

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### *National Health (Claims and under co-payment data) Rules 2012* PB 19 of 2012

#### **Authority**

These Rules are made pursuant to subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act). They relate to the supply of pharmaceutical benefits and concern (i) transmission of claims data, and (ii) transmission of data for medicines priced at or below the patient co-payment threshold.

#### **Purpose**

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 in connection with their supply of pharmaceutical benefits; and
- defining the procedures to be followed by the Secretary in processing and determining claims and making payments.

Instrument Number PB 49 of 2008 (as amended) presently sets out rules made under subsection 99AAA(8).

Section 98AC was inserted into the Act by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010*. Section 98AC 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. Section 98AC commences operation on 1 April 2012.

Subsection 98AC(4) 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; and
- defining the procedures to be followed by approved suppliers in giving information to the Secretary in connection with their supply of pharmaceutical benefits.

Subsection 98AC(6) of the Act provides that the rules made under section 98AC may be in the same document as rules made under subsection 99AAA(8).

### **Details of this Instrument**

The existing rules under subsection 99AAA(8) of the Act contained in PB 49 of 2008 have been reviewed and simplified. The application of the simplified rules has then been extended to cover situations where a pharmaceutical benefit is provided by an approved supplier but where there is no Commonwealth subsidy paid because the item is priced at or below the co-payment threshold, which currently stands at \$35.40 for general patients and \$5.80 for concessional patients.

PB 49 of 2008 is revoked by this Instrument and replaced by the streamlined and extended Rules contained in this Instrument.

This Instrument also updates the existing rules to reflect the transition of Medicare Australia to the Department of Human Services (which was effected by the *Human Services Legislation Amendment Act 2011*).

### **Consultation**

There has been extensive briefing of, and consultation with, stakeholders concerning the implementation of under co-payment data collection. Those advised and consulted include the Pharmacy Guild of Australia, the Office of the Australian Information Commissioner, medical and pharmacy professional organisations, hospitals and the Consumer Health Forum. The changes to the rules under subsection 99AAA(8) are minor and mechanical in nature.

### **General**

This legislative instrument commences on 1 April 2012.

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

## **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) Rules 2012***

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**

This Legislative Instrument sets out rules made pursuant to subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act). The rules relate to the transmission of data concerning the supply of pharmaceutical benefits to the Australian community under the Pharmaceutical Benefits Scheme (PBS). Transmission of such information is required to allow the Commonwealth to provide a subsidy to approved suppliers in situations where an amount is payable. Regardless of whether a subsidy is paid, the collection and analysis of such data also assists with health planning and monitoring.

#### **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 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 Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

This Legislative Instrument also engages the privacy human right, as the Instrument provides for the collection and transmission of personal information.

Article 17 of the International Covenant on Civil and Political Rights provides as follows (in full):

#### *Article 17*

1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.
2. Everyone has the right to the protection of the law against such interference or attacks.

The Legislative Instrument is required to be made by the Act. There is no incompatibility with the right to privacy as expressed in Article 17 of the ICCPR

(extracted above) and the provisions of this Instrument as the data collections and transmissions that will commence and that continue to occur under this Instrument are neither arbitrary nor an unlawful interference with the privacy of PBS clients.

In making the assessment that there is no incompatibility with human rights, the collection and transmission of personal data has been considered in relation to the fact that the PBS is the centrepiece of National Medicines Policy, which promotes the welfare of the Australian community. It was also noted that the Department of Health and Ageing, the Department of Human Services and the Office of the Australian Information Commissioner liaise regularly and each organisation acts to protect the privacy interests of PBS clients.

It was further considered that the PBS ensures access to affordable medicines for the Australian community and it necessarily requires the transmission of data to the Commonwealth where a subsidy is paid. Further, health planning and monitoring are assisted by the collection of a comprehensive data set concerning medicine usage which includes data regarding where a pharmaceutical is dispensed and a subsidy is not paid.

The Legislative Instrument does not require the provision of data for private (non-PBS) prescriptions.

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

### **Conclusion**

The Legislative Instrument is compatible with human rights because it facilitates the PBS which promotes the welfare of the Australian community, without arbitrarily or unlawfully interfering with the privacy of PBS clients.

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