EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024

Purpose and operation

The *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024* (Regulations) amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (Principal Regulations).

The Regulations make several amendments to the Principal Regulations identified during a thematic review of legislative instruments made under the *National Health Act 1953* (Act).

Under the Act the Minister may determine the maximum quantity or number of units (maximum quantity) of a pharmaceutical benefit that may be prescribed for supply on the one occasion and the maximum number of repeats that may be included in a Pharmaceutical Benefits Scheme (PBS) prescription. The Principal Regulations detail how a PBS prescriber may obtain a variation to the usual maximum quantity or maximum number of repeats. Currently, a PBS prescriber may only request a variation to the maximum quantity or number of repeats once they have already written a prescription that is not in accordance with the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*. The Regulations instead require prescribers to seek a variation before writing the prescription.

The Regulations update procedures for authorising increases to the maximum quantity or number of repeats of a pharmaceutical benefit that can be prescribed.

The Principal Regulations also deal with how medical practitioners and authorised nurse practitioners may obtain pharmaceutical benefits for supply directly to patients without the need for a prescription (prescriber bag arrangements). These arrangements support quick access to pharmaceutical benefits for short term, emergency use.

The Regulations include a new rule preventing medical practitioners or authorised nurse practitioners from stockpiling pharmaceutical benefits for prescriber bag supply where they already hold sufficient amounts of those benefits.

The Regulations also:

- repeal various strict liability offence provisions concerning the requirement for a person to acknowledge receipt of a pharmaceutical benefit from the Principal Regulations;

- amend the Principal Regulations to allow prescribers to write “reg 49”, “regulation 49” or “section 49” on the prescription when they are directing that a patient be supplied at the one time with an amount of pharmaceutical benefits equal to an original supply and all repeats; and

- make consequential amendments to the Principal Regulations resulting from the amendments outlined above.

Background

The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits. Part VII of the Act establishes the PBS, which provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines.

On 22 September 2022, the Attorney-General made the *Legislation (National Health Instruments) Sunset-altering Declaration 2022* (Declaration). The Declaration aligned the sunsetting dates for the following three legislative instruments to 1 April 2024:

- the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*;
- the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*;
- the *National Health (Prescriber bag supplies) Determination 2012*.

The PBS Thematic Review enabled the concurrent sunsetting review of the three legislative instruments, including to identify common opportunities to improve the operation and drafting of the instruments. Changes to the legislative instruments to replace the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* and the *National Health (Prescriber bag supplies) Determination 2012* from 1 April 2024, identified as part of the Thematic Review, requires consequential amendments to the Principal Regulations to ensure the coherent regulation of the PBS.

Authority

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that 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.

Commencement

The Regulations commence on 1 April 2024.

Consultation

Some practical implementation issues regarding the submission of prescription details versus the prescription itself have been raised by Services Australia where submissions are made via the post rather than electronically. The Department has built in additional time for the

changes to be implemented to allow for the required system changes to occur and reduce any negative impacts caused by the change to the process.

The removal of signature requirements has been identified as a potential risk for an increase in fraud and subsequent impact on the ability to criminally prosecute without the best evidence being available, which is currently the patient's signature on a dispensed prescription. To combat this, proposals are being developed to provide options for new, digitally-based fraud controls.

The amendments allowing prescribers to write three additional terms ("reg 49", "regulation 49" or "section 49") on prescriptions directing the supply of an original supply and all repeats at the one time is not expected to raise any practical issues.

The Department has consulted extensively with both internal and external stakeholders such as Services Australia and the Department of Veterans' Affairs regarding these amendments.

Stakeholders raised no concerns with the proposed amendments.

General

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of this instrument are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

ATTACHMENT A

Details of the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*.

Section 2 – Commencement

This section provides for the Regulations to commence on 1 April 2024.

Section 3 – Authority

This section provides that the Regulations are made under the *National Health Act 1953*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Regulations 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 – Amendments

Item [1] - Subsection 5(1) (definition of *authority prescription*)

This item repeals the definition of "authority prescription" in subsection 5(1) of the Principal Regulations and substitutes a new definition.

The new definition improves drafting to more closely align with legislation and makes minor drafting changes consequential on the substitution of a new section 30 of the Principal Regulations to be made by Item 2 (discussed below). However, no substantive changes to the definition are made and the categories of authority prescription remain prescriptions:

- written in accordance with an authorisation under section 30 of the Principal Regulations (authorisations relating to prescriptions directing an increased maximum quantity of benefit for supply or an increased number of repeats);
- authorised in accordance with authority required procedures that are part of circumstances determined under paragraph 85(7)(b) of the Act for prescribing the pharmaceutical benefit;
- authorised in accordance with authority required procedures that are part of conditions determined under subsection 85A(2A) of the Act for prescribing the standard maximum quantity or number of repeats of the pharmaceutical benefit; or
- if none of the above applies—prescriptions that have been authorised as part of the circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act, relating to circumstances in which the Commonwealth will pay a special patient contribution applying to the benefit.

The authority required procedures under paragraph 85(7)(b) and subsection 85A(2A) of the Act are currently determined in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* and from 1 April 2024 will be determined in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*.

The circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act are in the *National Health (Price and Special Patient Contribution) Determination 2022*.

Item [2] - Section 30

This item repeals section 30 of the Principal Regulations and substitutes a new section 30.

Section 30 sets out the process by which certain PBS prescribers can be authorised to write PBS prescriptions for more than the usual maximum quantity of pharmaceutical benefit or the maximum number of repeats.

Under paragraphs 85A(2)(a) and (b) of the Act, the Minister has determined:

- the maximum quantity or number of units of a pharmaceutical benefit, or a pharmaceutical benefit that has a pharmaceutical item, that a PBS prescriber may, in one prescription, direct to be supplied to a patient on any one occasion; and
- the maximum number of occasions on which the supply of a pharmaceutical benefit may be directed to be repeated in a PBS prescription.

These determinations are made in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, and from 1 April 2024 will be made in the proposed *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*. They can also be included with legislative instruments making special arrangements for section 100 of the Act.

Subsection 85A(3) of the Act provides that the regulations may authorise the variation of the application of a determination under paragraph 85A(2)(a) or (b) (85A(2) determination) in relation to persons included in a class of persons. Where such a variation is made, subsection 85A(3) provides that the 85A(2) determination is deemed to have effect as varied.

Situations in which a PBS prescriber may seek authorisation to write a prescription for increased maximum quantities for supply or increased number of repeats in a prescription include where a particular patient's dosage requirements mean that the standard maximum quantity would not provide the patient with a full month's treatment.

New subsection 30(1) provides that it makes provision for authorising the variation of the application of an 85A(2) determination.

New subsection 30(2) empowers the Minister to authorise the variation of the application of an 85A(2) determination where:

- a 'practitioner', being a medical practitioner, authorised nurse practitioner, authorised midwife or authorised optometrist, proposes to write a prescription that is not in accordance with an 85A(2) determination; and
- the prescription is either not a medication chart prescription, or is a medication chart prescription for a person receiving treatment in or at an approved hospital; and
- the practitioner provides details of the proposed prescription to the Minister.

In practice, officers in Services Australia process requests for authorisation of increases to maximum quantity or maximum repeats under delegation from the Minister through the Chief Executive Medicare.

New subsection 30(3) provides that if the Minister decides to authorise the requested variation, the Minister must allot a number to the prescription and tell the requesting practitioner that number.

A note to subsection 30(3) draws the reader's attention to section 40 and section 41 of the Principal Regulations which contain requirements for prescribers to write the allotted number on the prescription.

The process for seeking authorisation of increases to maximum quantity or maximum repeats in new section 30 differs from current section 30 of the Principal Regulations as follows:

- the prescriber submits details of a proposed prescription to Services Australia rather than submitting the prescription itself or a copy of the prescription;
- the section has been simplified to remove administrative detail about the different channels a prescriber can use to submit details of the proposed prescription to Services Australia;
- as Services Australia will now receive details of proposed prescriptions rather than prescriptions that have already been finalised by the prescriber, provisions requiring the prescriber to alter a prescription where requested by the Minister are now redundant and have been omitted;
- prescribers can no longer ask the Minister, in practice Services Australia, to send the prescription on to the patient.

New section 30 does not change the kinds of prescribers who can seek an authorisation to prescribe increased maximum quantities or maximum repeats or the kinds of prescriptions for which an increase can be authorised.

Item 18 (discussed in further detail below) contains a transitional provision enabling practitioners to also continue to use the current process for seeking authorisation to write a prescription for an increased maximum quantity or number of repeats for prescriptions written before 1 July 2024, ensuring prescribers have time to transition to the new process.

Items [3] through [7]

These items provide for various amendments to section 33 of the Principal Regulations to improve the readability of the section.

Section 33 of the Principal Regulations sets out the process by which authorised nurse practitioners and medical practitioners (other than approved medical practitioners under section 92 of the Act) can obtain pharmaceutical benefits from approved pharmacists for supply under the prescriber bag provisions in the Act (i.e. sections 93, 93AA and 93AB).

The prescriber bag provisions enable these practitioners to supply certain pharmaceutical benefits to patients without the need for a prescription. This is intended to enable these practitioners to quickly supply medicines intended for short term, emergency use.

Items 3 through 7 amend the heading of section 33, insert an application provision to clarify that the section only applies to practitioners other than approved medical practitioners and insert subheadings to assist readers to navigate the section.

Item [8] - After subsection 33(3)

This item makes amendments to section 33 of the Principal Regulations by inserting new subsection 33(3A). New subsection 33(3A) prevents medical practitioners and authorised nurse practitioners from stockpiling medicines for supply under the prescriber bag provisions.

The pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners under the prescriber bag provisions, and the maximum quantity of those pharmaceutical benefits that can be obtained by them each calendar month will, from 1 April 2024, be set out in the *National Health (Prescriber Bag Supplies) Determination 2024* (the Prescriber Bag Determination).

New subsection 33(3A) provides that a practitioner may obtain a pharmaceutical benefit that has a drug mentioned in an item in the Schedule to the Prescriber Bag Determination in the form mentioned in that item only if, at the time:

- the quantity (if any) of pharmaceutical benefits that have that drug in that form that the practitioner has in their possession, and that they obtained for the purposes of prescriber bag supply, is less than the maximum quantity set out in that item of the Schedule; and
- if the group number mentioned in that item is the same as the group number mentioned in another item in the Schedule to the Prescriber Bag Determination—the quantity (if any) of pharmaceutical benefits that have the drug mentioned in the other item in the form mentioned in the other item that the practitioner has in their possession, and that they obtained for the purposes of prescriber bag supply, is less than the maximum quantity set out in the other item.

For the purposes of section 14 of the *Legislation Act 2003*, the reference in new subsection 33(3A) to the Prescriber Bag Determination is a reference to that legislative instrument as in force from time to time.

The rule against stockpiling is currently found in subsection 6(3) of the *National Health (Prescriber bag supplies) Determination 2012*. However, that determination is being remade on 1 April 2024 without subsection 6(3), as the rule sits more appropriately in the Principal Regulations as a rule about the obtaining of pharmaceutical benefits under the prescriber bag provisions. While technical improvements to the drafting of the provision have been made, new subsection 33(3A) operates in the same way as subsection 6(3) of the *National Health (Prescriber bag supplies) Determination 2012.*

Examples

Some examples of how subsection 33(3A) operates in practice are outlined below.
For the purposes of the examples, assume Schedule 1 to the Prescriber Bag Determination contains the following table:

Group Number	Listed Drug	Form	Maximum Quantity
1	Drug A	Tablet 100 mg	5
2	Drug B	Injection 5g in 10 mL	10
3	Drug C	Tablet 50 mg	10
3	Drug D	Capsule 25 mg	5

Groups with 1 table item only
A practitioner wants to obtain a pharmaceutical benefit with Drug A in 100 mg tablet form for prescriber bag supply. The practitioner can only obtain a supply of that benefit if the practitioner has less than 5 units in total of any pharmaceutical benefit with Drug A in 100 mg tablet form that they have previously obtained for prescriber bag supply.

Groups with 2 or more table items
A practitioner wants to obtain a pharmaceutical benefit with Drug C in 50 mg tablet form for prescriber bag supply. The practitioner can only obtain a supply of that benefit if the practitioner both:

- has less than 10 units in total of any pharmaceutical benefit with Drug C in 50 mg tablet form that they have previously obtained for prescriber bag supply; and
- has less than 5 units in total of any pharmaceutical benefit with Drug D in 25 mg capsule form that they have previously obtained for prescriber bag supply.

Item 8 also inserts a heading for subsection 33(4) of the Principal Regulations to assist readers to navigate the section.

Items [9] and [15] - Paragraph 40(1)(i) and subparagraph 41(3)(a)(i)

Items 9 and 15 make amendments to sections 40 and 41 of the Principal Regulations, respectively. Section 40 of the Principal Regulations outlines the requirements for writing a valid PBS prescription that is not medication chart prescription. Section 41 outlines requirements for writing a valid PBS medication chart prescription.

Paragraph 40(1)(i) and subparagraph 41(3)(a)(i) currently require a prescriber to write on a PBS standard prescription or medication chart prescription any authority approval numbers allotted to the prescription, unless the prescription is to be posted or delivered to the Minister or Chief Executive Medicare for authorisation.

Item 9 repeals and substitutes a new paragraph 40(1)(i) of the Principal Regulations. Item 15 amends subparagraph 41(3)(a)(i) of the Principal Regulations. The provisions will not include reference to prescriptions being posted or delivered to the Minister or Chief Executive Medicare for authorisation.

These amendments are consequential amendments resulting from the new processes for authorisation of PBS prescriptions to take effect from 1 April 2024. This includes the substitution of new section 30 of the Principal Regulations by Item 2 of the Regulations and

also new processes for the authorisation of the writing of certain prescriptions in the proposed *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*, which will replace the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*.

Prescribers will now be submitting details of a proposed prescription to Services Australia, who will inform the prescriber of any authorisation number and the prescriber themselves will then add the authorisation number to the prescription, removing the need for the Minister or Services Australia to write authority numbers on prescriptions.

The transitional provision in Item 18 (discussed below), allows prescribers to continue to post or deliver prescriptions written before 1 July 2024 to Services Australia for authorisation in accordance with existing processes. For these prescriptions, it would not be necessary for the prescriber to write a number allotted by Services Australia on the prescription or medication chart prescription in accordance with section 40 or 41 of the Principal Regulations.

Items [9], [12], [13] and [16]

These items make technical amendments sections 40 and 41 of the Principal Regulations to improve drafting.

Subsections 40(5) and 41(3A) of the Principal Regulations both currently have the effect that requirements in paragraph 40(1)(i) and subparagraph 41(1)(b)(ii) to include authority approval numbers in a prescription do not apply to prescriptions requiring authorisation solely to enable the Commonwealth to pay a special patient contribution applying to the pharmaceutical benefit being prescribed.

The new definition of 'authority prescription' inserted by Item 1 enables paragraph 40(1)(i) and subparagraph 41(1)(b)(ii) to be simplified to directly exclude prescriptions requiring authorisation solely to enable the Commonwealth to pay a special patient contribution applying to the pharmaceutical benefit being prescribed, i.e. prescriptions other than those covered by paragraphs (a) or (b) of the definition. Subsections 40(5) and 41(3A) are therefore redundant and will be repealed.

Items [11] and [14]

These items provide for a note to be repealed and substituted at the end of subsection 40(1) and inserted at the end of 41(1), respectively, of the Principal Regulations. These notes explain that for authority prescriptions referred to in paragraph (c) of the definition of an 'authority prescription', being prescriptions requiring authorisation solely to enable the Commonwealth to pay a special patient contribution applying to the pharmaceutical benefit being prescribed, while an authority approval number is not required to write a valid prescription for the benefit it may still be needed if the Commonwealth is to pay the special patient contribution.

It is important to note that if other authority required procedures (outlined in paragraphs (a) or (b) of the definition of "authorised prescription") apply to a prescription or medication chart prescription, it will be necessary for an authority approval number to be written on a prescription for the prescription to be a valid PBS prescription under sections 40 or 41 of the Principal Regulations.

Item [10] - Paragraph 40(1)(j)

Paragraph 40(1)(j) of the Principal Regulations applies where a medical practitioner, authorised midwife or authorised nurse practitioner, acting under section 49 of the Principal Regulations, writes a prescription directing that, rather than a person being supplied pharmaceutical benefits as an original and a number of repeats, a quantity equal to the original and all repeats is supplied to the person on the one occasion.

Where this occurs, paragraph 40(1)(j) currently requires that the prescriber must write one of the following on the prescription to indicate the supply is a section 49 supply:

- Reg 24;
- Regulation 24;
- one supply; or
- 1 supply.

Regulation 24 was the provision corresponding to section 49 in the former *National Health (Pharmaceutical Benefits) Regulations 1960*.

Item 10 amends paragraph 40(1)(j) of the Principal Regulations to add the terms "Reg 49", "Regulation 49" and "Section 49", allowing the prescriber to alternatively write any of these terms in the prescription and satisfy the requirement in paragraph 40(1)(j) of the Principal Regulations.

Item [17] - Section 57

This item repeals section 57 of the Principal Regulations. Section 57 contains strict liability offence provisions for:

- persons who fail to comply with a request from an approved supplier (e.g. an approved pharmacist) to acknowledge receipt of a pharmaceutical benefit;
- approved suppliers who fail to certify the date on which a pharmaceutical benefit was supplied and why it was not practicable to obtain a person's acknowledgement of receipt; and
- approved suppliers that knowingly ask a person to provide an acknowledgement of receipt when no pharmaceutical benefit has been supplied.

Item [18] - In the appropriate position in Part 9

This item inserts new section 104 in Part 9 of the Principal Regulations.

New section 104 is a transitional provision regarding the process by which the Minister may vary the application of an 85A(2) determination.

New subsection 104(1) provides that the section applies in relation to prescriptions for the supply of pharmaceutical benefits written before 1 July 2024.

New subsection 104(2) provides that despite the repeal of section 30 of the Principal Regulations and substitution of a new section 30 (see Item 2):

- a practitioner may submit a prescription to the Minister in accordance with subsection 30(3) of the Principal Regulations as in force immediately before 1 April 2024 (the date these Regulations commence); and
- the Minister may make a variation under subsection 30(1) of the Principal Regulations as in force immediately before 1 April 2024 in relation to the practitioner; and
- the prescription is taken to have been written in accordance with an authorisation under proposed new section 30 of the Principal Regulations (see Item 2) if the prescription is authorised in accordance with subsection 30(4) of the Principal Regulations as in force immediately before 1 April 2024.

Section 104 ensures that prescribers have a period to transition to new processes for seeking authorisations to prescribe more than the standard maximum quantity or number of units of a pharmaceutical benefit set out in the new section 30, minimising any risk of disruption to the timely supply of pharmaceutical benefits to patients.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024

This Disallowable Legislative 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 *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024* (Regulations) amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (Principal Regulations).

The Regulations make several amendments to the Principal Regulations identified during a thematic review of legislative instruments made under the Act, including to update procedures for authorising increases to the maximum quantity or number of repeats of a pharmaceutical benefit that can be prescribed.

The Principal Regulations also deal with how medical practitioners and authorised nurse practitioners may obtain pharmaceutical benefits for supply to patients without a prescription under prescriber bag arrangements. The Regulations include a new rule preventing medical practitioners or authorised nurse practitioners from stockpiling pharmaceutical benefits for prescriber bag supply where they already hold sufficient amounts of those benefits.

The Regulations also:

- repeal various strict liability offence provisions concerning the requirement for a person to acknowledge receipt of a pharmaceutical benefit from the Principal Regulations;
- amend the Principal Regulations to allow prescribers to write “reg 49”, “regulation 49” or “section 49” on the prescription when they are directing that a patient be supplied at the one time with an amount of pharmaceutical benefits equal to an original supply and all repeats; and
- make consequential amendments to the Principal Regulations resulting from the amendments outlined above.

Human Rights implications

The Regulations do not engage any of the applicable rights or freedoms.

It does not engage or interfere with the right of individuals to the enjoyment of the highest attainable standard of physical and mental health (Articles 2 or 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)).

This is because the Regulations maintain provisions to ensure ongoing and unchanged access for eligible individuals to the Pharmaceutical Benefits Scheme (PBS). Any additional provisions or changes made from the Principal Regulations clarify and reinforce current arrangements and policy intent. The new Regulations do not alter the operation of the PBS; do not result in any change to PBS entitlements, PBS eligibility or cost to consumers.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Mark Butler
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