**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***National Health (Claims and under co-payment data) Amendment (Extension of exceptional circumstances dates) Rule 2017***

**PB 24 of 2017**

**Authority**

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

**Purpose**

The purpose of this Instrument is to amend the *National Health (Claims and under co‑payment data) Rules 2012* (PB 19 of 2012) (the Principal Rules) to extend the cut-off date from 1 April 2017 to 1 February 2018 allowing approved suppliers to continue to comply with the old Principal Rules and not the current Principal Rules for certain information, provided that the Chief Executive Medicare is satisfied that exceptional circumstances exist in relation to that approved supplier.

The Principal Rules specify the information and procedures for claims for payment for pharmaceutical benefits or providing information on under co‑payment prescriptions to the Commonwealth.

The Principal Rules include a transitional period within which approved suppliers can choose to continue to submit information and follow procedures for Pharmaceutical Benefits Scheme/Repatriation Pharmaceutical Benefits Scheme (PBS/RPBS) supplies in accordance with the old Principal Rules regarding:

* removal of the requirement to send prescriptions to the Commonwealth, and the introduction of electronic certification instead; and
* provision of information relating to ‘actual patient contribution’ and ‘contribution discount’.

**Consultation**

A number of State and Territory Departments of Health have raised with the Department of Health that they will be unable to meet the 1 April 2017 deadline to comply with the requirements of the current Principal Rules due to difficulties with implementation of pharmacy software updates necessary to support the changes.

After consultation with the Department of Human Services, the Department of Health considers it appropriate to extend the transitional arrangements until 1 February 2018. This will ensure sufficient time for necessary software implementation and will prevent any adverse access to medicines issues that may result for patients should the extension not be granted.

This Instrument commences on the day after registration.

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

**ATTACHMENT**

**DETAILS OF THE *NATIONAL HEALTH (CLAIMS AND UNDER CO-PAYMENT DATA) AMENDMENT (EXTENSION OF EXCEPTIONAL CIRCUMSTANCES DATES) RULE 2017***

**Rule 1 Name**

This rule provides that the name of this Instrument is the *National Health (Claims and under co-payment data) Amendment (Extension of exceptional circumstances dates) Rule 2017.* It can also be cited as PB 24 of 2016.

**Rule 2 Commencement**

This section provides that this Instrument commences on the day after the instrument is registered on the Federal Register of Legislation.

**Rule 3 Authority**

This rule provides that this Instrument is made under subsections 98AC(4) and 99AAA(8) of 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 effect according to its terms.

**Schedule 1 Amendments**

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

**Item 1 Subrule 12(3)**

Item 1 amends current subrule 12(3) of the Principal Rules to change the date from 1 April 2017 to 1 February 2018.

Rule 12 is a transitional provision relating to the removal of the requirement for approved suppliers to send prescriptions to the Commonwealth and the introduction of electronic certification instead.

Subrule 12(2) of the transitional rule allows approved suppliers of a pharmaceutical benefit to continue to give information in accordance with the old Principal Rules if at least one of the supplies was made before 1 July 2015.

Subrule 12(3) currently permits the Chief Executive Medicare to determine a date later than 1 July 2015 for these transitional arrangements if the Chief Executive Medicare is satisfied that exceptional circumstances exist in relation to the approved supplier. However, current subrule 12(3) only enables the Chief Executive Medicare to set a date that is before 1 April 2017. These amendments have the effect that the Chief Executive Medicare may set a date after 1 April 2017 providing that the date is before 1 February 2018.

**Item 2 Subrule 13(2)**

Item 2 amends current subrule 13(2) to change the date from 1 April 2017 to 1 February 2018.

Rule 13 is a transitional provision relating to changes introduced by the *National Health (Claims and under co-payment data) Amendment (Discount co-payment and patient charges data) Rule 2015*. This amendment introduced two new data fields called ‘Actual contribution’ and ‘Contribution discount’. The ‘Contribution discount’ field does not apply to approved hospital suppliers or when giving under co-payment data.

Subrule 13(1) allows approved suppliers to continue to give information in accordance with the old Principal Rules if at least one of the supplies was made before 1 March 2016 by an approved pharmacist or approved medical practitioner, or before 1 July 2016 by an approved hospital authority.

Subrule 13(2) currently permits the Chief Executive Medicare to determine a date later than 1 March 2016 or 1 July 2016 (as applicable) if the Chief Executive Medicare is satisfied that exceptional circumstances exist in relation to the approved supplier. However, current subrule 13(2) only enables the Chief Executive Medicare to set a date that is before 1 April 2017. These amendments have the effect that the Chief Executive Medicare may set a date after 1 April 2017 providing that the date is before 1 February 2018.

**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 (Extension of exceptional circumstances dates) Rule 2017***

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 subsection 98AC(4) and 99AAA(8) of the *National Health Act 1953*, is to amend the *National Health (Claims and under co-payment data) Rules 2012* (the Principal Rules) to extend the cut-off date from 1 April 2017 to 1 February 2018 allowing approved suppliers to continue to comply with the old Principal Rules and not the current Principal Rules for certain information, provided that the Chief Executive Medicare is satisfied that exceptional circumstances exist in relation to that approved supplier.

**Human Rights Implications**

This Legislative Instrument engages Articles 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 assists with advancement of these human rights by providing for subsidised access to medicines. This Legislative Instrument is a positive step towards attaining the highest standard of health for all Australians. Allowing more transition time will ensure vital IT system testing occurs, resulting in robust dispensing software and avoidance of rejected claims. This in turn can assist health professionals to achieve improved health outcomes for patients.

**Conclusion**

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

**Julianne Quaine**

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**Pharmaceutical Access Branch**

**Pharmaceutical Benefits Division
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**Statement of Compatibility with Human Rights**

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

***National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2013 (No. 4)***

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 100(1) and 100(2) of the Act, is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement), to make changes to the special arrangement relating to the efficient funding of chemotherapy.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines (‘chemotherapy pharmaceutical benefits’) to eligible patients being treated for cancer, to reflect the 2010 budget measure titled ‘Revised arrangements for the efficient funding of chemotherapy drugs’. This Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment (‘related pharmaceutical benefits’) at certain public hospitals.

This Instrument:

* adds 4 new listed brands for the listed drugs ‘Doxorubicin’, and ‘Gemcitabine’;
* adds 1 new listed form for the listed drug ‘Aprepitant’;
* removes 2 listed brands for the listed drug ‘Docetaxel’; and
* adds new circumstance codes and the associated circumstances for the listed drug ‘Aprepitant’.

**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. The recommendatory role of the Pharmaceutical Benefits Advisory