SUPPLEMENTARY EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

Purpose of supplementary explanatory statement

This supplementary explanatory statement clarifies the consultation referred to in the explanatory statement to the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024 [F2024L00380]* (the Amendment Regulations). The Amendment Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations).

Additional notes on consultation

Consultation on the Amendment Regulations was conducted internally within the Department of Health and Aged Care (the Department) and with external Government bodies (Department of Veterans' Affairs and Services Australia) regarding all the changes.

Given the nature of the following amendments it was determined that no external consultation was required as the changes are minor and improve/clarify processes.

Section 30 - repeal and substitution of section 30

The changes to section 30 involved the removal of the requirement for prescribers to submit an actual prescription as part of a written application for an increase to maximum quantity or repeats (or *details* of a prescription if the prescription was submitted by telephone or other electronic means). These requirements have been replaced with the requirement to provide details of a *proposed* prescription.

Unnecessary detail and outdated wording around telephone/fax/electronic submission pathways was also removed, but the administrative processes and outcomes relating to authority requests submitted using these pathways will be largely the same. Rather than providing details of an *actual* prescription, the prescriber submits details of a *proposed* prescription.

The change from providing details of an actual prescription to providing details of a proposed prescription was made to improve the alignment of processes around increases in section 30 with the Act.

The changes also provide additional support to Services Australia's digital transformation project which is expected to result in faster response times for many authority approval requests by supporting online submission and assessment. A three-month transition period has been included in the new section 104 of the Principal Regulations, to allow Services Australia time to familiarise prescribers with the simplified procedure.

Section 33 – amendments relating to obtaining pharmaceutical benefits for prescriber bag supplies

Section 33 of the Principal Regulations deals with procedures for medical practitioners (other than approved medical practitioners) and authorised nurse practitioners to obtain pharmaceutical benefits from approved pharmacists for supply without prescription as a 'prescriber bag' supply.

The substantive change to section 33 was the insertion of new subsection 33(3A), the purpose of which is to prevent medical practitioners (other than approved medical practitioners) and authorised nurse practitioners from being able to stockpile prescriber bag medicines. This is done by limiting the quantity of prescriber bag medicines they can obtain from an approved pharmacist depending on the amount of the same or similar medicine they already have in their possession.

It was determined that it was not necessary to consult on this amendment to prevent medical practitioners or authorised nurse practitioners from stockpiling pharmaceutical benefits under the prescriber bag provisions because there were no substantive changes to the underlying policy. Instead, what is now subsection 33(3A) of the Principal Regulations was moved from subsection 6(3) of the *National Health (Prescriber bag supplies) Determination 2012* (superseded Prescriber Bag Determination).

Following a thematic review related to the sunsetting of the superseded Prescriber Bag Determination it was identified that subsection 6(3) more appropriately sat in the Principal Regulations as a rule about the obtaining of pharmaceutical benefits under the prescriber bag provisions. New subsection 33(3A) operates in the same way as subsection 6(3) of the superseded Prescriber Bag Determination.

Other amendments to section 33 were all technical improvements to the drafting of the provision that did not affect its operation.

Therefore, consultation on amendments to section 33 was not considered necessary.

<u>Subsection 40(1) – identifying prescriptions where repeated supply directed for supply on one occasion</u>
Subsection 40(1) of the Principal Regulations deals with requirements for writing prescriptions (other than medication chart prescriptions).

The key amendment to subsection 40(1) of the Principal Regulations is about 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. Prescribers can continue to use existing terms to identify such prescriptions, including "Regulation 24" and "Reg 24". Accordingly, the amendment provides greater flexibility for prescribers to use additional terms but does not prevent them from continuing with existing practice of referring to regulation 24 (which was replaced by section 49 when the Principal Regulations replaced the *National Health (Pharmaceutical Benefits) Regulations 1960*).

This is therefore very unlikely to raise any practical issues for affected individuals.

<u>Section 57 – repeal of section 57</u>
Section 57 of the Principal Regulations created offences relating to evidencing receipt of supply of a pharmaceutical benefit. During the COVID-19 pandemic, section 16 of the *National Health (COVID Supply of Pharmaceutical Benefits (Special Arrangement) 2020*

(the Special Arrangement) modified the application of section 57 of the Principal Regulations so that it would not be an offence if an approved supplier is unable to obtain written acknowledgement from a person receiving a benefit because it was not practical to do so.

The Special Arrangement expired on 31 March 2023, however, given the regulatory burden on patients and pharmacists and it was extended for 12 months for the Department to make permanent legislative changes. The amendments to the Principal Regulations have repealed section 57 to remove all offences. Given that this amendment has removed a regulatory burden it was therefore considered unnecessary to consult affected individuals.

Peak bodies and pharmacists have made a number of representations to the Government and the Department to remove the requirement for patients to sign prescriptions for over 12 months, therefore it was considered that sufficient input has been received from stakeholders to inform making this change and continuing arrangements that were already in place since 2020.