PB 24 of 2014

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

National Health Act 1953

I, Kim Bessell, Assistant Secretary, Pharmaceutical Access Branch, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make the following determination under paragraph 93A (2) (b) of the *National Health Act 1953.*

Dated 30 May 2014

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

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1 Name of Instrument

(1) This Instrument is the *National Health (Residential Medication Chart) Amendment Determination 2014 (No.1)*.

(2) This Instrument may also be cited as PB 24 of 2014.

2 Commencement

This Instrument commences on 1 June 2014.

3 Authorisation

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

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

Schedule 1 amends the *National Health (Residential Medication Chart) Determination 2012*.

Schedule 1 Amendments

1 Section 1.03, after *healthcare identifier*

Insert:

multi-dose pack means a tamper-evident adherence device which is capable of storing, in separate dosage compartments arranged according to a daily dose schedule, one or more drugs or medicinal preparations that have been removed from the manufacturer's original packaging.

2 Subsection 2.02(1)

Repeal the subsection, substitute:

(1) The standard fields on a residential medication chart must include the standard fields mentioned in:

(a) sections 2.03 to 2.07; and

(aa) for an applicable pharmaceutical benefit to which section 2.08 applies – section 2.08; and

(b) for an applicable pharmaceutical benefit to which section 2.09 applies – section 2.09; and

(ba) for an applicable pharmaceutical benefit to which section 2.09A applies – section 2.09A; and

(c) for an applicable pharmaceutical benefit to which section 2.10 applies – section 2.10; and

(d) for an applicable pharmaceutical benefit to which section 2.11 applies – section 2.11; and

(e) for an applicable pharmaceutical benefit to which section 2.12 applies – section 2.12; and

(ea) for an applicable pharmaceutical benefit to which section 2.12A applies – section 2.12A.

3 Paragraph 2.02(2)(a)

After "and (c)", insert "or paragraphs 2.04 (a) and (c)".

4 Section 2.05

Repeal the section, substitute:

2.05 Standard fields information—commencement and expiry dates

The standard fields for the period of validity of the residential medication chart must include a standard field for the chart's:

(a) commencement date; and

(b) expiry date.

5 Paragraph 2.07(a)

Repeal the paragraph, substitute:

(a) full name and signature:

(i) on the front page of the residential medication chart for a patient; and

(ii) for each pharmaceutical benefit that the medical practitioner prescribes for the patient using the residential medication chart; and

6 Paragraph 2.07(d)

Repeal the paragraph, substitute:

(d) contact details sufficient to make contact with the practitioner at any time.

7 Section 2.08

Repeal the section, substitute:

2.08 Standard fields information—regularly administered pharmaceutical benefits

(1) The standard fields for a regularly administered applicable pharmaceutical benefit must include a standard field for:

(a) particulars sufficient to identify the applicable pharmaceutical benefit, including the name, pharmaceutical dose form and strength, expressed as 'medicine/form/strength'; and

(b) the applicable pharmaceutical benefit's:

(i) date of prescribing; and

(ii) dose; and

(iii) route of administration; and

(iv) frequency of administration; and

(c) the day, month and year of the date (the ***start date***) to start administering the pharmaceutical benefit; and

(d) the day, month and year of the date (the ***stop date***) to stop administering the pharmaceutical benefit; and

(e) a check box next to the words 'Valid for duration of chart'; and

(f) a check box next to the words 'Brand substitution not permitted'; and

(g) a check box next to the expression 'CTG'; and

(h) the expression 'PBS/RPBS'; and

(i) the words 'Streamlined Authority Code' and (immediately next to those words) 4 empty boxes, with each box being large enough for a single digit number to be clearly written in the box; and

(ia) additional instructions (if any) to be added by the medical practitioner, expressed as 'Additional instructions'; and

(j) a box next to the heading, enclosing the name of each calendar month; and

(i) next to a box enclosing the words 'Date' and 'Times'—a numbered box for each day of each month, laid out on the page horizontally and numbered consecutively, beginning with '1' and ending with '31'; and

(ii) under the box enclosing the words ‘Date’ and ‘Times’–a column of several boxes, laid out on the page vertically, with each box being empty and large enough for the time the applicable pharmaceutical benefit is administered, if not administered by means of a multi-dose pack, to be clearly written in the box; and

(iii) next to the column of empty boxes mentioned in subparagraph (ii) —several rows of boxes, laid out on the page horizontally, with each box being large enough for the initials of the person who administered the pharmaceutical benefit to be clearly written in the box.

(2) The standard fields for a regularly administered applicable pharmaceutical benefit must also include a standard field to record the administration of the benefit if the benefit has been administered by means of a multi-dose pack, being:

(a) a box enclosing the name of each calendar month; and:

(i) next to a box enclosing the words ‘Date’ and ‘Times’—a numbered box for each day of each month, laid out on the page horizontally and numbered consecutively, beginning with ‘1’ and ending with ‘31’; and

(ii) under the box enclosing the words ‘Date’ and ‘Times’—a column of several boxes, laid out on the page vertically, with:

(A) a box including the word ‘Breakfast’; and

(B) below that, a box including the word ‘Lunch’; and

(C) below that, a box including the word ‘Dinner’; and

(D) below that, a box including the word ‘Bed time’; and

(E) each other box being empty and large enough for the time when the applicable pharmaceutical benefit is administered as part of the multi-dose pack to be clearly written in the box; and

(iii) next to the column of boxes mentioned in subparagraph (ii)—several rows of boxes, laid out on the page horizontally, with each box being large enough for the initials of the person who administered the pharmaceutical benefit as part of the multi-dose pack to be clearly written in the box.

(3) For paragraphs (1) (j) (iii) and (2) (a) (iii), there must be enough rows and enough boxes in the rows to allow the administration of the pharmaceutical benefit to be recorded for each day of the 4 month period of validity of the residential medication chart.

(4) For the standard fields mentioned in subparagraphs (2) (a) (ii), the boxes mentioned in sub-subparagraphs 2 (a) (ii) (A) to (D) may be preceded, separated or followed by one or more of the empty boxes mentioned in sub-subparagraph 2 (a) (ii) (E).

(5) For the standard fields at paragraphs (1) (d) and (e), the fields must be enclosed in the same box and clearly presented as being mutually exclusive.

Note 1 See section 2.05 for the requirements for the standard field for the expiry date of a residential medication chart.

Note 2 For a provision that may affect whether the special patient contribution mentioned in subsection 85B (4) of the Act is payable by the Commonwealth if the Streamlined Authority Code is not written in the related section of the chart, see subsection 85B (5) of the Act.

8 Heading to section 2.09

After "**insulin**", add "**pharmaceutical benefits (non-PRN) and blood glucose level (BGL) recording**".

9 Subsection 2.09(1)

After "that is insulin", insert "that is not required to be administered PRN (as required)".

10 Paragraph 2.09(1)(a)

Omit "subparagraphs 2.08 (1) (j) (ii) and (iii)", replace with "subparagraphs 2.08 (1) (b) (ii) and (iv) and paragraphs 2.08 (1) (f), (i) and (j)".

11 After paragraph 2.09(1)(a)

Insert:

(aa) the applicable pharmaceutical benefit's dose, which must include the word 'units'; and

(ab) the applicable pharmaceutical benefit's time of administration; and

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

After "dose", insert ", in units,".

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

Omit "word 'Initial';", insert "term 'Initial 1';".

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

Add:

; and

(g) immediately under the row of boxes mentioned in paragraph (f)—a row of boxes, laid out on the page horizontally, with:

(i) the first box enclosing the term 'Initial 2'; and

(ii) each other box being empty and large enough for the initials of the person who administers the pharmaceutical benefit to be clearly written in the box.

15 Subsection 2.09(2)

Omit "(1) (b) to (f)", replace with "(1) (ab) to (g)".

16 After section 2.09

Add:

2.09A Standard fields information – insulin PRN (as required) pharmaceutical benefits

(1) The standard fields for an applicable pharmaceutical benefit that is insulin that is required to be administered PRN (as required) must include standard fields for:

(a) the information mentioned in paragraphs 2.08 (1) (a), (c), (d), (e), (g) and (h), and paragraph 2.08(1) (b) other than subparagraph (iv).

(b) the applicable pharmaceutical benefit's time of administration; and

(c) the expression 'Max dose/24hr'; and

(d) a column of 4 boxes, laid out on the page vertically, with:

(i) the first box enclosing the word 'Date'; and

(ii) the second box enclosing the word 'Time': and

(iii) the third box enclosing the word 'Dose'; and

(iv) the fourth box enclosing the word 'Initial'; and

(e) 4 rows of empty boxes next to the column of 4 boxes mentioned in paragraph (d):

(i) laid out on the page horizontally; and

(ii) with each box in each row being large enough for the information mentioned in subparagraph (d) (i), (ii), (iii) or (iv) to be clearly written in the box.

17 Section 2.10 (not including heading)

After "benefit", insert ", other than insulin,".

18 Heading to section 2.12

After "**benefits**", add "**(non-insulin)**".

19 Subsection 2.12(1)

After "pharmaceutical benefit" (first appearing), insert ", other than insulin,".

20 Paragraph 2.12(1)(a)

Omit "subparagraphs 2.08 (1) (j) (ii) and (iii)", replace with "paragraph 2.08 (1) (j)".

21 After paragraph 2.12(1)(a)

Insert:

(aa) a box enclosing the name of each calendar month; and

(ab) next to a box enclosing the word 'Date'—a numbered box for each day of each month, laid out on the page horizontally and numbered consecutively, beginning with '1' and ending with '31'; and

22 Paragraphs 2.12(1)(c) and (d)

Omit "enclosing the abbreviation 'mg' and".

23 After paragraph 2.12(1)(d)

Insert:

(da) a row of boxes, laid out horizontally, with:

(i) the first box enclosing the word ‘Time’; and

(ii) each other box being empty and large enough for the time at which the pharmaceutical benefit is administered to be clearly written in the box; and

24 Subparagraph 2.12(1)(e)(i)

Omit “word ‘Initials’;”, replace with “term ‘Initial 1’;”.

25 Paragraph 2.12(1)(f)

Repeal the paragraph, substitute:

(f) a row of boxes, laid out horizontally, with:

(i) the first box enclosing the term ‘Initial 2’; and

(ii) each other box being empty and large enough for the initials to be clearly written in the box.

26 After section 2.12

Insert:

2.12A Standard fields information—nutritional supplements pharmaceutical benefits

(1) The standard fields for an applicable pharmaceutical benefit that is a nutritional supplement must include standard fields for:

(a) particulars sufficient to identify the applicable pharmaceutical benefit, including the name and strength, expressed as ‘nutritional supplement’; and

(b) the applicable pharmaceutical benefit’s:

(i) date of prescribing; and

(ii) dose; and

(iii) route of administration; and

(iv) frequency of administration; and

(c) the day, month and year of the date (the ***start date***) to start administering the pharmaceutical benefit; and

(d) the day, month and year of the date (the ***stop date***) to stop administering the pharmaceutical benefit; and:

(e) a check box next to the words ‘Valid for duration of chart’; and

(f) a check box next to the words ‘Brand substitution not permitted’; and

(g) a check box next to the expression ‘CTG’; and

(h) the expression ‘PBS/RPBS’; and

(i) additional instructions (if any) to be added by the medical practitioner, expressed as ‘Additional instructions’.

27 Paragraph 2.13(1)(b)

Repeal the paragraph, substitute:

(b) paragraphs 2.03 (b) and (c) and 2.04 (a) and (c).

28 Subsection 2.13(2)

Omit "field for the", replace with "fields for the commencement date and".

29 Subparagraph 2.14(b)(i)

Omit "medicine", replace with "medicine/form/strength".

30 Subparagraph 2.14(b)(vi)

Omit "frequency", replace with "route".

31 Subparagraph 2.14(b)(vii)

Omit "route", replace with "frequency".

32 Subparagraph 2.14(b)(viii)

Omit "word 'Ongoing',", replace with "words 'Valid for duration of chart',".

33 Subparagraph 2.14(b)(xii)

Repeal the subparagraph, replace with:

(xii) the medical practitioner's signature:

(A) on the front page of the residential medication chart for a patient, mentioned in subparagraph 2.07 (a) (i); and

(B) for each pharmaceutical benefit that the medical practitioner prescribes for the patient using the residential medication management chart, mentioned in subparagraph 2.07 (a) (ii).

34 At the end of paragraph 2.14(b)

Add:

Note 3 Regulation 21A of the *Health Insurance (Pharmaceutical Benefits) Regulation 1960* provides that an approved pharmacist or approved medical practitioner may only supply a pharmaceutical benefit on the basis of a residential medication chart if the approved pharmacist or medical practitioner is given a copy of the chart.