

EXPLANATORY STATEMENT

Select Legislative Instruments 2012 No. 141

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 3)

Section 140 of the *National Health Act 1953* (the Act) provides, in part, that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act

As of 1 July 2012, the Act will provide for the determination of conditions for supply, and the eligible pharmaceutical benefits that can be supplied, by continued dispensing (new section 89A); and supply from a medication chart in residential aged care facilities (section 93A).

New section 89A of the Act, and a minor amendment to section 93A of the Act, will commence on 1 July 2012 when Schedules 1 and 2 to the *National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012* commence.

The regulation amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to enable, together with other legislative instruments under the Act, the implementation of two new initiatives:

- The *Supply and Pharmaceutical Benefits Scheme (PBS) Claiming from a Medication Chart in Residential Aged Care Facilities* which permits approved pharmacists and approved medical practitioners to supply and claim for Pharmaceutical Benefits directly from a 'residential medication chart' within aged care facilities, without the need for a separate prescription; and
- The *Continued Dispensing of PBS Medicines in Defined Circumstances* which allows pharmacists to supply certain medicines to a patient in the absence of a valid prescription, under specified circumstances.

These amendments do not override state and territory poisons laws. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to these initiatives.

The regulation also gives effect to technical changes consistent with the Act (as amended) which support prescribing practices where approval as an authority prescription is required to prescribe a medicine and which allow rules to be determined for deciding approvals to prescribe a quantity of a medicine or number of repeats which is different from the listed amounts.

The amendments also include a number of technical changes to reflect the current drafting style for regulations, remove an inactive regulation, and correct two cross-references to schedules.

Details of the regulation are set out in the Attachment.

Consultation

Fifth Community Pharmacy Agreement initiatives

Broad consultation has been undertaken throughout the development of the initiatives. A public written consultation process was undertaken in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists, aged care and consumers. The responses provided both positive and constructive feedback that was utilised in finalising policy parameters for the initiatives. The Department has continued to engage with stakeholder groups as individual issues are identified. In particular, throughout the development of both the professional guidelines to support Continued Dispensing and the National Residential Medication Chart both the Pharmaceutical Society of Australia and the Australian Commission on Safety and Quality and Healthcare have established expert reference groups made up of key industry representatives. These groups have been integral to the development of the implementation models for these initiatives

In addition, the Department has regularly engaged and consulted with State and Territory Departments of Health to seek their input and support for the initiatives. The Department has also undertaken direct consultation with the Department of Human Services and Department of Veterans' Affairs on this Amending Regulation.

Authority Required Prescription matters

The amendments regarding authority prescriptions are technical changes consistent with established practice and procedures for prescribing authority required medicines. Consultation with medical peak bodies regarding requirements for authority required prescriptions was undertaken in 2010. The changes support the Government's commitment to expand provisions for streamlining prescribing for authority required medicines. No subsequent consultation was undertaken as, under section 18 of the Legislative Instruments Act 2003, consultation is not required where changes are minor or machinery in nature and do not substantially alter existing arrangements.

The Act specifies no conditions that need to be met before the power to make the regulation may be exercised.

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

The regulation commences on 1 July 2012.

Authority: Section 140 of the
National Health Act 1953

ATTACHMENT**Details of the *National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 3)*****Section 1 – Name of Regulation**

This section provides for the regulation to be referred to as the *National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 3)*.

Section 2 – Commencement

This section provides for the regulation to commence on 1 July 2012.

Section 3 – Amendment of the *National Health (Pharmaceutical Benefits) Regulations 1960*

This section provides that Schedule 1 amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations).

Schedule 1 – Amendments**Item [1] – Subregulation 5(1), definition of *authority prescription*, including the note**

This item substitutes a new definition of *authority prescription*. The new definition expands the meaning of authority prescription to include prescriptions referred to in subparagraphs (b)(ii) and (iii).

Subsection 85B(5) of the Act enables the Minister to determine the circumstances in which the Commonwealth will pay the special patient contribution, which otherwise the patient receiving that pharmaceutical benefit would have to pay. The circumstances determined by the Minister may require that the prescription be authorised in accordance with ‘authority required procedures’. Those procedures are set out in a legislative instrument. Subparagraph (b)(ii) covers prescriptions that have been authorised in accordance with these procedures.

Subparagraph (b)(iii) covers prescriptions authorised under authority required procedures that are part of conditions determined by the Minister under subsection 85A(2A) of the Act. Under that subsection the Minister may determine conditions that must be satisfied when writing a prescription for pharmaceutical benefit to which a determination of a maximum quantity or number of repeat supplies that may be prescribed in one prescription, applies. The conditions determined by the Minister may require that the prescription be authorised in accordance with ‘authority required procedures’. This is a reference to the ‘authority required procedures’ set out in the legislative instrument.

Items [2] to [4] – Subregulation 5(1), definition of *concessional benefit prescription*, *concession card prescription*, and *entitlement card prescription*

Items [2] to [4] removes the definitions of ‘concessional benefit prescription’, ‘concession card prescription’, and ‘entitlement card prescription’. These definitions

are removed because they are not used in the Principal Regulations.

Item [5] – Subregulation 5(1)

This item includes a new definition for a ‘medication chart prescription’ which refers to a prescription mentioned in subregulation 19AA(1). Medical practitioners will be able to write a prescription for the supply of a pharmaceutical benefit from a ‘residential medication chart’ for persons receiving ‘residential care’ in a residential care service within the meaning of the *Aged Care Act 1997* (‘residential aged care facility’). An approved supplier will then be able to supply and claim the prescribed pharmaceutical benefit from the residential medication chart. Each individual benefit prescribed by the medical practitioner on the residential medication chart will be recognised as a medication chart prescription.

Item [6] – Subregulation 5(1), definition of *paper-based prescription*

This item removes the reference to an authority prescription from the definition of a ‘paper-based prescription’. With the insertion of a reference to an authority prescription in the definition of a ‘prescription’ by item [9] below, the reference in the definition of a paper-based prescription will no longer be needed.

Item [7] – Subregulation 5(1)

This item inserts a new definition for a ‘paperless claim for payment’. In circumstances when approved suppliers are permitted to submit a paperless claim for payment, the information to support the claim is provided via the Claims Transmission System. The claim will not require a prescription to be submitted to the Department of Human Services for the purposes of substantiating the claim. The circumstances in which a paperless claim for payment can be made will be included in the rules made under subsection 99AAA(8) of the Act. The regulation will support a paperless claim for payment from a medication chart prescription.

Item [8] – Subregulation 5(1)

This item inserts a new definition of a ‘supply certification form’. This form will be used by approved suppliers to certify the supply of pharmaceutical benefits where a paperless claim is made. The minimum set of details required for this form is outlined in the newly created subregulation 5(4).

Item [9] – Subregulation 5(1), definition of *prescription*

This item amends the definition of ‘prescription’ to include references to an authority prescription and medication chart prescription.

Item [10] – Subregulation 5(1)

This item inserts a definition for a ‘repeat authorisation form’. The insertion of this definition is required to give effect to the use of the form for a different purpose where a continued dispensing supply under subsection 89A(1) of the Act is undertaken. Item [46] below establishes the use of the form to support claiming requirements where such a supply occurs.

Item [11] – Subregulation 5(1)

This item provides that the term ‘residential care’ has the same meaning as defined by section 41–3 of the *Aged Care Act 1997*.

Item [12] – Subregulation 5(1)

This item inserts a new definition for a ‘residential medication chart’ giving it the same meaning as provided for in subregulation 19AA(5). For persons receiving care in residential aged care facilities, a medication chart may be used for the prescribing, and recording of the administration, of pharmaceutical benefits. The chart will be required to include a set of standard fields and characteristics that will be determined under paragraph 93A (2) (b) of the Act.

Item [13] – After subregulation 5(3)

This item establishes the purpose of and minimum details required for the ‘supply certification form’. The form will be utilised by an approved supplier to certify that, within the specified claim period, the supply of a pharmaceutical benefit has occurred where the claim for that supply is not accompanied by a paper prescription, that is, the claim is being made by a ‘paperless claim for payment’.

The supply certification form establishes the bulk certification of paperless claims for pharmaceutical benefits supplied within the same claim period. Due to the nature of the paperless claim it will never be practicable for the person to make a written acknowledgement that they have received the benefit as per usual practices established under subregulation 31(1). The introduction of the form enables the approved supplier to certify that the pharmaceutical benefit has been supplied by a paperless claiming mechanism for the claim period and replaces the need for individual certification on a physical prescription for each supply.

Items [14] to [16] – Part II, Part IIAA, Part IIAA, headings

Item [14] to [16] provides technical amendments to ensure the headings are drafted in keeping with current drafting practices. Item [15] also updates the heading to reflect the current content of the Part.

Item [17] – Regulation 9AF

This item provides a technical amendment to ensure that regulation 9AF refers to the correct schedule, being Schedule 6 to the Principal Regulations.

Item [18] – Part IIA, heading

This item provides a technical amendment to ensure the heading is drafted in keeping with current drafting practices.

Item [19] – Regulation 9BA

This item provides a technical amendment to ensure that regulation 9BA refers to the correct schedule, being Schedule 6 to the Principal Regulations.

Item [20] – Part III, heading

This item provides a technical amendment to ensure the heading is drafted in keeping with current drafting practices.

Item [21] – After subregulation 13(1)

This item inserts a Note after subregulation 13(1) alerting readers to the fact that the exercise of the Minister’s power in the subregulation is subject to rules determined by the Minister under subsection 85A(3A) of the Act.

The Minister has the power under paragraphs 85A(2)(a) and (b) of the Act respectively to determine the maximum quantity and maximum number of repeats allowable for the prescribing of particular pharmaceutical benefits

Subregulation 13(1) enables the Minister to authorise a variation of the application of these determinations so a prescriber may prescribe a quantity or number of repeats which is different from that determined under paragraphs 85A(2)(a) and (b) of the Act. Subsection 85A(3A) of the Act enables the Minister to determine rules that must be applied when deciding whether to authorise such a variation.

Items [22] and [23] – Part IV and Part V, headings

Items [22] and [23] provide technical amendments to ensure two headings are drafted in keeping with current drafting practices.

Item [24] – Before regulation 19

This item inserts a new regulation 18B to provide that, unless otherwise specified, ‘Part 5 – Prescriptions and Supply’ is made for section 105 of the Act.

Item [25] – Subregulation 19(1)

This item removes reference to an ‘authority prescription’ as this is to be included in the broader definition of a prescription. The item also includes an exemption for subregulation 19(1) applying where the pharmaceutical benefit is prescribed and supplied from a medication chart prescription.

Item [26] – Paragraph 19(1)(b)

This item excludes authority prescriptions mentioned in new subregulation 19(6) from the operation of paragraph 19(1)(b). Subregulation 19(6) is inserted in the Principal Regulations by item [31].

Item [27] – Subparagraph 19(1)(b)(ii)

This item substitutes a new subparagraph 19(1)(b)(ii). The descriptions of the Declarations and Determinations in the existing subparagraph do not properly describe the instrument in which the relevant determination under paragraph 85(7)(b) of the Act is now made. New sub-subparagraph (A) replaces the existing subparagraph. New sub-subparagraph (B) refers to determinations made under subsection 85A(2A) of the Act; prescriptions to which these determinations apply have been included in the definition of an ‘authority prescription’ by item [1] above.

Item [28] – Paragraph 19(1)(c)

This item makes a technical amendment by removing a duplicated reference to the PBS prescriber signing the prescription. Paragraph 19(1)(aa) of the Principal Regulations already requires the PBS prescriber to sign the prescription after it is prepared.

Item [29] – Subregulation 19(1), note

This item provides a technical amendment to remove the note at the end of subregulation 19(1). This note is no longer required due to new regulation 18B (at item [24]).

Item [30] – Subregulation 19(2)

This item allows a pharmaceutical benefit to be supplied from a ‘medication chart prescription’ on multiple occasions with the same date of prescribing. Each supply of the pharmaceutical benefit will be taken to be an original supply with the same date of prescribing but a different date of supply. The supplies must be consistent with the prescriber’s intended duration of therapy, and multiple supplies provided only to fulfil the prescriber’s order. Further commentary on supply options from a ‘medication chart prescription’ are provided at item [37] below.

Item [31] – After subregulation 19(5)

This item inserts a new subregulation (6) into regulation 19. Paragraph 19(1)(b) requires that, for an authority prescription, the prescriber must include the authority approval number allotted to that prescription. New subregulation (6) provides that this requirement does not apply to authority prescriptions that have been authorised in accordance with authority required procedures applying as part of the circumstances determined for a pharmaceutical benefit by the Minister under subsection 85B(5) of the Act.

Under subsection 85B(5) the Minister determines the circumstances in which the Commonwealth will pay the special patient contribution, which otherwise the patient receiving that pharmaceutical benefit will have to pay. The circumstances determined by the Minister may require that the prescription be authorised in accordance with authority required procedures.

Currently, if an authority prescription does not comply with the requirements of paragraph (1)(b) because the authority approval number is not written on it, the prescription is not ‘duly written’ and is not valid for the purposes of supply as a pharmaceutical benefit. Section 89 of the Act provides that a person is only entitled to receive a pharmaceutical benefit if they present a prescription written in accordance with the Act and regulations made under the Act. Thus, if a prescription does not comply with paragraph 19(1)(b), the patient will not be entitled to receive the pharmaceutical benefit.

The effect of excluding authority prescriptions relating to payment of the special patient contribution by the Commonwealth from paragraph 19(1)(b) is that non-compliance with that paragraph will not have the effect of invalidating the prescription for PBS purposes. The Commonwealth will not pay the special patient contribution because the circumstances determined under subsection 85B(5) have not

been satisfied, but the prescription is not invalidated. However, the prescription may be invalid for PBS purposes if it does not comply with other authority required procedures it is required to comply with.

Compliance with authority required procedures may be required as part of the circumstances determined under paragraph 85(7)(b) for prescribing a pharmaceutical benefit. Some of the pharmaceutical benefits for which the Minister has made a determination under subsection 85B(5) requiring compliance with authority required procedures for payment by the Commonwealth of the special patient contribution, also are the subject of a determination under paragraph 85(7)(b) requiring compliance with authority required procedures for the prescribing the pharmaceutical benefit. If compliance with authority required procedures is required under both determinations, failure to comply with the subsection 85B(5) circumstances means the Commonwealth will not pay the special patient contribution but the prescription is still duly written; but if there is also a failure to comply with the paragraph 85(7)(b) circumstances, the prescription will not be duly written and the patient will not be entitled to receive the pharmaceutical benefit.

Item [32] – After regulation 19

This item inserts a new provision to enable medication chart prescriptions to be written in a residential medication chart. For the item in the residential medication chart to be taken as a prescription for a pharmaceutical benefit, the medical practitioner will be required to complete all the required fields in the section, write the date on which the order was written, write his or her signature and ensure that the letters PBS appear against the item.

This item defines a ‘residential medication chart’ as a document that contains the required fields for Pharmaceutical Benefits Schedule/Repatriation Pharmaceutical Benefits Schedule (PBS/RPBS) claiming, and safety-related characteristics, as per the determination under paragraph 93A(2)(b) of the Act. The required fields include, among other things, information sufficient to identify the prescribed pharmaceutical benefit, and how it should be administered. Some of the required fields on a residential medication chart are not required to be completed for every medication chart prescription, but only when the information is relevant to the prescription. For example, a streamlined authority code field is required for each prescribed medicine on the residential medication chart, although the medical practitioner will complete this field only when applicable.

A medical practitioner cannot use a single residential medication chart to prescribe pharmaceutical benefits for more than one person.

Development and testing of the National Residential Medication Chart by the Australian Commission on Safety and Quality in Health Care will drive change in the sector. The National Residential Medication Chart will be a compliant, standardised residential medication chart. Residential aged care facilities may choose to adopt other residential medication charts that are compliant with legislation, although this is at the discretion of the facility, as no accreditation process will be put into place.

Item [33] – Regulation 19A, heading

This item provides a technical amendment to ensure the heading of regulation 19A better reflects the intent of the regulation.

Item [34] – Before subregulation 19A(1)

This item excludes the requirements of regulation 19A from applying to a medication chart prescription. The collection and use of a patient's concessional information for a medication chart prescription is provided for in the new regulation 21C (item [37]), as referred to in the new note.

Item [35] – Regulation 20

This item removes regulation 20 from the Principal Regulations, which is no longer required. Regulation 20 was made for the purpose of Division 2 or 2AA of the Act. These Divisions no longer exist. Regulation 20 relates to Dental Services Committees of Inquiry and Medical Services Committees of Inquiry, which no longer exist.

Item [36] – Before subregulation 21(1)

This item excludes the requirements of regulation 21 from applying where the supply of the pharmaceutical benefit is made from a medication chart prescription. Different requirements for supply from a medication chart prescription will be established through new regulation 21A.

Item [37] – After regulation 21

This item inserts a new regulation 21A, 'Supply of a pharmaceutical benefit on basis of medication chart prescription', which will allow approved pharmacists and approved medical practitioners to supply pharmaceutical benefits from a medication chart prescription if a copy of the current residential medication chart, containing the medication chart prescription, is given to the approved pharmacist or approved medical practitioner.

The period of validity of the medication chart will be no longer than four months from the date of prescribing of the first entry on the chart. A residential medication chart will be required to contain pre-printed administration dates, consisting of the numerals 1 to 31, in the sections of the chart in which the administration of medicines to the resident is recorded, for each of the four calendar months set out in the chart. Therefore, the chart validity period will be less than four full calendar months where the first order on the residential medication chart is not started on the first day of the first calendar month, as the chart will expire on the last day of the fourth calendar month regardless of the day the chart commenced. For example, if the first prescription is written in a residential medication chart on 11 June, the period of validity of the residential medication chart starts on 11 June and ends on 30 September.

There are three possible scenarios that inform the duration of supply authorised by the medical practitioner from a medication chart prescription:

- ongoing to the end of the validity period of the chart – ‘ongoing’ being marked on the medication chart prescription (ongoing);
- stop date written on the medication chart prescription (stop date); or
- where neither option 1 nor option 2 is indicated, authorisation for supply defaults to up to one maximum PBS quantity (single quantity).

Where the prescriber has indicated option 1 (ongoing) or option 2 (stop date) on the medication chart prescription, an approved pharmacist or approved medical practitioner may supply multiples of up to the maximum PBS quantity, as determined under subparagraph 85A(2)(a) of the Act, if required by the prescriber’s order. Each supply will be treated as an ‘original supply’ and there are no ‘repeat authorisations’. The quantity required to be supplied on each occasion and the number of supplies required throughout the validity period of the chart will be determined by the prescribed dose and frequency of administration; the date of prescribing or start date of administration (if indicated) and the stop date (if indicated).

Where option 1 (ongoing) or option 3 (single quantity) apply, the administration of the last quantity/single quantity supplied from the residential medication chart may overrun the chart validity period. Where option 2 (stop date) is indicated, the quantity supplied must only be the quantity sufficient for administration to the resident up to and including the stop date, and not beyond that date.

The date of supply from a medication chart prescription must be during the validity period of the chart and no later than the stop date for that completed item (if any). The approved pharmacist or approved medical practitioner will endorse each supply on the copy of the residential medication chart from which they have supplied the pharmaceutical benefit.

This item inserts a new regulation 21B, ‘Continued dispensing supply of pharmaceutical benefit’, requiring an approved pharmacist to endorse a supply by continued dispensing on the repeat authorisation form that is part of the claim for pharmaceutical benefits.

This item inserts a new regulation 21C, ‘Information about status of person—continued dispensing and medication chart prescriptions’, requiring the approved pharmacist, or approved medical practitioner where applicable, to collect information about a person’s status at the time of a continued dispensing supply or a supply on the basis of a medication chart prescription. This provision allows the approved pharmacist or approved medical practitioner to collect information that for standard prescriptions would usually be included in the prescription by the prescriber, and requires that the information collected be included in the claim for the pharmaceutical benefit.

Item [38] – Subregulation 22(5)

This item excludes regulation 22 from applying to a supply made from a medication chart prescription. Regulation 22 relates to supply on an ‘owing’ prescription. A ‘medication chart prescription’ cannot be used for regulation 22.

Items [39] and [40] – Paragraph 24(1)(a) and subregulation 24(2)

Items [39] and [40] make two technical amendments to reflect current drafting practice.

Item [41] – After subregulation 24(2)

This item excludes regulation 24 from applying to a medication chart prescription. Regulation 24 relates to certain PBS prescribers directing an approved supplier to supply the patient with the quantity of medicine provided for by the original prescription, plus the quantities of medicine provided for by all of the repeat authorisations, on one single occasion.

Item [42] – After regulation 24

This item insert a new regulation 24A which clarifies that when an approved pharmacist conducts a supply by continued dispensing under subsection 89A(1) of the Act, the pharmacist cannot provide the patient with a supply of medicine greater than the PBS maximum quantity, regardless of the circumstances under which the previous supply to the patient was made, including a direction under regulation 24.

Item [43] – Paragraph 25(2)(a)

This item provides a technical amendment to ensure the provision is drafted in keeping with current drafting practices.

Item [44] – After subregulation 25(4)

This item applies the principles of the ‘four’ and ‘twenty’ day supply rules, and allow an eligible approved supplier to certify that immediate supply is necessary within the period of time that the terms and conditions of supply usually allow (i.e. four or twenty days), for supplies made on the basis of a medication chart prescription or a continued dispensing supply.

For continued dispensing, subregulation 25(5) allows an approved pharmacist to endorse ‘immediate supply necessary’ on the repeat authorisation form being used to support the claim.

For supply made from a medication chart prescription, subregulation 25(6) allows an approved pharmacist or approved medical practitioner to write the words ‘immediate supply necessary’ on the copy of the medication chart prescription which is used for supply of the pharmaceutical benefit.

Further, subregulation 25(6) specifically excludes subregulation 25(1) as medication chart prescriptions do not include a specified number of times for which a pharmaceutical benefit can be supplied.

Item [45] – Before subregulation 26(1)

This item excludes regulation 26 from applying to supplies made from a medication chart prescription. That is, repeat authorisations from a medication chart prescription will not be permissible.

Item [46] – After regulation 26

This item inserts a new regulation 26AA to require the repeat authorisation form to be utilised for the purposes of making a claim for a supply of a pharmaceutical benefit made in accordance with subsection 89A(1) of the Act. The completed form cannot be used to issue repeated supplies of a pharmaceutical benefit where a continued dispensing supply is being undertaken.

Item [47] – Before subregulation 26A(1)

This item excludes the deferred supply provisions of regulation 26A from applying to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

Item [48] – Regulation 30

This item adds a reference to subsection 87(4) of the Act to regulation 30, being the provision in the Act for which regulation 30 is made. The inclusion of this reference is needed due to regulation 18B (item [24] above), which provides a signpost to section 105 of the Act as the power for this part of the regulations, unless otherwise specified.

Item [49] – Subregulation 31(1)

Subregulation 31(1) of the Principal Regulations requires a person who receives a pharmaceutical benefit (whether or not for the person's own use) from an approved pharmacist, approved medical practitioner or approved hospital authority (approved supplier) to:

- write on the prescription, 'repeat authorisation', or 'deferred supply authorisation' as an acknowledgement that the person has received the benefit, that is, the person collecting the medicine signs a statement of acknowledgement on the form; and
- write the date of supply of the benefit; and
- if the benefit is not for the person's own use – write the person's address, that is, the address of the person collecting the medicine.

Subregulation 31(4) provides that it is a strict liability offence if the person does not comply with subregulation 31(1).

Item [49] substitutes a subregulation 31(1) strict liability offence which differs from the current offence provision as follows:

- subregulation 31(1) does not apply if supply is by an approved supplier under subsection 89A(1) of the Act (continued dispensing). Item [50] below provides that subregulation 31(5) applies for continued dispensing supply;
- subregulation 31(1) applies if, at the time of supply, the approved supplier is not permitted to make a 'paperless claim for payment' in relation to the supply of the pharmaceutical benefit. Item [50] provides a subregulation 31(4) when an approved supplier makes a paperless claim for payment;
- the simpler phrase 'approved supplier' is used;
- subregulation 31(1) does not apply unless, at the time of supply, the approved supplier asks the person to write certain matters on the prescription, repeat

authorisation or deferred supply authorisation;

- clarification that the matters to be written by the person are to appear on the prescription, repeat authorisation or deferred supply authorisation;
- it must be practicable for the person to comply with the request from the approved supplier.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of \$2,000 (which converts to \$2,200, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offence in subregulation 31(1) remains at 0.2 penalty units, which is currently \$22 for an individual (section 4AA, *Crimes Act 1914*).

Retaining subregulation 31(1) as a strict liability offence, through subregulation 31(7), is considered appropriate to deter patients and their agents who receive pharmaceutical benefits under the PBS from declining to certify receipt of the pharmaceutical benefit on the prescription, repeat authorisation, or deferred supply authorisation. Regulation 31(1) is consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Item [50] – Subregulations 31(3) and (4)

Subregulation 31(3) of the Principal Regulations provides, if it is not practicable for an approved pharmacist, approved medical practitioner, or approved hospital authority to obtain an acknowledgement in accordance with subregulation 31(1) for the supply of a pharmaceutical benefit, that the pharmacist, medical practitioner or hospital authority must certify on the prescription:

- the date on which the supply was made; and
- the reason why it was not practicable to obtain the acknowledgement.

Subregulation 31(4) provides that it is a strict liability offence if the approved supplier does not comply with subregulation 31(3). The penalty is currently \$20.

Item [50] substitutes a subregulation 31(3) strict liability offence which differs from the current offence provision as follows:

- subregulation 31(3) does not apply if supply is by an approved supplier under subsection 89A(1) of the Act (continued dispensing). Item [50] provides that subregulation 31(6) applies for continued dispensing supply;
- subregulation 31(3) does not apply if the approved supplier makes a 'paperless claim for payment' at the time of supply. Item [50] provides a subregulation 31(4) when an approved supplier makes a paperless claim for payment;
- the simpler phrase 'approved supplier' will be used;
- clarification that the matters to be written by the approved supplier are to appear on the prescription, repeat authorisation or deferred supply authorisation;
- the penalty for the offence will be converted from \$20 to 0.2 penalty units.

Paperless claim for payment from the Commonwealth

Item [50] inserts a subregulation 31(4), a strict liability offence, which provides that an approved supplier commits an offence if the approved supplier supplies a pharmaceutical benefit under Part VII of the Act, other than under subsection 89A(1) of the Act (continued dispensing), the approved supplier makes a ‘paperless claim for payment’ in relation to the supply of the pharmaceutical benefit, and does not include a completed ‘supply certification form’. The requirements that must be met for a completed supply certification form are set out in subregulation 5(4).

Creating subregulation 31(4) as a strict liability offence, through subregulation 31(7), is considered appropriate to deter approved suppliers who supply a pharmaceutical benefit the subject of a ‘paperless claim for payment’ from declining to include a completed ‘supply certification form’ with the claim.

Continued dispensing supply of pharmaceutical benefits

Item [50] inserts a subregulation 31(5), a strict liability offence, which provides for an offence similar to subregulation 31(1), to apply only in the context of receipt of a pharmaceutical benefit (whether or not for the person’s own use) under subsection 89A(1) of the Act (continued dispensing).

Item [50] also inserts a subregulation 31(6), a strict liability offence, which provide for an offence similar to subregulation 31(3), to apply only to an approved pharmacist in the context of supply of a pharmaceutical benefit under subsection 89A(1) of the Act (continued dispensing).

Retaining subregulation 31(3), and creating subregulations 31(5) and 31(6), as strict liability offences, through subregulation 31(7), is considered appropriate to deter approved suppliers, patients or agents of patients from declining to meet their responsibilities for certifying supply of the pharmaceutical benefit in accordance with the requirements that apply for each circumstance.

The penalty for each strict liability offence in subregulations 31(4), (5) and (6) is 0.2 penalty units. Regulations 31(3), (4), (5) and (6) are consistent with *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers* (Attorney-General’s Department).

Item [51] – Part VI, heading

This item provides a technical amendment to ensure the provision is drafted in keeping with current drafting practices.

Item [52] – Before regulation 32

This item inserts a new regulation 31B to provide that, unless otherwise specified, ‘Part 6 Miscellaneous’ is made for section 105 or section 140 of the Act.

Item [53] – After subregulation 32(1)

This item precludes the usual record keeping requirements for prescriptions from applying to supplies made under subsections 89A(1) and 93A(4) of the Act. Separate record keeping provisions for continued dispensing supplies and those made from a medication chart prescription appear in item [54] below.

Item [54] – After regulation 32

This item provides for record keeping provisions for supplies made under subsections 89A(1) and 93A(4) of the Act, respectively.

This item also inserts subregulation 32A, a strict liability offence, which provides that an approved pharmacist commits an offence if:

- they supply a pharmaceutical benefit to a person under subsection 89A(1) of the Act (continued dispensing); and
- they do not keep the following information for at least two years from the date on which the pharmaceutical benefit was supplied by the approved pharmacist: the information that supports the claim for payment made under section 99AAA of the Act, and the information about the supply of the pharmaceutical benefit that is given to the PBS prescriber who most recently prescribed the pharmaceutical benefit to the person.

The ‘repeat authorisation form’ used when making a continued dispensing supply would be included in the claim made under section 99AAA, rather than supporting the claim. The repeat authorisation form is not retained by the approved pharmacist, but provided to the Department of Human Services, and is not covered by subparagraph 32A(2)(b)(i).

Creating subregulation 32A as a strict liability offence, through subregulation 32A(3), is considered appropriate to deter approved pharmacists from failing to keep the records required by regulation 32A.

This item also inserts subregulation 32B, a strict liability offence, which applies to a supply under subsection 93A(4) of the Act on the basis of a ‘medication chart prescription’, and provide that an approved pharmacist or approved medical practitioner (the relevant supplier) commits an offence if:

- the relevant supplier supplies a pharmaceutical benefit on the basis of a ‘medication chart prescription’; and
- the relevant supplier does not keep a copy of the ‘residential medication chart’ in which the prescription is written for at least 2 years from the date on which the last pharmaceutical benefit was supplied by the relevant supplier on the basis of a prescription in the ‘residential medication chart’.

Creating subregulation 32B as a strict liability offence, through subregulation 32B(3), is considered appropriate to deter the relevant supplier from failing to keep the records required by regulation 32B.

The penalty for the strict liability offence in subregulation 32A and in 32B is 0.2 penalty units. Subregulations 32A and 32B are consistent with the Attorney-General’s Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*

Item [55] – Regulation 35, at the foot

This item provides a technical amendment to insert, for handy reference, a note referring to paragraph 103(5)(f) of the Act, to which regulation 35 also relates.

Item [56] – Paragraph 36(2)(d)

This item inserts the word ‘or’ after paragraph 36 (2) (d), which relates to the insertion of new paragraph 36(2)(e) in item [57] below.

Item [57] – After paragraph 36(2)(d)

This item excludes the requirement for a pharmaceutical benefit to be labeled with the ‘full cost’ for supplies made under subsection 93A (4) on the basis of a ‘medication chart prescription’.

Item [58] – After regulation 37

This item inserts new regulation 37AA to provide for payment by the Commonwealth in respect of supply of a pharmaceutical benefit under section 93A of the Act. The regulation provides that an approved pharmacist or approved medical practitioner who supplies a pharmaceutical benefit under subsection 93A(4) of the Act, to a residential care service is entitled to payment from the Commonwealth at the rate, and subject to the conditions determined by the Minister, that apply at the time of supply. The determination provides for the usual rates and conditions that apply for general supply under the PBS by an approved pharmacist or approved medical practitioner to apply to supply to a residential care service.

Items [59] and [60] – Part VIA and Regulation 37A, heading

Items [59] and [60] provide two technical amendments to headings to ensure they are drafted in keeping with current drafting practice.

Item [61] – Regulation 37EA

This item provides for a technical amendment to regulation 37EA of the Principal Regulations, to correct a typing error, removing three already ‘struck out’ letters which currently inadvertently appear.

Items [62] to [64] – Regulation 38, 38A, and 38B, headings

Items [62] to [64] provide three technical amendments to headings to ensure they are drafted in keeping with current drafting practice.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 3)

This regulation 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 regulation

The purpose of the amendments to the *National Health (Pharmaceutical Benefits) Regulations 1960* is to enable the implementation of two new initiatives referred to in the Fifth Community Pharmacy Agreement, *Supply and Pharmaceutical Benefits Scheme (PBS) Claiming from a Medication Chart in Residential Aged Care Facilities* which will introduce supply and claiming of PBS medicines from a standardised medication chart within aged care facilities, and *Continued Dispensing of PBS Medicines in Defined Circumstances* which will allow pharmacists to supply certain medicines to a patient in the absence of a valid prescription, under specified circumstances.

Specifically, this regulation will introduce mechanisms that will enable an approved pharmacist to supply and claim for certain medicines on the basis of a previous prescription, where a valid prescription is unavailable and the ability for an approved supplier to supply and claim for certain PBS medicines from a medication chart to residents of aged care facilities.

The amendments regarding authority prescriptions are technical and provide for improved administration of the PBS. None of the amendments makes any substantive change to the Principal Regulations regarding the availability of or access to medicines under the Scheme.

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 PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access for people to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

Conclusion

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

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