

# **National Health (Continued Dispensing) Determination 2022**

PB 59 of 2022

made under subsection 89A(3) of the

National Health Act 1953

# Compilation No. 11

**Compilation date:** 1 August 2025

**Includes amendments:** F2025L00880

Prepared by the Office of Parliamentary Counsel, Canberra

# About this compilation

#### This compilation

This is a compilation of the *National Health (Continued Dispensing) Determination 2022* that shows the text of the law as amended and in force on 1 August 2025 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

#### **Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au).

#### Application, saving and transitional provisions

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

#### **Editorial changes**

For more information about any editorial changes made in this compilation, see the endnotes.

#### **Presentational changes**

The *Legislation Act 2003* provides for First Parliamentary Counsel to make presentational changes to a compilation. Presentational changes are applied to give a more consistent look and feel to legislation published on the Register, and enable the user to more easily navigate those documents.

#### **Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. Any modifications affecting the law are accessible on the Register.

#### **Self-repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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# Part 1—Preliminary

#### 1.01 Name

- (1) This instrument is the *National Health (Continued Dispensing) Determination 2022.*
- (2) This instrument may also be cited as PB 59 of 2022.

#### 1.03 Authority

This instrument is made under subsection 89A(3) of the *National Health Act* 1953.

#### 1.05 Definitions

(1) In this instrument:

Act means the National Health Act 1953.

*electronic prescription* has the meaning given by subsection 5(1) of the Regulations.

*increased maximum quantity*, for a pharmaceutical item, means a quantity or number of units that has been determined under paragraph 85A(2)(a) of the Act as the maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit that may, for a relevant purpose, be directed in a prescription to be supplied on any one occasion.

*patient*: see subsection 3.01(1).

purposes code has the meaning given by the National Health (Listing of Pharmaceutical Benefits) Instrument 2024.

**Regulations** means the National Health (Pharmaceutical Benefits) Regulations 2017.

relevant purpose, for a pharmaceutical benefit, means a purpose, mentioned in Part 1 of Schedule 4 of the National Health (Listing of Pharmaceutical Benefits) Instrument 2024 for a purposes code specified in Schedule 1 of that instrument for the pharmaceutical benefit, that includes the phrase "The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient".

requested supply: see subsection 3.01(1).

(2) Where an expression that is used in this instrument is defined for the purposes of Part VII of the Act, it has the same meaning in this instrument as it has in that Part. Expressions used in this instrument that are defined in Part VII include the following:

#### Section 1.06

- (a) approved pharmacist;
- (b) pbs prescriber;
- (c) pharmaceutical benefit has a drug;
- (d) pharmaceutical benefit;
- (e) pharmaceutical item;
- (f) schedule equivalent.

### 1.06 Purpose

The purpose of this instrument is to determine:

- (a) the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription; and
- (b) the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

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# Part 2—Pharmaceutical benefits that may be supplied without a prescription

#### 2.01 Pharmaceutical benefits covered by this instrument

For the purposes of paragraph 89A(3)(a) of the Act, each pharmaceutical benefit that has a drug mentioned in an item in Schedule 1 is determined to be a pharmaceutical benefit that may be supplied by an approved pharmacist without a prescription.

Note:

A pharmaceutical benefit has the drug or medicinal preparation referred to in paragraph (a) of the definition pharmaceutical benefit in relation to that benefit – see subsection 84ABA(3).

# Part 3—Specified conditions for supplying pharmaceutical benefits without a prescription

#### 3.01 General

(1) For the purposes of paragraph 89A(3)(b) of the Act, the conditions specified in this Part are determined to be the conditions that must be satisfied when making a supply (the *requested supply*) of a pharmaceutical benefit to a person (the *patient*) requesting the supply without a prescription in accordance with subsection 89A(1) of the Act.

#### (2) In this Part:

- (a) a reference to the PBS prescriber is a reference to the PBS prescriber who most recently prescribed the supply of the pharmaceutical benefit to the patient; and
- (b) a reference to "the pharmaceutical benefit" in sections 3.03, 3.05, 3.06 and 3.07 includes a reference to a pharmaceutical benefit that is a Schedule equivalent.

#### 3.02 Condition—unable to obtain prescription

The approved pharmacist must be satisfied of either or both of the following:

- (a) the PBS prescriber is unable to be contacted;
- (b) the PBS prescriber is unable to provide an electronic prescription.

#### 3.03 Condition—previous supply of pharmaceutical benefit

The approved pharmacist must be satisfied that:

- (a) the patient has previously been supplied the pharmaceutical benefit on the basis of a prescription from a PBS prescriber; and
- (b) the PBS prescriber prescribed the supply of the pharmaceutical benefit for the patient in at least one of the circumstances determined for that pharmaceutical benefit under paragraph 85(7)(b) of the Act.

Note: The circumstances determined under paragraph 85(7)(b) of the Act relate to pharmaceutical benefits that are relevant pharmaceutical benefits under section 88A of the Act.

#### 3.04 Condition—stability of therapy

The approved pharmacist must be satisfied that the patient's therapy is stable.

#### 3.05 Condition—prior clinical review by PBS prescriber

The approved pharmacist must be satisfied that:

(a) the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period; and

(b) since the start of that period, the PBS prescriber has assessed the patient's condition and decided that there is a need for ongoing treatment with the pharmaceutical benefit.

Note: See paragraph 3.01(2)(a) for references to the PBS prescriber.

#### 3.06 Condition—prescription for last supply of pharmaceutical benefit

The approved pharmacist must be satisfied that the patient had a valid prescription under Part VII of the Act for the last supply of the pharmaceutical benefit to the patient before the requested supply.

#### 3.07 Condition—no continued dispensing in previous 12 months

The approved pharmacist must be satisfied that the patient was not supplied with the pharmaceutical benefit under subsection 89A(1) of the Act in the 12 months before the requested supply.

#### 3.08 Condition—declaration for supply of pharmaceutical benefit

The approved pharmacist must ensure that the patient, or an agent of the patient (other than the approved pharmacist), signs a declaration acknowledging that the patient is being supplied with the pharmaceutical benefit without the presentation of a valid prescription under Part VII of the Act.

#### 3.09 Condition—maximum quantity of supply

- (1) The approved pharmacist must supply a maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit determined under paragraph 85A(2)(a) of the Act.
- (2) However, where an increased maximum quantity has been determined for the pharmaceutical item in the pharmaceutical benefit, the approved pharmacist may only supply that increased maximum quantity if the last supply to the patient of the pharmaceutical benefit, or a pharmaceutical benefit that is Schedule equivalent, was on the basis of a prescription written for:
  - (a) a relevant purpose for the pharmaceutical benefit; or
  - (b) a relevant purpose for a pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit.

#### 3.10 Condition—preparing and recording information

- (1) The approved pharmacist must, when the pharmaceutical benefit is supplied:
  - (a) record the information that the pharmacist used to support the pharmacist's decision to supply the pharmaceutical benefit; and
  - (b) prepare information about the supply to the patient that the pharmacist will send to the PBS prescriber.
- (2) The information that must be recorded and prepared under subsection (1) must include the following:

#### Section 3.10

- (a) a statement that the pharmaceutical benefit supplied is a pharmaceutical benefit covered by Schedule 1;
- (b) a statement that the conditions mentioned in sections 3.02 to 3.05 are satisfied;
- (c) a statement that the approved pharmacist is satisfied that the pharmaceutical benefit needs to be supplied to the patient to facilitate continuity of treatment.

# Schedule 1—Pharmaceutical benefits that may be supplied without a prescription - pharmaceutical benefits that have certain listed drugs

Note: See section 2.01.

# 1 Pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist – pharmaceutical benefits that have certain listed drugs

Item	Listed drug
1	Abacavir
2	Abacavir with lamivudine
3	Acarbose
4	Alogliptin
5	Alogliptin with metformin
6	Amlodipine
7	Amlodipine with atorvastatin
8	Amlodipine with valsartan
9	Amlodipine with valsartan and hydrochlorothiazide
10	Atazanavir
11	Atazanavir with cobicistat
12	Atenolol
13	Atorvastatin
14	Beclometasone
15	Beclometasone with formoterol
16	Bictegravir with emtricitabine with tenofovir alafenamide
17	Bisoprolol
18	Budesonide
19	Budesonide with formoterol
20	Candesartan
21	Candesartan with hydrochlorothiazide

22	Captopril		
23	Carvedilol		
24	Chlortalidone		
25	Ciclesonide		
26	Dapagliflozin		
27	Dapagliflozin with metformin		
28	Dapagliflozin with sitagliptin		
29	Darunavir		
30	Darunavir with cobicistat		
31	Darunavir with cobicistat, emtricitabine and tenofovir alafenamide		
32	Diltiazem		
33	Dolutegravir with abacavir and lamivudine		
34	Dolutegravir with lamivudine		
35	Dolutegravir with rilpivirine		
36	Drospirenone		
37	Drospirenone with ethinylestradiol		
38	Dulaglutide		
39	Empagliflozin		
40	Empagliflozin with linagliptin		
41	Empagliflozin with metformin		
42	Emtricitabine with rilpivirine with tenofovir alafenamide		
43	Emtricitabine with tenofovir alafenamide		
44	Enalapril		
45	Enalapril with hydrochlorothiazide		
46	Eplerenone		
47	Eprosartan		
48	Eprosartan with hydrochlorothiazide		
49	Etravirine		
50	Ezetimibe and rosuvastatin		
51	Ezetimibe with atorvastatin		
52	Ezetimibe with simvastatin		
53	Felodipine		

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	Section
54	Fluticasone furoate
55	Fluticasone furoate with vilanterol
56	Fluticasone propionate
57	Fluticasone propionate with formoterol
58	Fluticasone propionate with salmeterol
59	Fluvastatin
60	Formoterol
61	Fosinopril
62	Furosemide
63	Glibenclamide
64	Gliclazide
65	Glimepiride
66	Glipizide
67	Hydrochlorothiazide
68	Hydrochlorothiazide with amiloride
69	Indacaterol
70	Indacaterol with mometasone
71	Indapamide
72	Insulin aspart
73	Insulin aspart with insulin aspart protamine suspension
74	Insulin degludec with insulin aspart
75	Insulin detemir
76	Insulin glargine
77	Insulin glulisine
78	Insulin isophane
79	Insulin lispro
80	Insulin lispro with insulin lispro protamine suspension
81	Insulin neutral
82	Insulin neutral with insulin isophane
83	Irbesartan
84	Irbesartan with hydrochlorothiazide
85	Labetalol

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86	Lamivudine		
87	Lamivudine with zidovudine		
88	Lercanidipine		
89	Lercanidipine with enalapril		
90	Levonorgestrel		
91	Levonorgestrel with ethinylestradiol		
92	Linagliptin		
93	Linagliptin with metformin		
94	Lisinopril		
95	Lopinavir with ritonavir		
96	Maraviroc		
97	Metformin		
98	Metoprolol		
99	Metoprolol succinate		
100	Nebivolol		
101	Nevirapine		
102	Nifedipine		
103	Norethisterone		
104	Norethisterone with ethinylestradiol		
105	Olmesartan		
106	Olmesartan with amlodipine		
107	Olmesartan with amlodipine and hydrochlorothiazide		
108	Olmesartan with hydrochlorothiazide		
109	Perindopril		
110	Perindopril with amlodipine		
111	Perindopril with indapamide		
112	Pioglitazone		
113	Pravastatin		
114	Propranolol		
115	Quinapril		
116	Ramipril		
117	Ramipril with felodipine		

	Section
118	Rilpivirine
119	Ritonavir
120	Rosuvastatin
121	Sacubitril with valsartan
122	Salbutamol
123	Salmeterol
124	Saxagliptin
125	Saxagliptin with dapagliflozin
126	Saxagliptin with metformin
127	Semaglutide
128	Simvastatin
129	Sitagliptin
130	Sitagliptin with metformin
131	Sotalol
132	Spironolactone
133	Telmisartan
134	Telmisartan with amlodipine
135	Telmisartan with hydrochlorothiazide
136	Tenofovir
137	Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat
138	Tenofovir with emtricitabine
139	Tenofovir with emtricitabine and efavirenz
140	Terbutaline
141	Trandolapril
142	Trandolapril with verapamil
143	Valsartan
144	Valsartan with hydrochlorothiazide
145	Verapamil
146	Vildagliptin
147	Vildagliptin with metformin
148	Zidovudine

#### **Endnotes**

#### **Endnote 1—About the endnotes**

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

#### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

#### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

#### **Editorial changes**

The Legislation Act 2003 authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

#### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

#### **Endnote 2—Abbreviation key**

ad = added or inserted orig = original am = amendedp = page(s)amdt = amendmentpara = paragraph(s)/subparagraph(s)/sub-subparagraph(s) C[x] = Compilation No. xch = Chapter(s)pres = presentcl = clause(s)prev = previous cont. = continued (prev...) = previously def = definition(s)pt = Part(s)Dict = Dictionary r = regulation(s)/Court rule(s) disallowed = disallowed by Parliament reloc = relocated div = Division(s)renum = renumbered ed = editorial change rep = repealed exp = expires/expired or ceases/ceased to have rs = repealed and substituted effect s = section(s)/subsection(s)/rule(s)/subrule(s)/order(s)/suborder(s) gaz = gazette LA = Legislation Act 2003 sch = Schedule(s)LIA = Legislative Instruments Act 2003 SLI = Select Legislative Instrument (md) = misdescribed amendment can be given SR = Statutory Rules effect sub ch = Sub-Chapter(s) sub div = Subdivision(s)(md not incorp) = misdescribed amendment cannot be given effect sub pt = Subpart(s)mod = modified/modification <u>underlining</u> = whole or part not commenced or to be commenced No. = Number(s)Ord = Ordinance

## Endnote 3—Legislation history

# **Endnote 3—Legislation history**

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Continued Dispensing) Determination 2022 (PB 59 of 2022)	30 June 2022 (F2022L00884)	1 July 2022 (s 1.02(1) item 1)	
National Health (Continued Dispensing) Amendment Determination 2022 (No. 1) (PB 88 of 2022)	30 Sept 2022 (F2022L01306)	1 Oct 2022 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 1) (PB 70 of 2023)	31 July 2023 (F2023L01045)	1 Aug 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 2) (PB 83 of 2023)	31 Aug 2023 (F2023L01156)	1 Sept 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 3) (PB 115 of 2023)	30 Nov 2023 (F2023L01576)	1 Dec 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 1) (PB 50 of 2024)	30 Apr 2024 (F2024L00507)	1 May 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 2) (PB 98 of 2024)	30 Sept 2024 (F2024L01242)	1 Oct 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 3) (PB 114 of 2024)	31 Oct 2024 (F2024L01393)	1 Nov 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 4) (PB 134 of 2024)	29 Nov 2024 (F2024L01544)	1 Dec 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2025 (No. 1) (PB 16 of 2025)	28 Feb 2025 (F2025L00218)	1 Mar 2025 (s 2(1) item 1)	_

#### **Endnotes**

# Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Continued Dispensing) Amendment Determination 2025 (No. 2) (PB 43 of 2025)	30 Apr 2025 (F2025L00537)	1 May 2025 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2025 (No. 3) (PB 87 of 2025)	31 July 2025 (F2025L00880)	1 Aug 2025 (s 2(1) item 1)	_

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#### **Endnotes**

## Endnote 4—Amendment history

# **Endnote 4—Amendment history**

Provision affected	How affected
Part 1	
s 1.02	rep LA s 48D
s 1.04	rep LA s 48C
s 1.05	am F2023L01576; F2024L01393
Part 2	
s 2.01	rs F2024L01393
Part 3	
s 3.09	rs F2023L01576
Part 4	rep F2024L01393
Schedule 1	
Schedule 1 heading	am F2024L01393
Schedule 1	am F2024L01393
s 1	am F2022L01306; F2023L01045; F2023L01156; F2024L00507; F2024L01242; F2024L01393; F2024L01544; F2025L00218; F2025L00537; F2025L00880
Schedule 2	rep LA s 48C

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