National Health (Continued Dispensing) Determination 2022

PB 59 of 2022

made under subsection 89A(3) of the

National Health Act 1953

Compilation No. 5

Compilation date: 1 May 2024

Includes amendments: F2024L00507

Registered: 9 May 2024

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 May 2024 (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. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

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.

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. For more information on any modifications, see the Register for the compiled law.

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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

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 2012*.

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

relevant purpose, for a pharmaceutical benefit, means a purpose, mentioned in Schedule 4 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* 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).

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.

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, the pharmaceutical benefits covered by an item in the table in Schedule 1 (being the listed drugs specified in the item) are determined to be pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription.

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:

(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.

Part 4—Application, savings and transitional provisions

4.01 Application of this instrument

Despite the repeal of the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*, that instrument (the ***emergency instrument***) continues to have effect, on and after 1 July 2022, for the purposes of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* in relation to a supply of a pharmaceutical benefit made in accordance with the emergency instrument on or before 30 June 2022 as if the repeal had not happened.

Section 1

Schedule 1—Pharmaceutical benefits that may be supplied without a prescription

Note: See section 3.01.

1 Pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist

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

Section 1

Item	Listed drug
26	Ciclesonide
27	Dapagliflozin
28	Dapagliflozin with metformin
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	Dulaglutide
37	Empagliflozin
38	Empagliflozin with linagliptin
39	Empagliflozin with metformin
40	Emtricitabine with rilpivirine with tenofovir alafenamide
41	Emtricitabine with tenofovir alafenamide
42	Enalapril
43	Enalapril with hydrochlorothiazide
44	Eplerenone
45	Eprosartan
46	Eprosartan with hydrochlorothiazide
47	Etravirine
48	Ezetimibe and rosuvastatin
49	Ezetimibe with atorvastatin
50	Ezetimibe with simvastatin
51	Felodipine
52	Fluticasone furoate
53	Fluticasone furoate with vilanterol
54	Fluticasone propionate
55	Fluticasone propionate with formoterol
56	Fluticasone propionate with salmeterol

Section 1

Item	Listed drug
57	Fluvastatin
58	Formoterol
60	Fosinopril
61	Fosinopril with hydrochlorothiazide
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
86	Lamivudine
87	Lamivudine with zidovudine
88	Lercanidipine

Section 1

Item	Listed drug
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	Oxprenolol
110	Perindopril
111	Perindopril with amlodipine
112	Perindopril with indapamide
113	Pioglitazone
114	Pravastatin
115	Propranolol
116	Quinapril
117	Quinapril with hydrochlorothiazide
118	Ramipril

Section 1

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

Item	Listed drug
149	Vildagliptin with metformin
150	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

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

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)	—

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
Part 3	
s 3.09	rs F2023L01576
Schedule 1	
s 1	am F2022L01306; F2023L01045; F2023L01156; F2024L00507
Schedule 2	rep LA s 48C