

## EXPLANATORY STATEMENT

*National Health Act 1953*

### ***National Health (Claims and under co-payment data) Amendment (Medication Chart Prescriptions) Rule 2015***

#### **PB 19 of 2015**

#### **Authority**

This rule is made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

#### **Purpose**

The purpose of this rule is to amend the *National Health (Claims and under co-payment data) Rules 2012* (PB 19 of 2012) (the Principal Rules).

A number of the amendments made by this instrument are consequential amendments to reflect changes to the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations), as amended by the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015* on 1 April 2015.

The Regulation amendments provide for a medication chart prescription to be used for hospital patients for prescribing, dispensing, and claiming on the Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS). The Regulation amendments implement the PBS Medication Charts for Public and Private Hospitals measure, announced by the Australian Government as part of the 2014-15 Budget.

Implementation of the measure will reduce the regulatory burden currently placed on PBS prescribers, approved suppliers and nurses in hospitals. It will remove the need for duplication of PBS/RPBS prescription information, and improve work flows for health professionals, and health outcomes, through a reduction of transcription errors. The hospital medication chart prescription builds on the existing medication chart prescription for persons at a residential aged care facility which already allows for PBS/RPBS claiming directly from a chart.

The Regulation amendments are aligned with and supported by the Australian Commission on Safety and Quality in Health Care (ACSQHC) PBS Hospital Medication Chart project. The ACSQHC is developing national standardised medication charts appropriate for use in hospital settings to support PBS/RPBS subsidy directly from a PBS prescriber's medication chart prescription without the need for separate PBS/RPBS prescriptions.

The amendments in this rule:

- align the Principal Rules to the Regulation amendments and provide for certain information to be provided in a PBS/RPBS claim or provision of under co-payment data when a medication chart prescription is used;
- remove the requirement to provide prescriptions with a PBS/RPBS claim and introduce electronic supply certification, enabled on and from 1 April 2015, and required on and from 1 July 2015; and
- remove an old 'CTS non-online' method of electronic claiming and provision of under co-payment data (commonly called diskette claiming) on and from 1 April 2015.

**Consultation**

Since the announcement of the PBS Medication Charts for Public and Private Hospitals measure in 2014, the Department of Health has undertaken an extensive consultation process involving all key health stakeholders. These consultations indicate widespread and strong support for the trial of the PBS Hospital Medication Chart and amendments required to the Regulations and associated legislative instruments to support the measure. Consulted stakeholders include States and Territories, Australian Private Hospital Association, Society of Hospital Pharmacists of Australia, Pharmaceutical Society of Australia, Pharmacy Guild of Australia, Australian Medical Association, Cancer Voices Australia, Consumers Health Forum of Australia, National Prescribing Service, the ACSQHC, and the National E-Health Transition Authority. Similarly, the Department of Human Services has received strong support from a range of stakeholders for the implementation of paperless (electronic) claiming of PBS/RPBS medicines. This includes support for transitional arrangements to ensure stakeholder readiness for the implementation of paperless PBS/RPBS claiming.

Details of the instrument are set out in the [Attachment](#).

This instrument commences on 1 April 2015.

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

**Details of the *National Health (Claims and under co-payment data) Amendment (Medication Chart Prescriptions) Rule 2015***

**Rule 1 Name**

This rule provides that the name of this rule is the *National Health (Claims and under co-payment data) Amendment (Medication Chart Prescriptions) Rule 2015*. It can also be cited as PB 19 of 2015.

**Rule 2 Commencement**

This rule provides that this instrument commences on 1 April 2015.

**Rule 3 Authority**

This rule provides that this instrument is made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*(the Act).

**Rule 4 Schedules**

This rule provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has affect according to its terms.

**Schedule 1 Amendments**

***National Health (Claims and under co-payment data) Rules 2012***

**Items 1 to 10 Rule 4**

Items 1 to 10 amend rule 4 of the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules) (Definitions), by:

- removing the definition of *CTS non-online claim*, and *diskette* as this old method of electronic claiming and provision of under co-payment data (commonly called diskette claiming) is ceasing on 1 April 2015;
- removing the definition of *online claim* and *CTS claim* as with the removal of CTS non-online (diskette) claiming there will be one ‘Claims Transmission System’ (that is, procedure for providing information by electronic means in accordance with subsections 98AC(4) and 99AAA(8) of the Act). The current Claims Transmission System is commonly known as online claiming;
- removing a formatting error in the definition of *medication chart prescription* which remains aligned with the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations);
- replacing the definition of ‘*ePrescription*’ with *electronic prescription* to align with the term used in the Regulations; and

- simplifying and relocating a note to the beginning of rule 4, and making some minor drafting amendments.

#### **Items 11 to 14 Rule 4**

Items 11 to 14 amend rule 4 of the Principal Rules by:

- removing the definition of *paperless claim for payment* and the note to that definition. The definition worked when a *paperless claim for payment* (that is, prescription not provided with the Pharmaceutical Benefits Scheme (PBS) or Repatriation PBS (RPBS) claim was an exceptional situation. Unless a manual system claim is made, not providing a prescription with the PBS/RPBS claim will be the usual approach;
- replacing a definition of *PBS prescriber* and inserting a definition of *pharmaceutical benefit*; and
- removing the definition of *original authority prescription* and *authority prescription*. Useful elements from these definitions for the purposes of the Principal Rules now appear in the definition of prescription. There is also a definition of *authority prescription* in the Regulations.

#### **Item 15 Rule 4 (definition of *prescriber bag supply form*)**

Item 15 repeals the definition of *prescriber bag supply form* and substitutes a definition which maintains alignment with the Regulations. For the purposes of the Principal Rules, a prescriber bag supply form is deemed to be a prescription. Unless a manual system claim is made, a *prescriber bag supply form* will no longer be provided to the Australian Government as part of a PBS/RPBS claim, aligned with the treatment of prescriptions generally.

#### **Item 16 Rule 4 (definition of *prescription*)**

Item 16 repeals the definition of *prescription* and substitutes a new definition. The definition remains an inclusive definition and seeks in particular to be of assistance, for the purpose of the Principal Rules, when working out which document may be provided to the Australian Government as the prescription under rule 5(2) if a manual system claim is made.

#### **Items 17 to 21 Rule 4**

Items 17 to 21 amend rule 4 of the Principal Rules by removing the definition of *supply certification form* as that definition worked when a *paperless claim for payment* (that is, prescription not provided with the PBS/RPBS claim) was an exceptional situation. An electronic supply certification, instead of a paper-based supply certification form accompanying prescriptions, will be made by the approved supplier at the point of time when the approved supplier is finalising their electronic claim/under co-payment data submission (commonly known as the ‘closing’ point of time in the process).

The definition of *print-outs* (which relates to electronic prescriptions) is removed as a reference to print-outs is made in the definition of *prescription*. New subrule 4(2)

provides, for clarity, that a reference to supplying a pharmaceutical benefit in the Principal Rules includes the obtaining of a pharmaceutical benefit by an approved medical practitioner (dispensing doctor) under section 93 of the Act (prescriber bag supply). The remaining amendments are minor drafting amendments.

**Item 22 After subrule 5(1)**

Item 22 inserts subrules 5(1A), (1B) and (1C) and relates to rule 5 (Procedures). This item amends rule 5 by:

- requiring a certification from the approved supplier; and
- expressly indicating that the certification may be included in the paper-based form under paragraph 5(1)(a) (retained for manual system claims).

The approved supplier will be able to check the information before providing electronic certification, assisted by identification of the range of ‘serial numbers’ for each ‘payment category’, the total number of pharmaceutical benefits for each ‘payment category’, and the identification of the ‘claim period number’ and the ‘claim reference’. This aligns with information provided by approved suppliers electronically (see Schedule 1 to the Principal Rules), and information required for the paper-based supply certification previously used when providing prescriptions with electronic PBS/RPBS claims.

**Item 23 subrule 5(2)**

Item 23 amends subrule 5(2) so that it requires a prescription to be provided with a PBS/RPBS claim if a manual system claim is made. It continues to be the case that under co-payment prescriptions are not provided to the Australian Government. This is because due to rule 9 of the Principal Rules under co-payment data is not provided if a manual system claim is made.

**Items 24 to 27 Paragraphs 5(2)(b), (f) and (g), and note to paragraph 5(2)(c)**

Items 24 to 27 make minor technical drafting amendments to paragraphs 5(2)(b), (f) and (g), and the note to paragraph 5(2)(c).

**Item 28 Subrule 5(2) (first note at the end of the subrule)**

Item 28 amends the first note at the end of subrule 5(2), which relates to the RPBS, to provide that prescriptions are only provided if a manual system claim is made.

**Item 29 Subrule 5(2) (second note at the end of the subrule)**

Item 29, when read together with item 30, re-locates the second note at the end of subrule 5(2), which also relates to the RPBS, so that it appears after subrule 5(3), with some minor drafting changes.

### **Item 30 Subrule 5(3)**

Item 30 repeals subrule 5(3) and substitutes new subrules 5(3), (4) and (5). These amendments:

- retain the requirement to group the prescriptions per payment category, whether a Claims Transmission System or the manual system is used; and
- do not apply to a medication chart prescription directly, because the detail about such matters as placement of serial number on the prescription is relevant for paper-based prescriptions only. However, a note refers to the Claims Transmission System, Schedule 1 and the equivalent requirement to provide a ‘serial number’ by ‘payment category’.

### **Item 31 Rules 6 and 7**

Item 31 repeals and substitutes new rule 6 (Claims Transmission System – procedures) and rule 7 (Information about supplies). These amendments have the same effect as current rules 6 and 7 except:

- if electronic certification is made by an approved supplier, one or more computer programs must ensure that prior to certification the approved supplier is given a warning that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*;
- references to ‘CTS non-online’ (ie diskette) are removed; and
- references to approved supplier approval number, name and address are fine-tuned to reflect the Claims Transmission System or the manual system, as appropriate, as prescriptions will not be provided as part of the PBS/RPBS claim when the Claims Transmission System is used.

The reference to ‘in writing’ in paragraph 6(2)(a) is simply to assist with activating the *Electronic Transactions Act 1999*.

### **Items 32 to 34 Rule 8 (note), Paragraph 10(a), and Rule 10 (note)**

Items 33 and 34 amend Rule 10 (Claim processing procedures) to reflect that unless the claim uses the manual system the prescriptions will no longer be submitted as part of the PBS/RPBS claim. A minor drafting change is made to update the note to Rule 10 to refer to the Claims Transmission System, and the note to Rule 8 (by item 32) to update paragraph cross-references to rule 7.

### **Item 35 Rule 12**

Item 35 repeals a spent transitional provision, and inserts a new transitional rule 12.

*Removal of requirement to send prescriptions, and introduction of electronic certification*

PBS/RPBS claiming without sending in prescriptions, while still providing a supply certification, is enabled on and from 1 April 2015, and required on and from 1 July 2015.

If a claim contains supplies before 1 April 2015 it is still processed under the old rules, with the prescriptions sent in. Subrule 12(1) provides that an approved supplier who provides information under the Principal Rules on or after 1 April 2015 will be required to provide the information in accordance with the Principal Rules as in force immediately before 1 April 2015 if at least one of the supplies of pharmaceutical benefit was made before 1 April 2015.

Subrule 12(2) provides that an approved supplier may PBS/RPBS claim without sending in prescriptions, while still providing a supply certification, or may have the claim processed under the old rules, provided none of the supplies was made before 1 April 2015 and at least one of the supplies was made before 1 July 2015.

If a claim contains no supplies made before 1 July 2015, it is processed under the Principal Rules as amended on 1 April 2015.

The Chief Executive Medicare may extend the 1 July 2015 cut-off date for a particular approved supplier on request, if the Chief Executive Medicare is satisfied exceptional circumstances exist. Any extension period must cease before 1 April 2017.

#### *Removal of CTS non-online claiming*

Subrule 12(4) provides for the removal of CTS non-online claiming (commonly known as diskette claiming) on 1 April 2015.

#### *Medication chart prescriptions – approved hospitals*

Subrule 12(5) provides that hospital medication chart prescriptions must be given in accordance with the Principal Rules as amended on 1 April 2015 – that is, no prescription is provided with the PBS/RPBS claim and a supply certification is provided. Hospital medication chart prescriptions apply to trial hospitals initially.

### **Item 36 Schedule**

Item 36 repeals and substitutes a new Schedule 1. The Schedule is the same as the previous Schedule 1, with changes in relation to medication chart prescriptions, and to remove CTS non-online claiming. The amendments require the approved supplier to provide the following information in a claim or in under co-payment data, if the approved supplier has supplied from a hospital medication chart prescription:

- either the new ‘patient category’ ‘Medication chart public hospital patient’ (indicated by an ‘M’) or ‘Medication chart private hospital patient’ (indicated by a ‘P’);
- the ‘Hospital Provider Number’; and
- the ‘Medication Chart Period of Validity’ (indicated by either a ‘1’, ‘4’ or ‘12’).

If the approved supplier has supplied from a ‘medication chart prescription’ for a person receiving treatment in a residential care service, the existing ‘patient category’ ‘Residential aged care facility patient (medication chart prescription) (indicated by ‘R’) continues to be provided, and information for the new ‘Medication Chart Period of Validity’ must also be provided (indicated by a ‘4’).

The amendments to Schedule 1 also remove reference to CTS non-line (diskette) claiming, and make some minor formatting and other drafting changes to ensure that the details in Column 2 work for all prescriptions.



## 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 (Medication Chart Prescriptions) Rule 2015***

This 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 Instrument**

The purpose of this legislative instrument, made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act) is to make consequential changes to align the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules) with changes to the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations), made by the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*.

The Regulations provide for hospital medication chart prescriptions to be used for prescribing, dispensing and claiming for supply of pharmaceutical benefits (medicines), without the need to produce a separate prescription for Pharmaceutical Benefits Scheme (PBS) or Repatriation PBS (RPBS) purposes. This improves workflow for health professionals, as a duplication burden is removed, and the risk of transcription error is reduced.

The Regulations, together with consequential amendments to other instruments under the Act and Regulations, such as the Principal Rules, implement the PBS Medication Charts for Public and Private Hospitals measure, announced by the Australian Government as part of the 2014-15 Budget. The measure is aligned with standardised hospital medication charts produced by the Australian Commission on Safety and Quality in Health Care.

This instrument, together with the Regulations, also assists with streamlining payment of claims submitted electronically by all approved suppliers of pharmaceutical benefits (ie, pharmacist, hospitals, dispensing doctors). Approved suppliers will no longer be required to send in prescriptions as part of their PBS/RPBS claim, instead providing an electronic supply certification, and, under the Regulations, keeping prescription documents previously provided to the Australian Government for 2 years. An old electronic claiming method, 'CTS non-online claiming' (commonly called diskette claiming) is also removed.

#### **Human rights implications**

This instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights 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 PBS assists with advancement of these human rights by providing for subsidised access to medicines. The Regulation amendments and this instrument are a positive step towards attaining the highest standard of health for all Australians. Increased efficiencies from the use of hospital medication charts for PBS purposes, assists to reduce duplication and improve workflow for health professionals. This in turn can assist health professionals to achieve improved health outcomes for patients.

#### **Conclusion**

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

Felicity McNeill  
First Assistant Secretary  
Pharmaceutical Benefits Division  
Department of Health