

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Residential Medication Chart) Amendment Determination 2014 (No.1)

Authority

Subsection 93A (2) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits or classes of pharmaceutical benefits that may be supplied to a prescribed institution under section 93A of the Act, and the conditions under which those benefits may be supplied under that section of the Act.

Purpose

The purpose of the *National Health (Residential Medication Chart) Amendment Determination 2014 (No. 1)* (the Amending Determination), made under section 93A (2) of the Act, is to amend the *National Health (Residential Medication Chart) Determination 2012* (the Determination). The Determination specifies the pharmaceutical benefits that may be supplied under section 93A of the Act to a prescribed institution which is a residential care service within the meaning of the *Aged Care Act 1997* and the conditions which must be met in order for that supply to occur.

Residential care services are able to use a standardised medication chart, known as a residential medication chart, as a prescription for the supply of most pharmaceutical benefits. The standardisation of charts seeks to improve resident safety, and reduce the administrative burden for pharmacists and pharmacy staff.

Prescribing, supplying and claiming of pharmaceutical benefits from a residential medication chart in residential care services can only occur where the chart meets the specified criteria in the Determination. The Determination sets out the mandatory standard fields that must be pre-printed on a medication chart for it to be considered a residential medication chart.

This Amending Determination makes minor changes to improve the clarity and functionality of the residential medication chart. These reflect changes to the previous standardised medication chart for use in residential aged care facilities that has been developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) as part of the National Residential Medication Chart (NRMC) Project. The changes made by the ACSQHC to the chart are aimed at improving the safety of medication management in residential aged care facilities.

The changes made by the Amending Determination include:

- changes to requirements for regularly administered pharmaceutical benefits, in particular new standard fields for recording administration of pharmaceutical benefits given as part of a multi-dose pack;

- new sections for nutritional supplements and insulin administered ‘PRN’ (i.e on an as needed basis); and
- changes relating to standard fields for recording the commencement date of the medication chart, and to allow the prescriber to specify on the medication chart a cessation (stop) date for each PBS medicine supply.

Consultation

Broad consultation has been undertaken throughout the *Supply and PBS claiming from a medication chart in residential aged care facilities* initiative. 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 providers and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiative.

As part of the development and implementation of the NRMC initiative, the ACSQHC established an expert reference group made up of key industry representatives. This group has been integral to the development of the implementation model for this initiative and the resulting changes made by the Amending Determination.

The Department has also undertaken direct consultation with the Department of Human Services and engaged with State and Territory Departments of Health to seek their input and support for these changes.

This Amending Determination is a result of direct consultations with the ACSQHC and stakeholder advice about further clarifications to improve the design and functionality of the NRMC.

This Amending Determination commences on 1 June 2014.

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

ATTACHMENT

**ITEM BY ITEM DESCRIPTION OF THE NATIONAL HEALTH
(RESIDENTIAL MEDICATION CHART) AMENDMENT DETERMINATION
2014 (No. 1)**

1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Residential Medication Chart) Amendment Determination 2014 (No. 1)* (the Amending Determination) and that the instrument may also be known as PB 24 of 2014.

2 Commencement

This section provides that the Amending Determination commences on 1 June 2014.

3 Authorisation

This Instrument is made under the *National Health Act 1953*.

4 Amendment to *National Health (Residential Medication Chart) Determination 2012*

This section provides that this Amending Instrument amends the *National Health (Residential Medication Chart) Determination 2012* (the Determination).

Schedule 1 Amendments

Item 1 - Section 1.03, after *healthcare identifier*

Item 1 inserts a definition of a *multi-dose pack* in the Determination. The definition is relevant for the standard fields that must be included in the section of a residential medication chart for regularly administered medicines.

A multi-dose pack is a tamper-evident adherence device that can store, in separate compartments arranged by daily dose schedule, one or more drugs or medicines that have been removed from the manufacturer's original packaging.

Item 2 - Subsection 2.02(1)

Item 3 - Paragraph 2.02(2)(a)

Section 2.02 of the Determination provides for the basic standard fields that must be present on a medication chart for it to be considered a valid residential medication chart. These fields must appear printed on the chart, usually with a blank portion for completion.

Item 2 of the Amending Determination amends subsection 2.02(1) of the Determination to include reference to the standard fields mentioned in new sections 2.09A and 2.12A, which deal with standard fields for pharmaceutical benefits that are insulin administered PRN (as required) and nutritional supplements, respectively.

Item 3 amends paragraph 2.02(2)(a) to include reference to the standard fields for the business name and Residential Aged Care Service ID of the relevant residential aged care service.

Item 4 - Section 2.05

Item 4 repeals section 2.05 of the Determination and substitutes a new section to provide that a residential medication chart is to contain a field that records its commencement date as well as its expiry date of the chart.

Item 5 - Paragraph 2.07(a)

Item 6 - Paragraph 2.07(d)

Section 2.07 of the Determination requires a residential medication chart to contain fields that enable the identification of the medical practitioner who prescribes a medication on the chart, including the medical practitioner's full name and address and PBS prescriber number.

Items 5 and 6 repeal paragraphs 2.07(a) and 2.07(d) respectively and substitute new paragraphs to clarify that:

- the full name and signature of a medical practitioner is required on the cover page of the chart and separately against each pharmaceutical benefit that the medical practitioner prescribes on the chart (paragraph 2.07(a)); and
- contact details of the medical practitioner sufficient to enable the practitioner to be contacted at any time are required (paragraph 2.07(d)).

Item 7 - Section 2.08

Section 2.08 of the Determination requires a residential medication chart to contain standard fields for the particulars of a regularly administered pharmaceutical benefit. Item 7 of the Amending Determination repeals section 2.08 and substitutes new text, which differs from the current Determination by requiring:

- a standard field for the form of the pharmaceutical benefit, as well as its name and strength (paragraph 2.08(1)(a));
- a check box to indicate the prescription is valid for the duration of the chart rather than 'ongoing' (paragraph 2.08(1)(e)) – this must be included in the same box as the field for recording the stop date for administration of the benefit and in a way that indicates that a benefit must be specified as either having either a specific stop date or be valid for the duration of the chart but not both (subsection 2.08(4));
- a standard field for additional instructions (if any) to be added by the medical practitioner (paragraph 2.08(1)(ia)); and
- standard fields to record the administration of pharmaceutical benefits by means of a multi-dose pack, including fields to record administration by reference to a patient's breakfast, lunch and dinner schedule (subsection 2.08(2)).

Section 2.08 also requires that there must be sufficient boxes to record the administration of a pharmaceutical benefit administered by means of a multi-dose pack for each day of a 4 month period (subsection 2.08(3)).

Items 8 to 15 – Section 2.09

Section 2.09 of the Determination deals with the standard fields for a pharmaceutical benefit that is insulin other than insulin administered ‘PRN’, and blood glucose level recording. Insulin administered PRN is insulin administered on an ‘as needed’ basis.

A new section 2.09A has been added to the Determination specifying standard fields for pharmaceutical benefits that are insulin administered PRN (see item 16).

Item 8 – Heading to section 2.09

Item 9 - Subsection 2.09(1)

Items 8 and 9 amends the heading of section 2.09 and subsection 2.09(1), respectively, to reflect that the section only deals with the standard fields for a pharmaceutical benefit that is insulin other than insulin administered ‘PRN’.

Item 10 - Paragraph 2.09(1)(a)

Paragraph 2.09(1)(a) of the Determination specifies certain standard fields for insulin (non-PRN). Item 10 of the Amending Determination makes minor changes to these standard fields, including changes consequential on the redrafting of section 2.09 as it relates to fields for dose and time of administration of a relevant benefit.

Item 11 – After paragraph 2.09(1)(a)

Item 12 - Subparagraph 2.09(1)(e)(ii)

Item 11 of the Amending Determination inserts paragraphs 2.09(1)(aa) and (ab), which provide that the standard fields for an applicable pharmaceutical benefit that is insulin not required to be administered PRN must include standard fields for the dose (in units) and the time of administration.

Item 12 makes a consequential amendment to subparagraph 2.09(1)(e)(ii) to clarify that the reference to dose is to ‘dose in units’.

Item 13 - Subparagraph 2.09(1)(f)(i)

Item 14 - At the end of paragraph 2.09(1)(f)

The Determination previously required that the standard fields for a pharmaceutical benefit that is insulin should include a row of boxes to be initialled on administration of the benefit.

Items 13 and 14 of the Amending Determination, which amend subparagraph 2.09(1)(f)(i) and add new paragraph 2.09(1)(g) respectively, require a residential medication chart to include standard fields for two rows of boxes allowing for initialling by more than one person.

Item 15 - Subsection 2.09(2)

Item 15 amends the reference to paragraphs 2.09(1)(b) to (f) of the Determination in subsection 2.09(2) to refer to paragraphs 2.09(1)(ab) to (f), consequential on the addition of new paragraph 2.09(1)(ab) to the Determination.

Item 16 - After section 2.09

Item 16 of the Amending Determination adds new section 2.09A to the Determination, which deals with the standard fields for pharmaceutical benefits that are insulin administered PRN, in other words insulin administered on an as needed basis. These include:

- the fields for particulars to identify the benefit including its name, form and strength, the date of prescribing, dose and frequency of administration, the date of starting and stopping administration (including whether it should be administered for the duration of the chart) - a field for the frequency of administration is not required; and
- fields to record the time of administration, the maximum dose in a 24 hour period, and boxes in which the administration of the benefit can be initialled by date, time and dose.

Item 17 - Section 2.10 (not including heading)

Section 2.10 of the Determination specifies standard fields for pharmaceutical benefits required to be administered PRN (as required). As a consequence of the inclusion of new section 2.09A of the Determination, item 17 amends section 2.10 to clarify that it only applies to PRN benefits other than insulin.

Item 18 – Heading to section 2.12**Item 19 - Subsection 2.12(1)**

Section 2.12 of the Determination deals with pharmaceutical benefits, other than insulin, that can be administered in variable doses. Items 18 and 19 of the Amending Determination alter the heading to section 2.12 and subsection 2.12(1) of the Determination, respectively, to make clear that the section applies only to pharmaceutical benefits other than insulin that can be administered in variable doses. This is consequential on the inclusion of new section 2.09A in the Determination.

Item 20 - Paragraph 2.12(1)(a)**Item 21 - After paragraph 2.12(1)(a)****Item 22 - Paragraphs 2.12(1)(c) and (d)****Item 23 - After paragraph 2.12(1)(d)****Item 24 - Subparagraph 2.12 (1)(e)(i)****Item 25 - Paragraph 2.12(1)(f)**

Items 20 to 25 make a number of minor amendments to the relevant standard fields for section 2.12 of the Determination. These amendments:

- re-order paragraphs in subsection 2.12(1) as a consequence of the amendments made by item 25 and make changes consequential on the revised drafting of section 2.08 (items 20, 21 and 23);
- remove the requirement that the standard fields include the abbreviation ‘mg’ (item 22); and
- require a second row of boxes to initial administration of the pharmaceutical benefit (items 24 and 25).

Item 26 - After Section 2.12

Item 26 adds new section 2.12A in the Determination, which specifies the standard fields for pharmaceutical benefits that are nutritional supplements. These include fields for:

- particulars enabling identification of the benefit, including its name and strength expressed as ‘nutritional supplement’;
- the benefit’s dose, date of prescribing, route and frequency of administration;
- start and stop dates for administration
- whether brand substitution permitted and any additional instructions from the prescribing medical practitioner.

Item 27 - Paragraph 2.13(1)(b)

Item 27 amends paragraph 2.13(1)(b) to require that the standard fields for the residential care service’s business name and Residential Aged Care Service ID must be easily readable and visible to a person looking at any page of the residential medication chart. .

Item 28 - Subsection 2.13(2)

Item 28 amends subsection 2.13(2) to require that the standard field for the residential medication chart’s commencement date must be on the chart’s front page.

Item 29 - Subparagraph 2.14(b)(i)**Item 30 - Subparagraph 2.14(b)(vi)****Item 31 - Subparagraph 2.14(b)(vii)****Item 32 - Subparagraph 2.14(b)(viii)****Item 33 - Subparagraph 2.14(b)(xii)****Item 34 - End of paragraph 2.14(b)**

Section 2.14 of the Determination specifies the conditions which must be met before an approved pharmacist or medical practitioner may supply a pharmaceutical benefit based on a residential medication chart. Items 29 to 34 of the Amending Determination revise a number of cross-references in section 2.14 of the Determination, consequential on the revised drafting of the Determination.

Statement of Compatibility with Human Rights

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

National Health (Residential Medication Chart) Amendment Determination 2014 (No.1)

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 regulation

The purpose of this Instrument, made under section 93A (2) of the Act, is to amend the *National Health (Residential Medication Chart) Determination 2012* (the Determination), which determines the pharmaceutical benefits that may be supplied under section 93A of the Act to a prescribed institution which is a residential care service within the meaning of the *Aged Care Act 1997* and the conditions which must be met in order for that supply to occur.

Residential care services are able to use a standardised medication chart, known as a residential medication chart, as a prescription for the supply of most pharmaceutical benefits. The standardisation of charts seeks to improve resident safety, and reduce the administrative burden for pharmacists and pharmacy staff.

Prescribing, supplying and claiming of pharmaceutical benefits from a residential medication chart in residential care services can only occur where the chart meets the specified criteria in the Determination. The Determination sets out the mandatory standard fields that must be pre-printed on a medication chart for it to be considered a valid residential medication chart.

This Amending Determination makes minor changes to improve the clarity and functionality of the residential medication chart. The changes include:

- changes to requirements for regularly administered pharmaceutical benefits, in particular new standard fields for recording administration of pharmaceutical benefits given as part of a multi-dose pack;
- new sections for nutritional supplements and insulin administered ‘PRN’ (i.e. on an as needed basis); and
- changes relating to standard fields for recording the commencement date of the medication chart, and to allow the prescriber to specify on the medication chart a cessation (stop) date for each PBS medicine supply.

These reflect changes to the standardised medication chart able to be used in residential aged care facilities, as developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) as part of the National Residential Medication Chart (NRMC) Project. The changes made by the ACSQHC to its chart are aimed at improving the safety of medication management in residential aged care facilities.

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 amendments made by the Amending Determination reflect improvements to the ACSQHC's standard residential aged care medication chart. The amendments are intended to ensure that the prescription and supply of pharmaceutical benefits under the PBS to residents in residential care facilities using such charts continues to balance efficiency and the safety and protection of residents.

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.

Kim Bessell
Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health