

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024

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 20 June 2024

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 2024*.

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 July 2024. | 1 July 2024 |

Note: This table relates only to the provisions of this instrument as originally made.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*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 “212,790”, substitute “214,435”.

2 Subsection 7(2)

Omit “430”, substitute “455”.

3 Subsection 8(4)

Omit “117,390”, substitute “118,305”.

4 Subsection 8(4)

Omit “430”, substitute “455”.

5 Subsection 12(4)

Omit “430”, substitute “455”.

6 Section 14 (table item 1)

Omit “15,440”, substitute “16,410”.

7 Section 14 (table item 2)

Omit “20,980”, substitute “22,290”.

8 Subsection 22(2) (table)

Repeal the table, substitute:

| Fees and deposits for providing submission services | | | |
| --- | --- | --- | --- |
| Item | Column 1  Evaluation categories of submissions | Column 2  Fee ($) | Column 3  Deposit ($) |
| 1 | Category 1 | 264,595 | 455 |
| 2 | Category 2 | 206,435 | 455 |
| 3 | Category 3 | 45,155 | 455 |
| 4 | Category 4 | 35,405 | 455 |
| 5 | Committee Secretariat category | 12,785 | 455 |
| 6 | New brand or new oral form of existing pharmaceutical item category | 6,830 | 0 |
| 7 | Standard re‑entry pathway category | 204,245 | 455 |
| 8 | Early re‑entry pathway category | 43,785 | 455 |
| 9 | Early resolution pathway category | 43,935 | 455 |
| 10 | Facilitated resolution pathway category | 280,175 | 72,440 |

9 Subsection 22(2) (note 4)

Omit “430”, substitute “455”.

10 Subsection 35(6)

Omit “430”, substitute “455”.

11 Subsection 41(1) (table item 1)

Omit “140,280”, substitute “148,955”.

12 Subsection 41(1) (table item 2)

Omit “111,200”, substitute “118,005”.

13 Subsection 41(1) (table item 3)

Omit “73,780”, substitute “78,215”.

14 Subsection 41(1) (table item 4)

Omit “20,050”, substitute “21,345”.

15 Subsection 41(1) (table item 5)

Omit “12,430”, substitute “13,225”.

16 Subsection 41(2)

Omit “430”, substitute “455”.

17 Paragraph 41(3)(a)

Omit “131,640”, substitute “139,975”.

18 Paragraph 41(3)(b)

Omit “102,560”, substitute “109,025”.

19 Paragraph 41(3)(c)

Omit “65,140”, substitute “69,235”.

20 Subsection 51(5)

Omit “430”, substitute “455”.

21 Subsection 56(1) (table item 1)

Omit “4,980”, substitute “5,300”.

22 Subsection 56(1) (table item 2)

Omit “1,990”, substitute “2,060”.

23 Subsection 56(1) (table item 3)

Omit “10,820”, substitute “11,230”.

24 Subsection 56(1) (table item 4)

Omit “6,910”, substitute “7,350”.

25 Subsection 56(1) (table item 5)

Omit “4,880”, substitute “5,190”.

26 Subsection 60(2)

Omit “8,640”, substitute “8,980”.

27 In the appropriate position in Part 9

Insert:

Division 4—Amendments made by the National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024

87 Application provision for the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024*

(1) The amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024* 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 July 2024;

(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 July 2024.

(2) 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.