EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (CLAIMS AND UNDER CO-PAYMENT DATA) AMENDMENT RULES 2012 (No. 1)

PB 49 of 2012

Authority

Subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act) provide for the Minister to make rules related to the supply of pharmaceutical benefits and concern transmission of claims data, and transmission of data for medicines priced at or below the patient co-payment threshold.

Purpose

The purpose of this legislative instrument, made under subsections 98AC(4) and 99AAA(8) of the Act, is to amend the *National Health* (*Claims and under co-payment data*) *Rules 2012* (PB 19 of 2012) (the claims rules), to make changes to the rules related to the provision of claims and under co-payment data.

The Pharmaceutical Benefits Scheme (PBS) is established under Part VII of the Act. Under the PBS, approved suppliers provide pharmaceutical benefits to the Australian community. In situations where a Commonwealth subsidy is payable for a pharmaceutical benefit, an approved supplier may make a claim for payment.

Subsection 99AAA(8) of the Act provides that the Minister must make rules:

- specifying the information to be given to the Secretary by approved suppliers following their supply of pharmaceutical benefits;
- defining the procedures to be followed by approved suppliers in making claims for payment for their supply of pharmaceutical benefits; and
- defining the procedures to be followed by the Secretary in processing and determining claims and making payments.

Section 98AC of the Act mandates the provision of information where a pharmaceutical benefit is provided by an approved supplier but there is no Commonwealth subsidy paid because the item is priced at or below the co-payment threshold.

On and from 1 July 2012 the Act will provide for continued dispensing supplies (new section 89A) and supply from a medication chart in residential aged care facilities (section 93A).

New section 89A of the Act, and a minor amendment to section 93A of the Act, will commence on 1 July 2012 when Schedules 1 and 2 of the *National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012* commence.

This Instrument makes changes to the claims rules to specify information/procedures to be included or not required to be included for claims and under co-payment data transmission for continued dispensing supplies and supplies from a medication chart in residential aged care facilities. This Instrument also makes certain other minor and mechanical changes.

A provision by provision description of this Instrument is contained in the Attachment.

Consultation

Broad consultation has been undertaken throughout the development of the *Continued Dispensing of Eligible PBS Medicines in Defined Circumstances* and *Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities* initiatives. A public written consultation process was undertaken in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiatives. The Department has continued to engage with stakeholder groups as individual issues are identified.

In addition, the Department also consulted with the Department of Human Services, the Department of Veterans' Affairs and state and territory Departments of Health.

Other changes made by this instrument are minor and mechanical in nature.

This Instrument commences on 1 July 2012.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act* 2003.

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (CLAIMS AND UNDER CO-PAYMENT DATA) AMENDMENT RULES 2012 (No.1)

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Claims and under co-payment data) Amendment rules 2012 (No.1)* and that it may also be cited as PB 49 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2012.

Section 3 Amendments to PB 19 of 2012

This section provides that Schedule 1 amends the *National Health* (*Claims and under co-payment data*) *Rules 2012* (PB 19 of 2012) (the claims rules).

Schedule 1

Item 1 amends the definition of 'authority prescription' in rule 4 of the claims rules by amending paragraph (b) of the definition to provide that an authority prescription includes a prescription that has been authorised in accordance with authority required procedures as part of conditions for increasing the maximum quantity or number of repeats under subsection 85A(2A) of the Act or as part of conditions for when the Commonwealth will pay a special patient contribution under subsection 85B(5) of the Act. This reflects amendment to the definition of 'authority prescription' in the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) commencing 1 July 2012.

New subsection 85A(2A) of the Act is being inserted by Schedule 3 of the *National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012* and commences 1 July 2012. The inclusion of subsection 85B(5) of the Act in the definition reflects amendments to the Regulations commencing 1 July 2012 to clarify that the circumstances determined by the Minister may require that the prescription be authorised in accordance with authority required procedures.

Item 2 amends the note to the definition of 'authority prescription' to make it clear that a streamlined authority code may fulfil the requirements of amended paragraph (b) of the definition.

Items 3, 4 and 5 amend rule 4 of the claims rules to insert definitions for 'continued dispensing', 'medication chart prescription' and 'paperless claim for payment'.

Item 6 amends the definition of 'prescription' in rule 4 of the claims rules to include a medication chart prescription.

Item 7 amends the definition of 'RPBS' in rule 4 of the claims rules to include reference to the *Repatriation Pharmaceutical Benefits Scheme* (Australian Participants in British Nuclear Tests) 2006 (RPBS (APBNT)) and the *Military Rehabilitation and Compensation Act* 2004 *Pharmaceutical Benefits Scheme* (MRCA PBS) as well as the *Repatriation Pharmaceutical Benefits Scheme* (RPBS), being schemes administered by the Department of Veterans' Affairs.

Section 24 of the RPBS (APBNT), MRCA PBS and RPBS provide for claims made under those schemes to be made using the same claims procedures as in section 99AAA of the Act and the same rules as determined under subsection 99AAA(8) of the Act. Section 32A of the RPBA (APBNT) and section 40A of the MRCA PBS and RPBS, which commenced 1 April 2012, provide for under co-payment data to be provided in accordance with the same procedures as in section 98AC of the Act and the rules that apply for provision of under co-payment data under subsection 98AC(4) of the Act.

The notes at the end of rule 5 of the claims rules explain the bundling of 'RPBS' prescriptions. The descriptions of some elements in the Schedule to the claims rules make provision for some different information to be provided for 'RPBS' claims and under copayment data transmission. This amendment makes it clear that these explanatory references apply to claims and under co-payment data transmission (as applicable) under all three schemes.

Item 8 amends the definition of 'repeat authorisation' in rule 4 of the claims rules to include continued dispensing using a repeat authorisation form.

Items 9 amends rule 4 of the claims rules to insert a definition for 'repeat authorisation form'.

Item 10 amends rule 4 of the claims rules to insert a definition for 'supply certification form'.

Item 11 amends subrule 5(2) of the claims rules. This amendment, together with the inclusion of new subrule 5(3) of the claims rules, provides that the prescription does not need to be provided with a claim when supply is made based on a medication chart prescription.

Item 12 adds a note after subparagraph 5(2)(c)(iv) of the claims rules to make it clear that in the claims rules there is an extended definition of 'prescription' and 'repeat authorisation' and therefore repeat authorisation forms for continued dispensing and emergency drug supply forms are part of the bundles of prescriptions specified in paragraph 5(2)(c) of the claims rules.

Item 13 inserts new subrule 5(3) of the claims rules. This amendment, together with the amendment to subrule 5(2) of the claims rules, provides that the prescription does not need to be provided with a claim when supply is made based on a medication chart prescription. A claim for supply based on a medication chart prescription is a 'paperless claim for payment', as defined in the amendment to the Regulations commencing 1 July 2012 and as indicated in the new definition for 'paperless claim for payment' in the claims rules made by these amendments. Under new subregulation 31(4) of the Regulations it is an offence for a 'paperless claim for payment' to not include a 'supply certification form'.

Item 14 amends the Schedule to the claims rules by inserting an element for Health Practitioner (AHPRA) number. This number is a pharmacist's registration number that is issued by the Pharmacy Board of Australia and published by the Australian Health Practitioner Regulatory Agency. This number is only required to be supplied for a continued dispensing supply.

This amendment ensures that not only the approved pharmacist but also the individual pharmacist who conducted the continued dispensing supply is identified if the approved pharmacist did not dispense the pharmaceutical benefit personally.

Item 15 amends the element for Date of Prescribing in the Schedule to the claims rules to provide that this information does not need to be included for a continued dispensing supply.

Item 16 amends the element for Date of Previous Supply in the Schedule to the claims rules to provide that this information does not need to be included for a continued dispensing supply or supply from a medication chart prescription.

Item 17 amends the elements for Original PBS Approval Number and Original Unique Pharmacy Prescription Number in the Schedule to the claims rules to provide that this information does not need to be included for a continued dispensing supply or supply from a medication chart prescription.

Item 17 also amends the element for Patient Category in the Schedule to the claims rules to include categories for 'continued dispensing patient' and 'residential aged care facility patient (paperless)'.

There are already categories for 'paperless private hospital patient' and 'paperless public hospital patient' in the description of this element. These two categories reflect special arrangements under section 100 of the Act which make provision for situations where the prescription does not have to be included with the claim. One section 100 special arrangement, the *National Health (Highly specialised drug program for hospitals) Special Arrangement 2010*, is amended commencing 1 July 2012 to make it clear that where a 'paperless claim for payment' is made the 'supply certification form' does not need to be provided with the claim as would otherwise be required by new subregulation 31(4) of the Regulations. Otherwise, section 100 special arrangements that relate to hospital patients already have the effect that the new requirement in subregulation 31(4) of the Regulations to provide a 'supply certification form' does not apply.

Item 18 amends the element for Prescriber ID in the Schedule to the claims rules to provide that this information does not need to be included for a continued dispensing supply.

Item 19 amends the Schedule to the claims rules by including an element for Residential Aged Care Facility ID. This is the ID number for a residential care service, as defined in the *Aged Care Act 1997*, that needs to be included for supplies based on a medication chart prescription, or for any other supply made to a resident of a residential aged care service.

Item 20 amends the element for Serial Number in the Schedule to the claims rules to provide that multiple sequences of numbers may be used within a payment category for different types of prescriptions within that category, for example a sequence for medication chart prescriptions within the 'concessional benefit and concession card' payment category. It is proposed that the serial number will start at 10,000 for medication chart prescriptions.

Item 21 amends the element for Streamlined Authority Code in the Schedule to remove the words 'If the element is not provided, claim not rejected on that basis', which were a final stage in the transitioning to the provision of streamlined authority codes as part of claims and under co-payment data.

Item 22 amends the element for Unique Pharmacy Prescription Number in the Schedule to the claims rules to make it clear that this number is allocated by an approved pharmacist's dispensing software to each supply of a pharmaceutical benefit by the approved pharmacist.

Statement of Compatibility with Human Rights

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

National Health (Claims and under co-payment data) Amendment Rules 2012 (No.1)

This 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 purpose of this legislative instrument, made under subsections 98AC(4) and 99AAA(8) of the Act, is to amend the *National Health* (*Claims and under co-payment data*) *Rules 2012* (PB 19 of 2012) (the claims rules), to make changes to the rules related to the provision of claims and under co-payment data.

Subsection 99AAA(8) of the Act provides that the Minister must make rules defining the procedures for making a claim and the information that needs to be provided.

Section 98AC of the Act mandates the provision of information where a pharmaceutical benefit is provided by an approved supplier but there is no Commonwealth subsidy paid because the item is priced at or below the co-payment threshold.

This Instrument makes changes to the claims rules to specify information to be included or not required to be included for claims and under co-payment data transmission for continued dispensing supplies (new section 89A of the Act) and supplies from a medication chart in residential aged care facilities (section 93A of the Act), and certain other minor and mechanical changes.

Human rights implications

This legislative instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

This legislative instrument also engages the right to not be subject to arbitrary or unlawful interference with privacy in Article 17 of the International Covenant on Civil and Political Rights (ICCPR), as the Instrument provides for the collection and transmission of personal information. There is no incompatibility with the right to privacy as expressed in Article 17 of the ICCPR and the provisions of this Instrument as the data collections and transmissions that will commence with the amendments made by this Instrument are neither arbitrary nor an unlawful interference with the privacy of PBS clients.

The data will be collected and disclosed in accordance with the *Privacy Act 1988* and the secrecy provisions of the Act.

Conclusion

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

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