or number of units for the pharmaceutical benefit that is allowed, from 1 July 2023, to be directed in a prescription to be supplied to a patient on the one occasion.

Maximum quantities for PBS prescribing purposes are determined under subsection 85A(2) of the Act. However, section 30 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (**Regulations**) provides a mechanism for a delegate of the Minister to authorise prescribers to write a prescription for an increase in the maximum quantity or number of units. Where an increased maximum quantity is authorised, section 30 of the Regulations requires prescribers to be given an authorisation number which must be marked on the prescription.

Where subsection 42(2) applies:

- the application of the determination of the maximum quantity or number of units for the pharmaceutical benefit is taken to have been varied under section 30 of the Regulations and the prescription is taken to have been authorised in accordance with the Regulations; and

- the number P2023OD is taken to have been given to, and marked on, the prescription for the purposes of the Regulations. This number is commonly referred to as the Authority Approval Number.

All references to the Regulations are to the Regulations as in force from time to time.

Subsection 42(3) applies where, when pre-commencement prescription is first presented to a supplier on or after 1 July 2023, the period of time remaining in the directed dispensing period is not more than 28 days, in other words is up to 4 weeks' supply. Under new section 45 of the HSD Special Arrangement, if an approved supplier is supplying an ODT medicine for the first time on or after 1 July 2023, and it is not the first time the prescription is presented to the approved supplier, it will be deemed to be a supply on the first presentation of the prescription. This means that even if an approved supplier is already in possession of the prescription on 1 July 2023, the first supply on or after 1 July can be on the first presentation of the prescription for the patient.

Where subsection 42(3) applies, for PBS purposes the pre-commencement prescription is taken to direct the supply on one occasion of the total quantity or number of units required for the remaining period, with no repeats.

Subsection 42(4) applies where, when a pre-commencement prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period in the directed dispensing period is more than 28 days but not more than 55 days – in other words, 4 weeks' or more supply but less than 8 weeks' supply. Where subsection 42(2) applies, for PBS purposes the prescription is taken to direct the supply on one occasion of the total quantity or number of units required for 28 days with no repeats. This is because the remaining period is not sufficient for two supplies of 28 days.

Subsection 42(5) applies where, when a pre-commencement prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period in the directed dispensing period is more than 55 days but not more than 83 days – in other words, 8 weeks' or more supply but less than 3 months' supply. Where subsection 42(5) applies, for PBS purposes the prescription is taken to direct the supply on one occasion of the total quantity or number of units required for 28 days' supply, and also that the supply be repeated once. This is because the remaining period is not sufficient for three supplies of 28 days.

Subsection 42(6) applies where, when a pre-commencement prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period is 84 days or more. Where subsection 42(6) applies, for PBS purposes the prescription is taken to direct the supply on one occasion of the total quantity or number of units required for 28 days' supply and that the supply be repeated twice. This is because ODT medicines can have up to a maximum of 2 repeated supplies.

Section 43 – Prescriptions directing supply of buprenorphine for injection

New section 43 establishes transitional arrangements for a pre-commencement prescription written for the drug buprenorphine, where the manner of administration (**MoA**) of the drug is by injection. Separate transitional arrangements are required as

pre-commencement prescriptions for buprenorphine by injection are less likely to be written in terms of dosage over a specified period and may be written directing repeated supply.

Subsections 43(1) and 43(2) together provide that section 43 applies where a pre-commencement prescription is for the supply of buprenorphine with the MoA injection and the prescription directs the supply of more than the ***standard quantity*** of buprenorphine, being:

- for the brand is Buvidal Weekly, 4 injections – in other words, 1 month's supply; or
- for the brand is Buvidal Monthly or Sublocade, 1 injection.

Subsection 43(3) applies if, when a pre-commencement prescription covered by subsection 43(1) is first presented to an approved supplier on or after 1 July 2023, the quantity remaining to be supplied on the prescription is not more than the standard quantity. In that case, the prescription is taken for PBS purposes to direct the supply on one occasion of the remaining quantity with no repeats.

Subsection 43(4) applies if, when a pre-commencement prescription covered by subsection 43(1) is first presented to an approved supplier on or after 1 July 2023, the quantity remaining to be supplied on the prescription is more than the standard quantity for the medication but less than twice the standard quantity for the medication. In that case, the prescription is taken for PBS purposes to direct the supply on any one occasion of the standard quantity for the medication with no repeats. This is because the remaining period is not sufficient for two supplies of the standard quantity.

Subsection 43(5) applies if, when a pre-commencement prescription covered by subsection 43(1) is first presented to an approved supplier on or after 1 July 2023, the quantity remaining for supply is more than twice the standard quantity for the medication but is less than 3 times the standard quantity for the medication. In that case, for PBS purposes the prescription is taken to direct the supply of the standard quantity of the medication, and that there is one repeat. This is because the remaining period is not sufficient for three supplies of the standard quantity.

Subsection 43(6) applies if, when a pre-commencement prescription covered by subsection 43(1) is first presented to an approved supplier on or after 1 July 2023, the quantity remaining for supply is 3 or more times the standard quantity. In that case, the prescription is taken for PBS purposes to direct the supply of the standard quantity of the medication, and that there are two repeats. This is because medicines for the treatment of opioid dependence can have up to a maximum of 2 repeated supplies of the standard quantity.

<u>Section 44 – Prescriptions directing supply of methadone</u>

Subsection 44(1) provides that the section applies to a pre-commencement prescription for methadone.

Under subsection 44(2), the person for whom the pre-commencement prescription was written is entitled to receive, and an approved supplier may supply to the person, any of the pharmaceutical benefits with the drug methadone mentioned in Schedule 1. Subsection 44(3) provides that section 44 applies despite section 89 and paragraph 103(2)(a) of the Act.

Section 44 is included to ensure that, despite revised PBS listings for pharmaceutical benefits including methadone taking effect on 1 July 2023, patients with prescriptions for the pre-1 July 2023 listings of methadone can still use that prescription to receive PBS supplies on and after 1 July 2023.

Section 45 – First supply on or after 1 July 2023 deemed to be supply on first presentation

Section 45 provides that if the first supply of an ODT pharmaceutical benefit made on or after 1 July 2023, and on the basis of a pre-commencement prescription, is not a supply of that medication on first presentation of the prescription to the supplier, it is taken to be a supply of that benefit on first presentation of the prescription.

The Regulations include different requirements for PBS approved suppliers, depending on whether they are supplying a pharmaceutical benefit on the first presentation or subsequent prescriptions of a prescriptions. Section 45 will ensure that, for the purposes of the transition of PBS supply of medications for the treatment of opioid dependence to the HSD Special Arrangement, all supplies will start as if they were supplies based on the first presentation of the prescription to the approved supplier.

Section 46 – Supply on first presentation of prescription (Regulations s 44)

Subparagraphs 44(2)(a)(i) and 44(3)(a)(i) of the Regulations require a prescription to have been written in accordance with the Regulations in order for a valid PBS supply to be made. Prescriptions written under the special arrangement for opioid dependence treatment medication that was in place before 1 July 2023 were not required to be consistent with the Regulations.

New section 46 of the HSD Special Arrangement provides that subparagraphs 44(2)(a)(i) and 44(3)(a)(i) of the Regulations do not apply to a supply of an ODT pharmaceutical benefit, where the supply is made on the basis of a pre-commencement prescription. It ensures that those subparagraphs will not result in patients being unable to use prescriptions written before 1 July 2023 for supplies after that date.

Section 47 – Repeat authorisations (Regulations s 52)

Section 52 of the Regulations sets out requirements for approved suppliers to prepare ‘repeat authorisations’ where a patient has repeats left on their prescription.

Subsection 47(1) provides that section 52 of the Regulations applies to the supply of a pharmaceutical benefit on the basis of a pre-commencement prescription to which subsections 42(5) or 42(6), or subsections 43(5) or 43(6), of the HSD Special

Arrangement applies as if the benefit were supplied in the circumstances set out in subsection 52(2) of the Regulations. This will require approved providers to prepare a repeat authorisation in accordance with subsection 52(3), even where the prescription does not meet the form requirements mentioned in subsection 52(2) of the Regulations.

When preparing repeat authorisations under subsection 52(3) of the Regulations, if the prescription is a 'authority prescription', suppliers are required to, among other things, mark the number of the authority prescription on the repeat authorisation. From 1 July 2023, prescriptions for ODT medications will be authority prescriptions, as prescribers will need to follow 'Streamlined authority' procedures.

Subsection 47(2) has the effect that subsection 52(3) of the Regulations applies in relation to a pre-commencement prescription as if it had been authorised in accordance with the Streamlined authority required procedures, in other words as if the prescription is an authority prescription.

References to the Regulations are to the Regulations as in force from time to time. The Regulations can be accessed free of charge on the Federal Register of Legislation.

Sections 48 and 49 - Prescriptions written in electronic form—additional procedures for giving information (Claims Rules s 7) and keeping documents, Information to be given using Claims Transmission System (Claims Rules Schedule 1)

Sections 48 and 49 make transitional rules to facilitate approved suppliers making claims for Commonwealth payment for supplies of ODT medicines, where the prescription is a pre-commencement prescription.

These rules are required because prescriptions written before 1 July 2023 may not include all the information required by Schedule 1 to the Claims Rules to submit claims through Services Australia's Claims Transmission System (**CTS**). In addition, modifications to the application of the Claims Rules are required so that claims for supplies made on the basis of pre-commencement prescriptions written in electronic form can be made through the CTS.

The inclusion of ODT medicines in the HSD Special Arrangement does not mean that pre-commencement prescriptions, including those written electronically, cease to be valid for PBS purposes (noting that the transitional arrangements in Division 2 of Part 6 may affect the quantity or amount that can be supplied on the PBS on the basis of the prescription).

However, the complex transitional arrangements needed to ensure that patients can continue to receive supplies of ODT medicines on the basis of prescriptions written before 1 July 2023 that do not comply with standard PBS prescription requirements, and that suppliers can continue to make claims using the CTS, has meant that for the purposes of making claims to Services Australia suppliers will need to make claims for supplies made of the basis of an electronic prescription as if the supply had been made using a paper-based prescription. In practice, this may mean that suppliers will manually enter details of the electronic prescription in their dispensing software in the same way as they would for a paper-based prescription.

Section 7 of the Claims Rules requires approved suppliers to mark certain information on prescriptions, for example whether the prescription was an authority prescription. Subsection 48(1) provides that section 7 of the Claims Rules applies in relation to a pre-commencement prescription written in electronic form as if any references in section 7 to a prescription were a reference to a print-out of the prescription.

Subsection 48(2) provides that if an approved supplier supplies a pharmaceutical benefit on the basis of a pre-commencement prescription written in electronic form, the approved supplier must keep a print-out of the prescription for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

Section 49 provides that the table in clause 1 of Schedule 1 of the Claims Rules, which sets out information required to be included in a claim using the CTS, applies to a pre-commencement prescription as follows:

- as if, for the purposes of item 2 of the table, the Authority Prescription Number for the prescription were 00000641. This ensures that approved suppliers are able to complete the field for item 2 of the table, even where the pre-commencement prescription was not written using a PBS authority prescription form;
- as if, for the purposes of item 8 of the table, the prescription was signed on 1 July 2023. PBS claims for Commonwealth payment for the supply of medications for the treatment of opioid dependence were not previously required to be made using Services Australia's CTS. This transitional arrangement is required so that the CTS does not reject claims made on prescriptions written before 1 July 2023. It does not alter the original prescribing date and is intended only to be applied for the purposes of submitting a claim;
- if the authorised nurse practitioner or medical practitioner who wrote the prescription did not write their PBS prescriber number or prescriber ID on the prescription—as if, for the purposes of items 28 and 31 respectively of the table, that number were written on the prescription;
- if the prescription was written in electronic form, as if for item 32 of the table the prescription was a paper-based prescription;
- as if, for the purposes of item 40 of the table, the authorised nurse practitioner or medical practitioner who wrote the prescription had written the prescription in accordance with Streamlined authority procedures, including writing the words "Streamlined Authority Code" and the relevant streamlined authority codes on the prescription. This is also required to ensure that patients are not required to get a new prescription by 1 July 2023.

Section 49 also provides that clause 2 of Schedule 1 to the Claims Rules, which sets out additional information requirements when submitting claims for supplies made on the basis of an electronic prescription, do not apply to a pre-commencement prescription written in electronic form.

Section 50 – Pre-commencement benefits

Section 50 sets out the table of ODT medicines that are pre-commencement benefits.

Schedule 2—Maximum Dispensed Quantities

National Health (Listing of Pharmaceutical Benefits) Instrument 2012

Schedule 2 of the Instrument amends Schedules 1 and 4 of the Main Listing Instrument to increase the maximum dispensed quantity (MDQ) for 256 PBS items (see table 1). Schedule 2 will take effect on 1 September 2023. These items include some medicines for chronic conditions such as cardiovascular disease, Crohn disease, gout, heart failure, high cholesterol, hypertension, osteoporosis, and ulcerative colitis.

The MDQ is the maximum quantity or number of units of a pharmaceutical benefit that a PBS prescriber can direct to be supplied to a patient on the one occasion. The MDQ for the relevant items is currently an amount sufficient to one month's supply. Schedule 2 will amend the entries for the relevant items in Schedule 1 of the Main Listing Instrument to include a new MDQ, sufficient for two months' supply, along with the applicable new 'purposes codes' and 'circumstances codes'.

Schedule 2 of the Instrument will also amend Schedule 4 of the Main Listing Instrument to detail, for the new purposes and circumstances codes, the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient's condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

Table 1: PBS medicines and item codes to which the increased MDQ will apply alongside the current PBS listing at 1 September 2023.

Drug	*Form (strength and presentation)*	*Item Code*
adapalene with benzoyl peroxide	adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g	08955H
alendronate	alendronate 70 mg tablet, 4	08511Y
allopurinol	allopurinol 100 mg tablet, 200	02600W
	allopurinol 300 mg tablet, 60	02604C
amiloride and hydrochlorothi-azide	amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50	01486F
amlodipine	amlodipine 5 mg tablet, 30	02751T
	amlodipine 10 mg tablet, 30	02752W
amlodipine and valsartan and hydrochlorothi-azide	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	05285E
	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	05286F
	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	05287G
	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25	05288H

Drug	*Form (strength and presentation)*	*Item Code*
	mg tablet, 28	
	amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28	05289J
amlodipine and valsartan	amlodipine 5 mg + valsartan 320 mg tablet, 28	05459H
	amlodipine 10 mg + valsartan 320 mg tablet, 28	05460J
	amlodipine 5 mg + valsartan 80 mg tablet, 28	09375K
	amlodipine 5 mg + valsartan 160 mg tablet, 28	09376L
	amlodipine 10 mg + valsartan 160 mg tablet, 28	09377M
amlodipine and atorvastatin	amlodipine 5 mg + atorvastatin 10 mg tablet, 30	09049G
	amlodipine 5 mg + atorvastatin 20 mg tablet, 30	09050H
	amlodipine 5 mg + atorvastatin 40 mg tablet, 30	09051J
	amlodipine 5 mg + atorvastatin 80 mg tablet, 30	09052K
	amlodipine 10 mg + atorvastatin 10 mg tablet, 30	09053L
	amlodipine 10 mg + atorvastatin 20 mg tablet, 30	09054M
	amlodipine 10 mg + atorvastatin 40 mg tablet, 30	09055N
	amlodipine 10 mg + atorvastatin 80 mg tablet, 30	09056P
apixaban	apixaban 5 mg tablet, 60	02735Y
	apixaban 2.5 mg tablet, 60	02744K
atenolol	atenolol 50 mg tablet, 30	01081X
	atenolol 50 mg/10 ml oral liquid, 300 ml	02243C
atorvastatin	atorvastatin 10 mg tablet, 30	08213G
	atorvastatin 20 mg tablet, 30	08214H
	atorvastatin 40 mg tablet, 30	08215J
	atorvastatin 80 mg tablet, 30	08521L
baclofen	baclofen 10 mg tablet, 100	02729P
	baclofen 25 mg tablet, 100	02730Q
balsalazide	balsalazide sodium 750 mg capsule, 280	11351K
bisoprolol	bisoprolol fumarate 2.5 mg tablet, 28	08604W
	bisoprolol fumarate 5 mg tablet, 28	08605X
	bisoprolol fumarate 10 mg tablet, 28	08606Y
calcipotriol and betamethasone	calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g	09494Q
	calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g	11091R
calcitriol	calcitriol 0.25 microgram capsule, 100	02502Q
calcium	calcium carbonate 1.5 g (calcium 600 mg) tablet, 240	03117C
	calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120	11726E
candesartan	candesartan cilexetil 4 mg tablet, 30	08295N
	candesartan cilexetil 8 mg tablet, 30	08296P
	candesartan cilexetil 16 mg tablet, 30	08297Q
	candesartan cilexetil 32 mg tablet, 30	08889W
candesartan and hydrochlorothi-azide	candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30	09314F
	candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30	08504N
	candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30	09315G
carvedilol	carvedilol 6.25 mg tablet, 60	08256M
	carvedilol 12.5 mg tablet, 60	08257N
	carvedilol 25 mg tablet, 60	08258P
chlortalidone	chlortalidone 25 mg tablet, 50	01585K
clonidine	clonidine hydrochloride 150 microgram tablet, 100	03141H
	clonidine hydrochloride 100 microgram tablet, 100	03145M
clopidogrel	clopidogrel 75 mg tablet, 28	09354H

Drug	*Form (strength and presentation)*	*Item Code*
		08358X
clopidogrel and aspirin	clopidogrel 75 mg + aspirin 100 mg tablet, 30	09296G
dabigatran	dabigatran etexilate 110 mg capsule, 60	02753X
	dabigatran etexilate 150 mg capsule, 60	02769R
enalapril	enalapril maleate 10 mg tablet, 30	01368B
	enalapril maleate 20 mg tablet, 30	01369C
	enalapril maleate 5 mg tablet, 30	01370D
enalapril and hydrochlorothi-azide	enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30	08477E
eplerenone	eplerenone 25 mg tablet, 30	08879H
	eplerenone 50 mg tablet, 30	08880J
ezetimibe	ezetimibe 10 mg tablet, 30	08757X
ezetimibe and simvastatin	ezetimibe 10 mg + simvastatin 40 mg tablet, 30	08881K
	ezetimibe 10 mg + simvastatin 80 mg tablet, 30	08882L
	ezetimibe 10 mg + simvastatin 10 mg tablet, 30	09483D
	ezetimibe 10 mg + simvastatin 20 mg tablet, 30	09484E
ezetimibe and rosuvastatin	ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60	10207F
	ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60	10201X
	ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60	10208G
ezetimibe and atorvastatin	ezetimibe 10 mg + atorvastatin 80 mg tablet, 30	10376D
	ezetimibe 10 mg + atorvastatin 40 mg tablet, 30	10377E
	ezetimibe 10 mg + atorvastatin 10 mg tablet, 30	10392Y
febuxostat	febuxostat 80 mg tablet, 28	10445R
felodipine	felodipine 2.5 mg modified release tablet, 30	02361G
	felodipine 5 mg modified release tablet, 30	02366M
	felodipine 10 mg modified release tablet, 30	02367N
fenofibrate	fenofibrate 48 mg tablet, 60	09022W
	fenofibrate 145 mg tablet, 30	09023X
fluvastatin	fluvastatin 80 mg modified release tablet, 28	02863Q
furosemide	furosemide (frusemide) 20 mg tablet, 50	01810G
	furosemide (frusemide) 10 mg/ml oral liquid, 30 ml	02411X
	furosemide (frusemide) 40 mg tablet, 100	02412Y
	furosemide (frusemide) 20 mg tablet, 100	02414C
	furosemide (frusemide) 500 mg tablet, 50	02415D
glyceryl trinitrate	glyceryl trinitrate 5 mg/24 hours patch, 30	01515R
	glyceryl trinitrate 10 mg/24 hours patch, 30	01516T
	glyceryl trinitrate 400 microgram/actuation spray, 200 actuations	08171C
hydralazine	hydralazine hydrochloride 50 mg tablet, 100	01639G
	hydralazine hydrochloride 25 mg tablet, 100	01640H
hydrochlorothi-azide	hydrochlorothiazide 25 mg tablet, 100	01484D
indapamide	indapamide hemihydrate 2.5 mg tablet, 90	02436F
	indapamide hemihydrate 1.5 mg modified release tablet, 90	08532C
irbesartan and hydrochlorothi-azide	irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30	08404H
	irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30	08405J
	irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30	02136K
irbesartan	irbesartan 75 mg tablet, 30	08246B
	irbesartan 150 mg tablet, 30	08247C
	irbesartan 300 mg tablet, 30	08248D

Drug	*Form (strength and presentation)*	*Item Code*
isosorbide dinitrate	isosorbide dinitrate 5 mg sublingual tablet, 100	02588F
isosorbide mononitrate	isosorbide mononitrate 60 mg modified release tablet, 30	01558B
labetalol	labetalol hydrochloride 100 mg tablet, 100	01566K
lercanidipine	lercanidipine hydrochloride 10 mg tablet, 28	08534E
	lercanidipine hydrochloride 20 mg tablet, 28	08679T
lercanidipine and enalapril	lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28	09144G
	lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	09145H
lisinopril	lisinopril 5 mg tablet, 30	02456G
	lisinopril 10 mg tablet, 30	02457H
	lisinopril 20 mg tablet, 30	02458J
mesalazine	mesalazine 250 mg enteric tablet, 100	01611T
	mesalazine 500 mg modified release tablet, 100	02214M
	mesalazine 2 g modified release granules, 60 sachets	02287J
	mesalazine 1 g modified release tablet, 60	03413P
	mesalazine 500 mg modified release granules, 100 sachets	08598M
	mesalazine 1 g modified release granules, 100 sachets	08599N
	mesalazine 500 mg enteric tablet, 100	08731M
	mesalazine 1.5 g modified release granules, 60 sachets	09206M
	mesalazine 1.2 g modified release tablet, 60	09353G
	mesalazine 4 g modified release granules, 30 sachets	10254Q
	mesalazine 3 g modified release granules, 30 sachets	10257W
	mesalazine 800 mg enteric tablet, 90	11210B
	mesalazine 1 g enteric tablet, 60	11554D
	mesalazine 1 g modified release granules, 100 sachets	12203G
	mesalazine 1.6 g enteric tablet, 60	12463Y
	mesalazine 1.2 g modified release tablet, 120	13247F
methyldopa	methyldopa 250 mg tablet, 100	01629R
metoprolol tartrate	metoprolol tartrate tablet 50 mg, 100	01324Q
	metoprolol tartrate tablet 100 mg, 60	01325R
metoprolol succinate	metoprolol succinate tablet 47.5 mg (controlled release), 30	08733P
	metoprolol succinate tablet 95 mg (controlled release), 30	08734Q
	metoprolol succinate tablet 190 mg (controlled release), 30	08735R
moxonidine	moxonidine 200 microgram tablet, 30	09019Q
	moxonidine 400 microgram tablet, 30	09020R
nebivolol	nebivolol 5 mg tablet, 28	09311C
	nebivolol 10 mg tablet, 28	09312D
	nebivolol 1.25 mg tablet, 28	09316H
nicorandil	nicorandil 10 mg tablet, 60	08228C
	nicorandil 20 mg tablet, 60	08229D
nifedipine	nifedipine 30 mg modified release tablet, 30	01906H
	nifedipine 60 mg modified release tablet, 30	01907J
olmesartan	olmesartan medoxomil 20 mg tablet, 30	02147B
	olmesartan medoxomil 40 mg tablet, 30	02148C
olmesartan and hydrochlorothi-azide	olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	02161R
	olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30	02166B
	olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30	02170F
olmesartan and	olmesartan medoxomil 40 mg + amlodipine 10 mg +	02836G

Drug	*Form (strength and presentation)*	*Item Code*
amlodipine and hydrochlorothi-azide	hydrochlorothiazide 12.5 mg tablet, 30	
	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30	02864R
	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	02880N
	olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	10005N
	olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30	02953K
olmesartan and amlodipine	olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30	05292M
	olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30	05293N
	olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30	05294P
pancreatic extract	pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	05453B
	pancreatic extract 10 000 units modified release capsule, 100	08020D
	pancreatic extract 25 000 units modified release capsule, 100	08021E
	pancreatic extract 35 000 units modified release capsule, 100	12595X
penicillamine	penicillamine 125 mg tablet, 100	02721F
	penicillamine 250 mg tablet, 100	02838J
perindopril and indapamide	perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30	02190G
	perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30	02845R
	perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30	08449Q
perindopril	perindopril erbumine 2 mg tablet, 30	03050M
	perindopril erbumine 4 mg tablet, 30	03051N
	perindopril erbumine 8 mg tablet, 30	08704D
	perindopril arginine 2.5 mg tablet, 30	09006B
	perindopril arginine 5 mg tablet, 30	09007C
	perindopril arginine 10 mg tablet, 30	09008D
perindopril and amlodipine	perindopril arginine 5 mg + amlodipine 5 mg tablet, 30	09346X
	perindopril arginine 5 mg + amlodipine 10 mg tablet, 30	09347Y
	perindopril arginine 10 mg + amlodipine 5 mg tablet, 30	09348B
	perindopril arginine 10 mg + amlodipine 10 mg tablet, 30	09349C
potassium	potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200	01841X
	potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60	03012M
pravastatin	pravastatin sodium 10 mg tablet, 30	02833D
	pravastatin sodium 20 mg tablet, 30	02834E
	pravastatin sodium 40 mg tablet, 30	08197K
	pravastatin sodium 80 mg tablet, 30	08829Q
prazosin	prazosin 5 mg tablet, 100	01478T
	prazosin 1 mg tablet, 100	01479W
	prazosin 2 mg tablet, 100	01480X
probenecid	probenecid 500 mg tablet, 100	01940D
propranolol	propranolol hydrochloride 10 mg tablet, 100	02565B
	propranolol hydrochloride 40 mg tablet, 100	02566C
quinapril	quinapril 5 mg tablet, 30	01968N
	quinapril 10 mg tablet, 30	01969P
	quinapril 20 mg tablet, 30	01970Q

Drug	*Form (strength and presentation)*	*Item Code*
raloxifene	raloxifene hydrochloride 60 mg tablet, 28	08363E
ramipril	ramipril 10 mg tablet, 30	01316G
	ramipril 1.25 mg tablet, 30	01944H
	ramipril 2.5 mg tablet, 30	01945J
	ramipril 5 mg tablet, 30	01946K
	ramipril 10 mg capsule, 30	08470T
	ramipril 1.25 mg capsule, 30	09120B
	ramipril 2.5 mg capsule, 30	09121C
	ramipril 5 mg capsule, 30	09122D
ramipril and felodipine	ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30	02626F
	ramipril 5 mg + felodipine 5 mg modified release tablet, 30	02629J
risedronate	risedronate sodium 5 mg tablet, 28	08481J
	risedronate sodium 35 mg tablet, 4	08621R
	risedronate sodium 35 mg enteric tablet, 4	08972F
	risedronate sodium 150 mg tablet, 1	09391G
rivaroxaban	rivaroxaban 20 mg tablet, 28	02268J
	rivaroxaban 15 mg tablet, 28	02691P
	rivaroxaban 10 mg tablet, 30	11633G
	rivaroxaban 2.5 mg tablet, 60	12192Q
	rivaroxaban 2.5 mg tablet, 60	12197Y
rosuvastatin	rosuvastatin 20 mg tablet, 30	02574L
	rosuvastatin 40 mg tablet, 30	02594M
	rosuvastatin 5 mg tablet, 30	02606E
	rosuvastatin 10 mg tablet, 30	02628H
sacubitril and valsartan	sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56	11122J
	sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56	11123K
	sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56	11131W
simvastatin	simvastatin 10 mg tablet, 30	02011W
	simvastatin 20 mg tablet, 30	02012X
	simvastatin 5 mg tablet, 30	02013Y
	simvastatin 40 mg tablet, 30	08173E
	simvastatin 80 mg tablet, 30	08313M
spironolactone	spironolactone 25 mg tablet, 100	02339D
sulfasalazine	sulfasalazine 500 mg tablet, 100	02093E
	sulfasalazine 500 mg enteric tablet, 100	02096H
telmisartan	telmisartan 40 mg tablet, 28	08355R
	telmisartan 80 mg tablet, 28	08356T
telmisartan and hydrochlorothi-azide	telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28	08622T
	telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	08623W
	telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28	09381R
telmisartan and amlodipine	telmisartan 40 mg + amlodipine 5 mg tablet, 28	08978M
	telmisartan 40 mg + amlodipine 10 mg tablet, 28	08979N
	telmisartan 80 mg + amlodipine 5 mg tablet, 28	08980P
	telmisartan 80 mg + amlodipine 10 mg tablet, 28	08981Q
thiamine	thiamine hydrochloride 100 mg tablet, 100	01070H
ticagrelor	ticagrelor 90 mg tablet, 56	01418P
trandolapril	trandolapril 500 microgram capsule, 28	02791X
	trandolapril 1 mg capsule, 28	02792Y
	trandolapril 2 mg capsule, 28	02793B
	trandolapril 4 mg capsule, 28	08758Y
trandolapril and verapamil	trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28	02857J

Drug	*Form (strength and presentation)*	*Item Code*
	trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28	09387C
valsartan	valsartan 80 mg tablet, 28	09369D
	valsartan 160 mg tablet, 28	09370E
	valsartan 320 mg tablet, 28	09371F
valsartan and hydrochlorothi-azide	valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	09372G
	valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	09373H
	valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	09374J
	valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28	09481B
	valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28	09482C
verapamil	verapamil hydrochloride 240 mg modified release tablet, 30	01241H
	verapamil hydrochloride 80 mg tablet, 100	01250T
	verapamil hydrochloride 180 mg modified release tablet, 30	02208F

ATTACHMENT C

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023

PB 57 of 2023

The *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (**Instrument**) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The Instrument:

- amends the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (**HSD Special Arrangement**) to include pharmaceutical benefits used for the treatment of opioid dependence (**ODT medicines**) as a Section 100 Highly Specialised Drugs (HSD) Program (Community Access) listing. ODT medicines are already listed on the Pharmaceutical Benefits Scheme (**PBS**), but are not currently supplied under the HSD Special Arrangement. ODT medicines currently listed on the PBS include methadone oral liquid, buprenorphine sublingual tablets, buprenorphine with naloxone sublingual films and long-acting injectable buprenorphine; and
- amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to specify increased maximum dispensed quantity (MDQ) for 256 PBS item codes for 92 drugs, including for medicines for chronic conditions such as cardiovascular disease, Crohn disease, gout, heart failure, high cholesterol, hypertension, osteoporosis, and ulcerative colitis. These amendments take effect on 1 September 2023; and

Opioid Dependence Treatment

The overarching intent of the amendments to the HSD Special Arrangement is for existing Section 100 HSD Program community access arrangements to apply to ODT medicines. This means ODT medicines will be supplied in the same way as other community access Section 100 HSD Program medicines from PBS approved suppliers. These are approved community pharmacies, approved medical practitioners, and approved hospital authorities (public and private). For the purposes of the HSD Special Arrangement, certain 'HSD hospital authorities' that would not ordinarily be approved hospital authorities are PBS approved suppliers (of HSD medicines).

This implements a recommendation made by the Pharmaceutical Benefits Advisory Committee (**PBAC**) out-of-session in March 2023. The recommendation arose following the PBAC's consideration of the Interim Report for the Post-market Review (PMR) of Opioid Dependence Treatment Program medicines. The Interim Report is available at www.pbs.gov.au/info/reviews/post-market-review-of-opiate-dependence-

treatment-program.The inclusion of ODT medicines under the HSD Special Arrangement is intended to address the core issues of patient affordability and equitable access to ODT medicines through the PBS, such that access to PBS subsidised ODT medicines aligns with usual PBS arrangements including the PBS co-payment and safety net arrangements.

State and territory governments operate individual ODT programs in their respective jurisdictions. These program policies consider patient eligibility criteria, take-away dosing policies, as well as the approval or authorisation of participating prescribers (medical practitioners and nurse practitioners) and dispensing (dosing) points for participation in individual jurisdictional programs. The operation of state and territory ODT programs are currently and will continue to be governed by the respective policies, guidelines and regulations within each jurisdiction. The provision of ODT medicines under the PBS is intended to operate in parallel with jurisdictional ODT programs.

In addition to the movement of PBS supply of ODT medicines to the HSD Special Arrangement from 1 July 2023, funding of $377.3 million over 4 years from 2023-24 (and $98.4 million ongoing) was announced in the 2023-24 Budget to improve access to and affordability of ODT within the community pharmacy sector, by supporting the delivery of pharmacy services for people in treatment programs for opioid dependence. A new ODT Community Pharmacy Program will take effect from 1 July 2023 and will be administered by the Pharmacy Programs Administrator. The ODT Community Pharmacy Program will complement, but is not part of, PBS arrangements for the supply of ODT medicines.

Maximum Dispensed Quantity

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (**Main Listing Instrument**) determines the pharmaceutical benefits that are listed on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters, including relevantly the maximum quantity or number of units of a pharmaceutical benefit that a PBS prescriber can direct to be supplied to a patient on the one occasion, and the purposes for which and circumstances in which the MDQ can be prescribed.

The MDQ for the relevant items is currently an amount sufficient to one month's supply. The amendments to the Main Listing Instrument will include a new MDQ, sufficient for two months' supply, that can be prescribed where the patient's condition is stable and the prescriber considers the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

Human Rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and` Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

Opioid Dependence Treatment

The amendments made by the Instrument to include ODT medicines under the HSD Special Arrangement assist with the advancement of human rights by increasing access and affordability of ODT medicines under the PBS.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of PBAC ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The Section 100 HSD Program, implemented through the HSD Special Arrangement, is a well-established program that provides access to specialised PBS medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied. The addition of ODT medicines does not change the broader Section 100 HSD Program policy.

Currently, patients can be charged, by individual pharmacies, up to $150-200 each month in private dispensing fees for their ODT medicines and the amount paid does not contribute to a patient's PBS Safety Net threshold. The changes to PBS subsidised access to medicines for opioid dependence will significantly improve the lives of people dependence on opioids who need treatment as they will no longer have to pay private fees.

Under the Section 100 HSD Program, PBS-eligible patients pay the PBS co-payment ($30.00 for general patients and $7.30 if the patient has a concession card) for the supply of their ODT medicines (usually for up to 28 days' supply per pharmaceutical benefit prescribed) and in most cases, payments contribute towards their PBS Safety Net threshold. This includes eligible patients receiving treatment at, or from public hospitals as a day admitted patient, non-admitted patient or patient on discharge.

Section 87 of the *National Health Act 1953* prevents an approved supplier asking for or receiving a payment or other valuable consideration from a patient in respect of the supply of a pharmaceutical benefit, except as allowed under the section. PBS approved suppliers cannot charge patients additional private dispensing or dosing fees for the supply of their ODT medicine under the PBS.

Section 100 HSD Program community access arrangements, established in 2015, allow authorised community-based practitioners to prescribe certain HSD medicines on the PBS without the need to be affiliated with a hospital. Community pharmacists are able to dispense these medicines regardless of where the medicine is prescribed.

Maximum Dispensed Quantity

The amendments to the Main Listing Instrument made by the Instrument advance the right to health and the right to social security by providing new increased MDQ of 92 existing listed PBS drugs for patients with chronic stable medical conditions (eligible patients). Currently, under the PBS prescribers can only write a prescription for eligible patients directing one month's supply of these drugs to be dispensed on the one occasion.

This policy addresses the affordability of medicines and the cost-of-living pressures many Australians are currently facing. The PBS provides for Commonwealth subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based.

The amendments to the Main Listing Instrument made by the Instrument add new increased MDQs that can be prescribed to eligible patients equivalent to two months' supply for 256 PBS item codes for 92 drugs. This will increase the amount of these

drugs that eligible patients can receive for a single co-payment, which allows for greater patient access to these drugs, convenience and financial savings. The lowering of costs to patients is likely to have a positive impact on patient medication compliance and associated health outcomes. An increase in the MDQ for certain medicines treating chronic conditions will improve access to and affordability of PBS medicines and build on the recent PBS General Patient Co-Payment reduction to $30 on 1 January 2023. Co-payment amounts are capped under the *National Health Act 1953*. From 1 January 2023, these amounts are $30.00 for general patients and $7.30 for concession card holders.

The amendments to the Main Listing Instrument provide increased MDQ for relevant medicines for eligible patients.

In response to public concerns raised about potential shortages, the Minister sought advice from the PBAC through a request to the Chair, Professor Andrew Wilson AO. The PBAC noted that the number of patients and volume of medicines prescribed will not change significantly as a result of the policy, and that any shortages were likely to be short-term as the system adjusts to a new phased model of supply. Similarly, the former long-time PBAC Chair Emeritus Professor Lloyd Sansom AO commented that the staged introduction of the PBS changes and cooperation with medicine peak bodies Medicines Australia and the Generic and Biosimilar Medicines Association will help ameliorate any demand concerns during early implementation.

The TGA works with many stakeholders to manage shortages and can take a range of actions to assist, including temporarily approving overseas substitute medicines to bolster supply. The TGA can limit the impact of shortages by working with medicine sponsors and other stakeholders to manage inventory, including constraining supply to enable fair distribution of stock in Australia. The TGA can approve the supply of overseas-registered alternatives products under section 19A of the *Therapeutic Goods Act 1989*. The TGA can implement a Serious Scarcity Substitution Instrument, which allows pharmacists to dispense certain identified substitute medicines when a medicine is in shortage. The TGA can collaborate with health professional and consumer groups to provide guidance on managing demand during a shortage, including issuing guidance on prioritising prescribing for certain conditions.

The majority of the more than 300 medicines recommended by the PBAC for inclusion in the MDQ policy do not have material supply shortages in Australia. For those medicines affected by shortages, many shortages are of brands, strengths or formulations, rather than of the drug itself. Pharmacists and prescribers already manage these shortages in a number of ways on a daily basis. For many brands of medicine in shortage, the pharmacist can substitute an alternative PBS listed brand following consultation with the patient. For those PBS brands of medicine without a pharmacist substitutable PBS brand alternative, there may be clinically appropriate alternatives the prescriber can substitute. In these cases, the pharmacist may elect to contact the prescriber (without the patient returning to the prescriber) to discuss substitution of a different dose or strength of the same medicine, or a medicine from the same therapeutic class of medicines, or a new PBS treatment option which suits the individual's circumstances, or, in those less common cases where there is no PBS alternative to advise how the individual may access treatment through another pathway.

A fundamental principle of the increased MDQ measure is that patients will only pay one co-payment for 2 months' supply instead of the current two co-payments for two one month' supplies of certain medicines for chronic stable conditions. If stock in the dispensing pharmacy is low, patients should not be negatively impacted by having to pay more frequent co-payments. The pharmacist may elect to supply the medicine in a lesser quantity than prescribed with the outstanding balance to be provided later, but must not charge a patient more in this circumstance.

Uptake of the increased MDQ measure from 1 September 2023 is likely to be gradual. Patients require a new prescription to access the increased MDQ and it will take time for all potentially eligible patients to see their prescriber, have their chronic medical condition assessed for eligibility for the measure and transition to increased MDQ prescriptions.

Finally, prescribers are not required to prescribe eligible patients a higher maximum quantity on the in-scope medicines. Prescribers retain the capacity to use their clinical judgement about whether a particular eligible patient should continue to only be dispensed one month's supply at a time.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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