



National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 13 July 2022

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

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1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 August 2022.	1 August 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

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

Note: See section 99YBA of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022

1 Subsection 7(2)

Omit “181,500”, substitute “177,830”.

2 Subsection 7(2)

Omit “430”, substitute “420”.

3 Subsection 8(4)

Omit “103,560”, substitute “101,520”.

4 Subsection 8(4)

Omit “430”, substitute “420”.

5 Subsection 12(4)

Omit “430”, substitute “420”.

6 Section 14 (table item 1)

Omit “15,700”, substitute “14,980”.

7 Section 14 (table item 2)

Omit “21,350”, substitute “20,360”.

8 Subsection 22(2) (table)

Repeal the table, substitute:

Fees and deposits for providing submission services			
Item	Column 1	Column 2	Column 3
	Evaluation categories of submissions	Fee (\$)	Deposit (\$)
1	Category 1	219,990	420
2	Category 2	166,850	420
3	Category 3	41,340	420
4	Category 4	32,050	420
5	Committee Secretariat category	11,210	420
6	New brand or new oral form of existing pharmaceutical item category	6,230	0
7	Standard re-entry pathway category	164,770	420
8	Early re-entry pathway category	39,930	420
9	Early resolution pathway category	40,070	420
10	Facilitated resolution pathway category	236,610	72,440

9 Subsection 22(2) (note 4)

Omit “430”, substitute “420”.

10 Subsection 35(6)

Omit “430”, substitute “420”.

11 Subsection 41(1) (table item 1)

Omit “142,540”, substitute “135,690”.

12 Subsection 41(1) (table item 2)

Omit “112,810”, substitute “107,480”.

13 Subsection 41(1) (table item 3)

Omit “74,680”, substitute “71,110”.

14 Subsection 41(1) (table item 4)

Omit “20,460”, substitute “19,070”.

15 Subsection 41(1) (table item 5)

Omit “12,690”, substitute “11,650”.

16 Subsection 41(2)

Omit “430”, substitute “420”.

17 Paragraph 41(3)(a)

Omit “134,200”, substitute “127,895”.

18 Paragraph 41(3)(b)

Omit “104,470”, substitute “99,685”.

19 Paragraph 41(3)(c)

Omit “66,340”, substitute “63,315”.

20 At the end of paragraph 51(2)(c)

Add “or the pricing application”.

21 Subsection 51(4)

Repeal the subsection, substitute:

(4) If:

(a) a notification is given:

(i) under subsection 50(1) or (2) after receipt of a notice of intent in relation to a proposed pricing application; or

(ii) under subsection 50(3) after receipt of a pricing application; and

(b) the notice of intent, or the pricing application, is withdrawn after the end of the period of 10 business days beginning on the day the notification mentioned in paragraph (a) is given; and

- (c) the proposed pricing application, or pricing application, was or would have been for pricing services relating to the entering into of a deed under section 85E of the Act (whether or not other pricing services were or would have been applied for); and
 - (d) all or part of the fee for providing pricing services in response to the pricing application was paid before the withdrawal of the notice of intent or the pricing application;
- the fee amount paid, except the relevant deposit referred to in subsection 41(3), must be refunded.

22 Subsection 51(5)

Omit “430”, substitute “420”.

23 Subsection 56(1) (table item 1)

Omit “5,080”, substitute “4,820”.

24 Subsection 56(1) (table item 2)

Omit “1,980”, substitute “1,950”.

25 Subsection 56(1) (table item 3)

Omit “10,410”, substitute “10,340”.

26 Subsection 56(1) (table item 4)

Omit “7,090”, substitute “6,670”.

27 Subsection 60(2)

Omit “8,340”, substitute “8,215”.

28 At the end of the Part 9

Add:

**Division 2—Amendments made by the National Health
(Pharmaceuticals and Vaccines—Cost Recovery)
Amendment (Fees) Regulations 2022**

**85 Application provision for the *National Health (Pharmaceuticals and
Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022***

- (1) Subject to subsection (2), the amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022* apply in relation to the following:
 - (a) if a notice of intent in relation to an application or a submission for the provision of services is not required—an application or a submission (including a remade application or submission) that is received by the Department on or after 1 August 2022;
 - (b) in any other case—an application or a submission (including a remade application or submission) for the provision of services, for which a notice of intent is given on or after 1 August 2022.

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- (2) The amendment of subsection 35(6) of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022* applies in relation to the withdrawal of a notice of intent in relation to a proposed submission, or a submission, if:
- (a) the notice of intent or the submission is given on or after 1 August 2022; and
 - (b) the notice of intent or the submission is withdrawn on or after 1 August 2022.
- (3) The repeal and substitution of subsection 51(4) of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2022* applies in relation to the withdrawal of a notice of intent in relation to a proposed pricing application, or a pricing application, if:
- (a) the notice of intent or the pricing application is given on or after 1 April 2022; and
 - (b) the notice of intent or the pricing application is withdrawn on or after 1 April 2022.
- (4) In this section:
- services* means any of the following:
- (a) ATAGI advice;
 - (b) the service of the Department holding a pre-submission meeting with a person;
 - (c) submission services;
 - (d) pricing services;
 - (e) list management services.