

## EXPLANATORY STATEMENT

*National Health Act 1953*

### ***National Health (Claims and under co-payment data) Amendment (Discount co-payment and patients charges data) Rule 2015***

#### **PB 128 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).

The Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package of measures (the Package), announced by the Australian Government in May 2015, established pharmacy funding, medicines pricing arrangements, and a range of sector improvements to ensure ongoing access to innovative medicines through a sustainable PBS. It contained measures negotiated following consultations with a wide range of stakeholders from pharmacy, pharmaceutical industry and consumer groups, including measures relating to the Sixth Community Pharmacy Agreement (6CPA) between the Commonwealth of Australia and the Pharmacy Guild of Australia.

The Package resulted in the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (the Amending Act), which amended the *National Health Act 1953* (the Act).

The changes to the Principal Rules are consequential changes resulting from Act amendments commencing on 1 January 2016.

The changes also relate to clause 7.7 of the 6CPA regarding data collection, and enhanced transparency, regarding the amount patients pay suppliers for PBS medicines.

The measures requiring consequential amendments to the Principal Rules are:

- discounting of patient co-payments;
- provision of data on the amount charged for each prescription supplied, and the amount of any discount; and
- expansion of early supply provisions.

#### *Maximum one dollar patient co-payment discount*

Community pharmacies are currently required by the Act to charge no less than the legislated amount as the co-payment for a PBS supply.

From 1 January 2016, pharmacists will be able to reduce co-payment amounts by up to one dollar for each dispensed medicine. Pharmacists can choose whether to offer a reduction, and the amount up to the one dollar maximum. A reduced co-payment supply will count for safety net purposes and the amount accruing to the safety net threshold is the reduced co-payment amount charged. Co-payments cannot be reduced

for 'early supply' prescriptions and, consistent with existing safety net policy, the usual full co-payment will apply.

There will be no change to the reimbursement from the Commonwealth for the supply of PBS medicines for any supply where the pharmacist elects to offer a discount on the relevant co-payment.

#### *Collection of data on amounts charged for PBS prescriptions*

The Principal Rules prescribe matters and set out the details regarding the information required to be provided by approved suppliers when making claims for payment for pharmaceutical benefits or providing information on under co-payment prescriptions to the Commonwealth.

Clause 7.7 of the 6CPA provides that the information approved suppliers must provide to the Commonwealth for each prescription supplied, including under co-payment prescriptions, includes the price charged, and the amount of any discount.

#### *Expansion of early supply provisions*

From 1 January 2016, changes made by the Amending Act remove 20 days as the period associated with an early supply of a specified pharmaceutical benefit. Instead, there is provision for the early supply period (as an interval in days) to be specified individually for a pharmaceutical item. This enables early supply rules to apply to any PBS medicine and the resupply interval to be appropriate to the particular medicine. It will allow the use of the medicine, the listed quantity and the resupply interval to be better aligned. Use of terms such as 'Safety Net 20 day rule' to refer to early supply provisions will be replaced by more neutral terms which do not incorporate an interval period.

Under early supply rules, if a repeat supply of a PBS medicine is obtained in less than the specified interval, safety net benefits do not apply. The patient payment does not count towards the PBS safety net, and if the patient co-payment would otherwise be reduced by PBS safety net, the patient co-payment for the PBS supply reverts as if the PBS safety net threshold were not met. The PBAC makes recommendations regarding the application of early supply rules.

Existing arrangements allowing pharmacists to dispense an early repeat supply with the usual PBS subsidy, but no safety net benefits, will continue.

### **Consultation**

A wide range of stakeholders from pharmacy, the pharmaceutical industry, and consumer groups were consulted during the development of the Package. The Department of Health consulted with the Department of Human Services regarding consequential amendments required to implement these changes. Consultation with pharmacy software providers has occurred as part of the implementation.

### **General**

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

This instrument commences on 1 January 2016.

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

## ATTACHMENT

### Details of the *National Health (Claims and under co-payment data) Amendment (Discount co-payment and patient charges data) Rule 2015*

#### **1. Name of Instrument**

Subrule 1(1) provides that this Rule is called the *National Health (Claims and under co-payment data) Amendment (Discount co-payment and patient charges data) Rule 2015*.

Subrule 1(2) provides that this Rule can also be cited as PB 128 of 2015.

#### **2. Commencement**

Rule 2 provides that this instrument commences on 1 January 2016.

#### **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).

#### **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 effect according to its terms.

#### **Schedule 1      Amendments**

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

#### **Items 1 to 5      Rule 4**

Items 1 to 5 amend Rule 4 of the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules) (Definitions) by:

- replacing the Note under the Definitions heading to add a reference to ‘special patient contribution’ which is used in the new definition of ‘actual contribution’; and
- inserting definitions for ‘actual contribution’, ‘allowable discount’, ‘contribution discount’, and ‘early supply of a specified pharmaceutical benefit’.

#### **Item 6      After Rule 12**

Item 6 inserts a new Rule to the Principal Rules for the application and transitional arrangements for these amendments.

The amendments do not apply to supplies made before 1 January 2016. For supplies made on or after 1 January 2016, it is possible to comply with the old claims rules, or the new claims rules until:

- 1 March 2016 (for approved pharmacists and approved medical practitioners); or
- 1 July 2016 (for approved hospital authorities).

In addition, it is possible for the Chief Executive Medicare to extend these dates, but not beyond 31 December 2016, if satisfied that exceptional circumstances exist.

#### **Item 7 Schedule**

Item 7 repeals and substitutes a new Schedule 1. The substitute Schedule includes all of the fields in the repealed Schedule 1, with the addition of two new fields for the collection of the Actual Contribution and the Contribution Discount amounts. The addition of the two new fields requires the approved supplier to provide the following information when using the Claims Transmission System:

- the Actual contribution paid by the patient or their agent; and
- the Contribution discount (if any) applied by the approved pharmacist or approved medical practitioner. Information is not required in this field for approved hospital authorities or when giving under co-payment data. There is no barrier in the Act to discounting by approved hospital authorities or for under co-payment dispensing.

In addition, details in Column 2 for one item are changed.

- ‘Immediate Supply Necessary’: when a prescription is supplied within the 4 or 20 day period in accordance with regulation 25, the approved supplier must also indicate if the prescription is an early supply. A reference to the ‘Safety Net 20 day rule’ is replaced with the neutral term *early supply of a specified pharmaceutical benefit* to reflect the amendment to the Act commencing 1 January 2016 providing the ability to specify a period other than 20 days.

## 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 (Discount co-payment and patients charges data) 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 Act 1953*, made by the *National Health Amendment (Pharmaceutical Benefits) Act 2015*, which commence 1 January 2016. The changes also relate to clause 7.7 of the Sixth Community Pharmacy Agreement regarding data collection, and enhanced transparency, about the amount patients pay suppliers for Pharmaceutical Benefits Scheme (PBS) medicines.

One of the measures will provide the option for pharmacies to discount patient co-payments by a maximum of one dollar per prescription, which could reduce out of pocket expenses for consumers.

The introduction of discounted co-payments and the collection of data relating to the actual amounts charged for PBS prescriptions is an additional impost on pharmacy software providers as changes to the dispensing programmes are required, and an additional impost on pharmacies as they are being required to disclose pricing information and discounting practices for the first time. However, the effect that these changes may have on the rights of those groups is justified as information on pricing will provide greater transparency regarding the actual cost of PBS medicines to consumers and assist the Government in making better informed decisions regarding affordability of medicines.

The extension of the safety net early supply rules will promote quality use of medicines and responsible use of PBS entitlements, as well as discourage waste and reduce the quantity of unused medicines in the community. It will also result in savings that can be used to list new and innovative medicines on the PBS.

#### **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. This instrument is a positive step towards attaining the highest standard of health for all Australians

#### **Conclusion**

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

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