

## **EXPLANATORY STATEMENT**

### *National Health Act 1953*

#### *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022*

##### **Purpose**

The *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022* (Rules) relate to the supply of pharmaceutical benefits and (i) the transmission of claims data and (ii) transmission of data for medicines priced at or below the patient co-payment threshold.

In the 2018-19 Budget, it was announced that prescribers and their patients would be provided with the option to use an electronic prescription or electronic medication chart as an alternative to a paper-based prescription. The Rules provide for the period of validity for electronic medication charts for use in residential aged care to be six months. Paper medication charts in residential aged care will expire after four months.

The Rules also include a requirement for a Medication Chart Start Date on a medication chart prescription in or at an approved hospital and in or at an approved residential care service.

The Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

##### **Authority**

The Rules are made pursuant to subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

The Pharmaceutical Benefits Scheme (PBS) is established under Part VII of the Act. It provides Australians with timely, reliable and affordable access to necessary medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. In situations where a Commonwealth subsidy is payable for a pharmaceutical benefit, an approved supplier may make a claim for payment.

Subsection 98AC(4) provides that the Minister must, by legislative instrument, make rules:

- specifying the information to be given to the Secretary by approved suppliers in relation to the supply by them of pharmaceutical benefits; and
- defining the procedures to be followed by approved suppliers in giving information to the Secretary in relation to the supply by them of pharmaceutical benefits

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

- defining the procedures to be followed by approved suppliers in making claims for payment in relation to the supply of pharmaceutical benefits; and
- specifying the information to be given to the Secretary by approved suppliers in relation to the supply by them of pharmaceutical benefits; and
- defining the procedures to be followed by approved suppliers in providing information by electronic means to the Secretary in relation to the supply by them of pharmaceutical benefits; and

- rules defining the procedures to be followed by approved suppliers in providing information otherwise than by electronic means to the Secretary in relation to the supply by them of pharmaceutical benefits; and
- rules defining the procedures to be followed by the Secretary in:
  - processing and determining claims by approved suppliers for payment relating to the supply of pharmaceutical benefits; and
  - making the payments.

The Rules named the *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022* is the current legislative instrument that sets out the rules for the purpose of subsections 98AC(4) and 99AAA(8) of the Act.

## **Background**

The Pharmaceutical Benefits Scheme (PBS) is established under the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Subsections 98AC(4) and 99AAA(8) of the Act provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by approved suppliers and by the Secretary, and specifying the information to be given to the Secretary by approved suppliers, in relation to the claim for payment relating to supply of pharmaceutical benefits. These rules are the *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022*

### **Reliance on subsection 33(3) of the *Acts Interpretation Act 1901***

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

### **Commencement**

The *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022* will commence the day after the Rules are registered on the Federal Register of Legislation.

### **Consultation**

There has been broad consultation with various stakeholders, including state and territory governments, the clinical software industry, pharmacists, prescribers and residential aged care representatives. These industries welcome the Rules, noting that the Rules support prescribers and staff within the residential aged care sector to facilitate the ongoing supply of PBS medicines and medication management for aged care facility residents.

Services Australia have also been consulted in relation to the PBS Online Claiming System to support the Rules.

A provision by provision description of the Rules is contained in the Attachment.

**Details of the *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022***

**Part 1 – Preliminary**

**Section 1 – Name**

Section 1 provides for the Rules to be referred to as the *National Health (Supply of Pharmaceutical Benefits–Under Co-payment Data and Claims for Payment) Rules 2022 (No.1)* (the Rules). The Rules may also be cited as PB 22 of 2022.

**Section 2 – Commencement**

Section 2 provides that the Rules commence on the day after the instrument is registered.

**Section 3 – Authority**

Section 3 provides that the Rules are made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

**Section 4 – Schedules**

Section 4 provides that each instrument specified in Schedule 2 to the Rules is amended or repealed as set out in the applicable items and any other item in that Schedule has effect according to its terms.

**Section 5 – Definitions**

Section 5 provides the definitions of certain terms used in the Rules.

**Part 2 – Information and procedures relating to supplies of pharmaceutical benefits**

**Section 6 – Procedures for giving information – form and period for giving information and certification**

Section 6 defines the general procedures to be followed by an approved supplier in giving information in relation to the supply of pharmaceutical benefits. It provides time limits for the provision of the information to the Chief Executive Medicare. This section provides that the approved supplier must provide information in relation to all the pharmaceutical benefits provided during a particular time period. This information must be provided within 30 days of the last day of that period.

Subsection 6(1) defines the procedures to be followed by an approved supplier in giving information to the Chief Executive Medicare, on behalf of the Secretary, in relation to the supply by the approved supplier of pharmaceutical benefits. Subsection 6(1) includes information given under subsection 98AC(1) or information related to making a claim under section 99AAA of the Act.

**Subsection 6(2) relates to the form for giving information.**

Subsection 6(2) relates to the form for giving information and requires that, if the Chief Executive Medicare has approved a form for an approved supplier to give information, the approved supplier must provide the information in accordance with that approved form.

Subsections 6(3) to 6(5) relate to the period for giving information.

Subsection 6(3) requires that the timeframe must not exceed 35 days for an approved supplier to provide information to the Chief Executive Medicare in relation to the pharmaceutical benefits provided during a period. Subsection 6(3) provides an exception from the requirement where the Chief Executive Medicare is satisfied that the approved supplier was unable to comply with the requirement through circumstances outside the approved supplier's control.

Subsection 6(4) requires that information must be given to the Chief Executive Medicare within 30 days after the end of the period in which the pharmaceutical benefits were provided. This subsection provides an exception from this requirement where the Chief Executive Medicare is satisfied that the approved supplier was unable to comply with that requirement and the reason for not being able to meet the requirement was through circumstances outside the approved supplier's control.

Subsection 6(5) requires that the approved supplier must only provide information to the Chief Executive Medicare once per calendar month. This is intended to reduce the administrative burden that would be imposed on the Chief Executive Medicare by approved suppliers providing information on a more frequent basis. This subsection provides an exception whereby the approved supplier can propose an arrangement for agreement by the Chief Executive Medicare on the basis that the proposed arrangement will not impose additional administrative expenses on the Chief Executive Medicare.

Subsections 6(6) to 6(8) relate to certification.

Subsection 6(6) requires an approved supplier to certify two things in relation to the supply of pharmaceutical benefits. That (a) each of the pharmaceutical benefits to which the information relates was supplied by or on behalf of the approved supplier and in accordance with the *National Health Act 1953* and the instruments made under it, or the Repatriation Pharmaceutical Benefit Scheme and (b) that the information provided was correct.

Subsection 6(7) relates to subsection 6(2) and paragraph 8(3)(d). Subsection 6(7) gives the approved supplier discretion to make the certification either in an approved form as described in subsection 6(2) or in another manner.

The note to subsection 6(7) refers to the requirements for the Claims Transmission System in relation to warnings and notifications if the certification is not included in a form approved under subsection 6(2). This means, if the approved supplier decides to make the certification in another manner, paragraph 8(3)(d) provides that the Chief Executive Medicare will be notified of the certification and that the approved supplier will be given a warning before the certification is made, that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*.

Subsection 6(8) sets out additional information that the approved supplier must provide. That is, the approved supplier must include the range of the serial numbers for each payment category, the total number of pharmaceutical benefits for each payment category, the claim

period and the claim reference. This information assists in identifying the benefits which are being certified as having been supplied in accordance with the legislation.

### **Section 7- Additional procedures for giving information**

Subsection 7(1) defines additional procedures to be followed by an approved supplier in giving information to the Chief Executive Medicare, on behalf of the Secretary, when the information is given under subsection 98AC(1) of the Act, which relates to under co-payment data and under section 99AAA of the Act, which relates to claims for payments.

#### Subsections 7(2) to (9) relate to claims made using the manual system.

Subsection 7(2) states that subsections 7(3) to (9) apply only when the approved supplier is making a claim using the manual system.

Subsection 7(3) provides that the information supplied under the additional procedures required by subsections 7(3) to (9) must be accompanied by the prescriptions which were presented for the supply of the pharmaceutical benefit.

Subsection 7(4) provides that on each prescription (other than an authority prescription, a repeat authorisation, a deferred supply authorisation or a prescriber bag supply form), there must be a stamp put on in such a way that it does not obscure any of the other information on the prescription. The stamp must be on the extreme left of the prescription and must align with the benefit to which it relates. The definition of *prescription* and *repeat authorisation* is applicable to subsection 7(4) and can be found in subsection 5(1) of the Rules.

Subsection 7(5) requires that the approved supplier must mark in the S section (or each S section where applicable), at least one serial number that relates to each pharmaceutical benefit, commencing in a specified allotment. This subsection provides four different categories of benefits and references to the allotment. These are:

- (a) general benefit prescriptions, commencing at 1 in each claim and continuing consecutively in respect of that claim;
- (b) concessional benefit prescriptions and concession card prescriptions, commencing at C1 in each claim and continuing consecutively in respect of that claim;
- (c) entitlement card prescriptions, commencing at E1 in each claim and continuing consecutively in respect of that claim; and
- (d) prescriber bag supply forms, commencing at 1 in each claim and continuing consecutively in respect of that claim.

The requirements are for the serial number depending on category of benefit it relates to. The requirements vary but in each case the numbering commences at 1 and continues consecutively in relation to that claim. The variation is in relation to the prefix of the number. The prefix identifies which of the four categories of benefit the prescription relates to.

Subsections 7(6) and (7) provide for additional requirements for the serial numbers in relation to authority prescriptions, repeat authorisations that relate to an authority

prescription (subsection 7(6)) and deferred supply authorisations (subsection 7(7)). These prefixes identify those pharmaceutical benefits that relate to these types of prescriptions and authorisations.

Subsection 7(8) does not apply to a prescription that the Chief Executive Medicare opines was not in the possession of the approved supplier due to reasons outside the approved supplier's control. For each applicable prescription, subsection 7(8) sets out additional requirements for information that must be marked in the A section of the prescription. This information relates to the price calculated by the approved supplier. This subsection has provision for three different circumstances:

- (a) Where the prescription is in respect of an extemporaneously prepared pharmaceutical benefit that is not a standard formula preparation and the approved supplier has made an election under subsection 31(3) of *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020 (the Determination)*. In this case paragraph 7(7)(a) requires that the approved supplier mark in the A section of the prescription the price calculated in accordance with section 18 of the Determination.
- (b) Where the prescription is an exceptional prescription and the approved supplier has not made an election under subsection 31(3) of the Determination. In this case paragraph 7(7)(b) requires that the approved supplier mark in the A section of the prescription the price calculated in accordance with section 18 of the Determination.
- (c) Where the prescription is for ear drops, eye drops or nasal instillations and the supply of the benefit in a glass bottle container is specified by the PBS prescriber or considered necessary by the approved supplier. In this case, paragraph 7(7)(c) requires that the approved supplier mark in the A section of the prescription the words 'glass bottle'.

The note to subsection 7(8) notes that the RPBS provides that an RPBS claim must be made in accordance with section 99AAA of the Act and the Rules unless the RPBS otherwise provides. If an RPBS claim is made using the manual system, RPBS prescriptions relating to the claim are given to the Chief Executive Medicare on behalf of the Secretary. The RPBS requires a serial number to be provided that uniquely identifies the RPBS benefit. This is done by the approved supplier placing the serial number on the 'S' section of the prescription commencing at 'R1' and continuing consecutively in respect of that claim.

Subsection 7(9) applies to manually claimed prescriptions referred to in subsections 7(3) to (8) and require that the prescriptions be grouped together according to which category of benefits they relate to under paragraph 7(5)(a), (b), (c) or (d). Further, the prescriptions must be sorted in accordance with the serial numbers allotted under the relevant paragraph and ordered from the first number allotted under each category.

The note to subsection 7(9) notes that the RPBS also requires an approved supplier to create a group of RPBS prescriptions sorted in accordance with the 'R' serial numbers allotted to

the prescriptions, starting with the first number allotted. This is consistent with the requirements for the other prescriptions.

Subsection 7(10) relates to claims made using the Claims Transmission System.

Subsection 7(10) provides that if the approved supplier makes a claim using the Claims Transmission System they must still comply with the requirements of subsections (3) to (9) in relation to the prescriptions that are the subject of the claim, however, the prescriptions do not need to accompany the information provided. This reduces the administrative burden on approved suppliers making a claim using the Claims Transmission System by not requiring that the prescription be attached.

Subsection 7(11) provides an exception for medication chart prescriptions.

Subsection 7(11) has the effect of exempting medication chart prescriptions from the requirements of section 7 by providing that any reference to a prescription in section 7 does not include a reference to a medication chart prescription.

The note located directly under subsection 7(11) provides that if information is given using the Claims Transmission System, Schedule 1 has the effect that a serial number is still allotted in relation to the supply of each pharmaceutical benefit on the basis of a medication chart prescription.

### **Section 8 – Procedures for giving information using Claims Transmission System**

Subsection 8(1) defines additional procedures to be followed by an approved supplier in giving information to the Secretary, when the information is given under paragraph 98AC(4)(b) of the Act, which relates to under co-payment data and under paragraph 99AAA(8)(c) of the Act, which relates to claims for payments.

Note 1 to subsection 8(1) sets out the procedures defined in this section constitute the Claims Transmission System.

Note 2 to subsection 8(1) subsection states that special arrangements made under section 100 of the Act result in the Claims Transmission System containing modifications. In addition, the Claims Transmission System may also contain modifications to facilitate the payment of additional fees that are not paid as a claim under section 99AAA of the Act.

Subsection 8(2) requires the approved supplier to give the information to the Chief Executive Medicare, on behalf of the Secretary in writing, electronically and in accordance with any other requirements that would need to be met under the *Electronic Transactions Act 1999* for the information to be considered to have been provided in writing. This means that if there are any changes to the requirements that are imposed by the *Electronic Transactions Act 1999* these changes will be incorporated into the requirements under this subsection.

The note to subsection 8(2) states that under the *Electronic Transactions Act 1999*, the Chief Executive Medicare has the discretion to require the information to be given in accordance

with particular information technology requirements or by means of a particular kind of electronic communication (or both).

Subsection 8(3) requires that the information be generated by one or more computer programs that can ensure the requirements set out in paragraphs 8(3)(a) to (d).

Paragraph 8(3)(a) states that the computer program used must not allow the approved supplier to alter the description of the pharmaceutical benefit or its PBS item code under Schedule 1. This requirement helps ensure the integrity of the information provided.

Paragraph 8(3)(b) contains subparagraphs 8(3)(b)(i) and (ii), which together provide that the computer system must provide the information in accordance with the Act as in force at the time the pharmaceutical benefit was supplied and when the information is given to the Chief Executive Medicare, the information needs to be in an encrypted form.

Paragraph 8(3)(c) contains subparagraphs 8(3)(c)(i) and (ii), which together requires the approved supplier to take reasonable precautions to ensure that the information provided does not include information relating to the supply of a substance that was not, in the circumstances, a pharmaceutical benefit or that was supplied contrary to section 89 of the Act.

This means, where a supply of a substance has not been dispensed as a pharmaceutical benefit (for example, when a substance has been supplied as a private prescription), this information should not be provided by an approved supplier for the purposes of this subsection.

Paragraph 8(3)(d) relates to subsections 6(2) and 6(7). Paragraph 8(3)(d) contains subparagraphs 8(3)(c)(i) and (ii), which together applies to situations where an approved supplier makes the necessary certification under subsection 6(6) otherwise than in a form approved under subsection 6(2). When the approved supplier makes the required certification in another manner, the Chief Executive Medicare will be notified of the certification and the approved supplier will be given a warning before the certification is made, that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*.

## **Section 9 – Information about supplies**

Subsection 9(1) states that for the purposes of paragraph 98AC(4)(a) (under co-payment data) and paragraph 99AAA(8)(b) (claims for payments) of the Act, subsection 9(2) specifies the information that must be given to the Secretary by approved suppliers in relation to the supply of pharmaceutical benefits.

Subsection 9(2) contains paragraphs 9(2)(a) to (e) which together specify the information that must be provided by approved suppliers.

Paragraph 9(2)(a) applies to all claims and provides that for all claims the information that must be supplied includes the approval number allotted under section 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017*.



Paragraphs 9(2)(b) to (d) applies to information given using the manual system and paragraph 9(2)(e) applies to information given using the Claims Transmission System.

Paragraphs 9(2)(b), (c) and (d) applies to information that must be provided if the approval number provided under paragraph 9(2)(a) is to be provided using the manual system. The information that must be included is:

- the approved supplier's name;
- in relation to pharmacists and hospitals the address of the premises to which the approval number relates (paragraphs 9(2)(b) and (d)); and
- in relation to medical practitioners the address to which the practitioner wishes correspondence to be sent (paragraph 9(2)(c)).

Paragraph 9(2)(e) applies to information that must be provided if the approval number is being provided using the Claims Transmission System. The information that is to be provided is the information required under Schedule 1 to be given in relation to the supply of the pharmaceutical benefit.

The note to subsection 9(2) explains that the information must be given to the Chief Executive Medicare on behalf of the Secretary as provided for under subsection 8(2).

### **Section 10 – Procedures for giving information in respect of claims using manual system**

Section 10 relates to the purpose of paragraph 99AAA(8)(d) of the Act and provides that an approved supplier, giving information in relation to the supply by the approved supplier of pharmaceutical benefits otherwise than by electronic means, must give the information in accordance with sections 6 and 7 of the Rules.

The note to section 10 also confirms that paragraphs 9(2)(a), (b), (c) and (d) of the Rules apply. These paragraphs set out information that must be provided by the approved supplier. Paragraph 9(2)(a) applies to all claims but paragraphs 9(2)(b) to (d) apply only to information provided using the manual system.

### **Section 11 – Procedures for giving information using manual system – under co-payment data not required**

Section 11 provides that an approved supplier who is permitted to make a claim using the manual system in accordance with section 99AAB of the Act is not required to give certain data known as 'under so-payment data' to the Chief Executive Medicare, on behalf of the Secretary, when using the manual system.

Section 99AAB of the Act provides for certain approved suppliers to be exempt from the requirement to use the Claims Transmission System.

For the approved suppliers exempted from the requirements to use the Claims Transmission System, this section provides that they are not required to give under so-payment data. This data relates to the situation where the cost of the script is such that it is less than the level where the patient would pay a co-payment. This is intended to remove an administrative burden on approved suppliers using the manual system.

The note to section 11 refers to subsections 99AAA(4) and (5) and section 99AAB of the Act. Subsection 99AAA(4) requires an approved supplier to use the Claims Transmission System unless exempted from that requirement by section 99AAB. Subsection 99AAA(5) provides that if an approved supplier does not use the Claims Transmission System the approved supplier must use the manual system to provide the information to the Secretary.

### **Section 12 – Procedures for processing and determining claims**

Subsection 12(1) states that for the purpose of subparagraph 99AAA(8)(e)(i) of the Act, subsection (2) defines the procedures to be followed by the Chief Executive Medicare, on behalf of the Secretary, in processing and determining claims by an approved supplier for payment relating to the supply of pharmaceutical benefits.

Paragraphs 12(2)(a) and (b) requires the Chief Executive Medicare on behalf of the Secretary to institute reasonable checks to satisfy the Chief Executive Medicare that (a) the information provided accurately reflects the information recorded on the prescriptions submitted in support of the claim and (b) the approved supplier is entitled to be paid an amount in respect of the claim.

The note to subsection 12(2) notes that advance payments associated with claims made using the Claims Transmission System are permitted and made in accordance with subsection 99AB(1) of the Act .

### **Section 13 – Procedures for making payments in respect of claims**

Subsection 13(1) states that for the purposes of paragraph 98AAA(8)(e)(ii) of the Act, subsection 13(1) defines the procedures to be followed by the Chief Executive Medicare, on behalf of the Secretary, in making payments in respect of claims by an approved supplier in relation to the supply of pharmaceutical benefits.

Subparagraphs 13(2)(a)(i) and (ii) provide requirements for the way payments are made.

Subparagraph 13(2)(a)(i) provides for payment to be made by way of an electronic funds transfer from the Commonwealth to an account nominated in writing by the approved supplier. Subparagraph 13(2)(a)(ii) provides for payment to be made by another form of electronic payment from the Commonwealth to the approved supplier nominated in writing by the approved supplier. This makes provision for the payment to be made to alternate approved supplier when the approved supplier making the claim has nominated the alternate supplier in writing.

Paragraph 13(2)(b) requires that a statement of account is given to the approved supplier in respect of each claim for payment.

The Rules contain an example of ‘other forms of electronic payment’ for the assistance of readers. This example explains that the term ‘other form of electronic payment’ includes PayID and payments through mobile phone applications.

## **Schedule 1 – Information to be given using Claims Transmission System**

### **Clause 1 - Information to be given using Claims Transmission System—general**

For the purposes of paragraph 9(2)(e) of the Rules, the table in clause 1 of Schedule 1 outlines the type of information that an approved supplier must give, in relation to the supply of a particular pharmaceutical benefit using the Claims Transmission System.

Note 1 to clause 1 provides that the table applies when an approved supplier is either providing under co-payment data (subsection 98AC(1) of the Act) or information that is being provided because the approved supplier is making or proposing to make a claim (subsection 99AAA(3) of the Act).

Note 2 to clause 1 provides that the details in column 2 of an item in the table may have the effect that information is not required to be given under that item in relation to a particular supply. An example of this is in item 2, where information under this item is not required to be provided under this item unless the approved form requires an authority prescription number to be entered.

Note 3 to clause 1 provides that clause 2 requires additional information to be provided by the approved supplier in relation to the supply of a pharmaceutical benefit on an electronic prescription.

### **Clause 2 - Additional information to be given using Claims Transmission System—supply on electronic prescriptions**

For the purposes of paragraph 9(2)(e) of the Rules, the table in subclause 2(1) of Schedule 1 outlines the type of information that an approved supplier must give, in relation to the supply of a pharmaceutical benefit on an electronic prescription.

Note 1 to subclause 2(1) provides that the table applies when an approved supplier is either providing under co-payment data or information that is being provided because the approved supplier is making or proposing to make a claim.

Note 2 to subclause 2(1) provides that the details in column 2 of an item in the table may have the effect that information is not required to be given under that item in relation to a particular supply. An example of this is in item 7 which provides in column 2 that the PBS Prescriber Healthcare Provider Identifier—Individual (HPI I) is only required if it is included in the electronic prescription.

Subclause 2(2) makes it clear that clause 2 has effect in addition to clause 1. That provides for additional requirement to the requirements imposed by clause 1.

## **Schedule 2 – Repeals**

Schedule 2 repeals the *National Health (Claims and under co-payment data) Rules 2012* in its entirety.

## Statement of Compatibility with Human Rights

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

### ***National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022***

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (the Rules) are 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 Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary medicines. The PBS operates under Part VII of the *National Health Act 1953* (the Act), which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

The Rules are made pursuant to subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act). It defines the procedures to be followed by an approved supplier in giving information to the Secretary in order to obtain payment for a subsidy under the PBS in relation to a claim for the supply of pharmaceutical benefits.

The Rules provide that the period of validity for electronic medication charts for use in residential aged care is six months. Paper medication charts in residential aged care will expire after four months. The Rules also include a requirement for a Medication Chart Start Date on a medication chart prescription in or at an approved hospital and in or at an approved residential care service.

### **Human Rights Implications**

The Rules engage Articles 2 and 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), by supporting the right to health and assisting in realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the '*highest attainable standard of health*' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health

The Rules do this by supporting the efficient operation and effective administration of the PBS scheme, which provides Australians with subsidised access to medicines.

The Rules also engage the right to privacy contained in Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR), by providing for the collection and transmission of personal information. There is no incompatibility with the right to privacy, as

the data collections and transmissions provided for by the Rules 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**

The Rules are 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.

**Nikolai Tsyganov, delegate of the Minister for Health and Aged Care**