

National Health (Continued Dispensing) Determination 2022

PB 59 of 2022

made under subsection 89A(3) of the

National Health Act 1953

**Compilation No. 1**

**Compilation date:** 1 October 2022

**Includes amendments up to:** F2022L01306

**Registered:** 8 October 2022

**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 October 2022 (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 Legislation 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 series page on the Legislation 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 series page on the Legislation 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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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.

1.02 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 2022. | 1 July 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.

1.03 Authority

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

1.04 Schedule 2

 Each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

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.

***patient***: see subsection 3.01(1).

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

***requested supply***: see subsection 3.01(1).

 (2) An expression that is used in this instrument and in Part VII of the Act has the same meaning in this instrument as it has in that Part.

Examples:

(a) approved pharmacist;

(b) listed brand;

(c) PBS prescriber;

(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.

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

 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.

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.

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 |
| 3 | Abacavir with lamivudine and zidovudine |
| 4 | Acarbose |
| 5 | Adefovir |
| 6 | Alogliptin |
| 7 | Alogliptin with metformin |
| 8 | Amlodipine |
| 9 | Amlodipine with atorvastatin |
| 10 | Amlodipine with valsartan |
| 11 | Amlodipine with valsartan and hydrochlorothiazide |
| 12 | Atazanavir |
| 13 | Atazanavir with cobicistat |
| 14 | Atenolol |
| 15 | Atorvastatin |
| 16 | Beclometasone |
| 17 | Beclometasone with formoterol |
| 18 | Bictegravir with emtricitabine with tenofovir alafenamide |
| 19 | Bisoprolol |
| 20 | Budesonide |
| 21 | Budesonide with formoterol |
| 22 | Candesartan |
| 23 | Candesartan with hydrochlorothiazide |
| 24 | Captopril |
| 25 | Carvedilol |
| 26 | Chlortalidone |
| 27 | Ciclesonide |
| 28 | Cromoglycic acid |
| 29 | Dapagliflozin |
| 30 | Dapagliflozin with metformin |
| 31 | Darunavir |
| 32 | Darunavir with cobicistat |
| 33 | Darunavir with cobicistat, emtricitabine and tenofovir alafenamide |
| 34 | Diltiazem |
| 35 | Dolutegravir |
| 36 | Dolutegravir with abacavir and lamivudine |
| 37 | Dolutegravir with lamivudine |
| 38 | Dolutegravir with rilpivirine |
| 39 | Dulaglutide |
| 40 | Efavirenz |
| 41 | Empagliflozin |
| 42 | Empagliflozin with linagliptin |
| 43 | Empagliflozin with metformin |
| 44 | Emtricitabine with rilpivirine with tenofovir alafenamide |
| 45 | Emtricitabine with tenofovir alafenamide |
| 46 | Enalapril |
| 47 | Enalapril with hydrochlorothiazide |
| 48 | Enfuvirtide |
| 49 | Entecavir |
| 50 | Eplerenone |
| 51 | Eprosartan |
| 52 | Eprosartan with hydrochlorothiazide |
| 53 | Ertugliflozin |
| 54 | Ertugliflozin with metformin |
| 55 | Ertugliflozin with sitagliptin |
| 56 | Etravirine |
| 57 | Exenatide |
| 58 | Ezetimibe and rosuvastatin |
| 59 | Ezetimibe with atorvastatin |
| 60 | Ezetimibe with simvastatin |
| 61 | Felodipine |
| 62 | Fluticasone furoate |
| 63 | Fluticasone furoate with vilanterol |
| 64 | Fluticasone propionate |
| 65 | Fluticasone propionate with formoterol |
| 66 | Fluticasone propionate with salmeterol |
| 67 | Fluvastatin |
| 68 | Formoterol |
| 69 | Fosamprenavir |
| 70 | Fosinopril |
| 71 | Fosinopril with hydrochlorothiazide |
| 72 | Furosemide |
| 73 | Glibenclamide |
| 74 | Gliclazide |
| 75 | Glimepiride |
| 76 | Glipizide |
| 77 | Hydrochlorothiazide |
| 78 | Hydrochlorothiazide with amiloride |
| 79 | Indacaterol |
| 80 | Indacaterol with mometasone |
| 81 | Indapamide |
| 82 | Insulin aspart |
| 83 | Insulin aspart with insulin aspart protamine suspension |
| 84 | Insulin degludec with insulin aspart |
| 85 | Insulin detemir |
| 86 | Insulin glargine |
| 87 | Insulin glulisine |
| 88 | Insulin isophane |
| 89 | Insulin lispro |
| 90 | Insulin lispro with insulin lispro protamine suspension |
| 91 | Insulin neutral |
| 92 | Insulin neutral with insulin isophane |
| 93 | Irbesartan |
| 94 | Irbesartan with hydrochlorothiazide |
| 95 | Labetalol |
| 96 | Lamivudine |
| 97 | Lamivudine with zidovudine |
| 98 | Lercanidipine |
| 99 | Lercanidipine with enalapril |
| 100 | Levonorgestrel |
| 101 | Levonorgestrel with ethinylestradiol |
| 102 | Linagliptin |
| 103 | Linagliptin with metformin |
| 104 | Lisinopril |
| 105 | Lopinavir with ritonavir |
| 106 | Losartan |
| 107 | Maraviroc |
| 108 | Metformin |
| 109 | Metoprolol |
| 110 | Metoprolol succinate |
| 111 | Nebivolol |
| 112 | Nevirapine |
| 113 | Nifedipine |
| 114 | Norethisterone |
| 115 | Norethisterone with ethinylestradiol |
| 116 | Norethisterone with mestranol |
| 117 | Olmesartan |
| 118 | Olmesartan with amlodipine |
| 119 | Olmesartan with amlodipine and hydrochlorothiazide |
| 120 | Olmesartan with hydrochlorothiazide |
| 121 | Oxprenolol |
| 122 | Perindopril |
| 123 | Perindopril with amlodipine |
| 124 | Perindopril with indapamide |
| 125 | Pindolol |
| 126 | Pioglitazone |
| 127 | Pravastatin |
| 128 | Propranolol |
| 129 | Quinapril |
| 130 | Quinapril with hydrochlorothiazide |
| 131 | Raltegravir |
| 132 | Ramipril |
| 133 | Ramipril with felodipine |
| 134 | Rilpivirine |
| 135 | Ritonavir |
| 136 | Rosuvastatin |
| 137 | Sacubitril with valsartan |
| 138 | Salbutamol |
| 139 | Salmeterol |
| 140 | Saquinavir |
| 141 | Saxagliptin |
| 142 | Saxagliptin with dapagliflozin |
| 143 | Saxagliptin with metformin |
| 144 | Semaglutide |
| 145 | Simvastatin |
| 146 | Sitagliptin |
| 147 | Sitagliptin with metformin |
| 148 | Spironolactone |
| 149 | Telmisartan |
| 150 | Telmisartan with amlodipine |
| 151 | Telmisartan with hydrochlorothiazide |
| 152 | Tenofovir |
| 153 | Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat |
| 154 | Tenofovir with emtricitabine |
| 155 | Tenofovir with emtricitabine and efavirenz |
| 156 | Terbutaline |
| 157 | Tipranavir |
| 158 | Trandolapril |
| 159 | Trandolapril with verapamil |
| 160 | Valsartan |
| 161 | Valsartan with hydrochlorothiazide |
| 162 | Verapamil |
| 163 | Vildagliptin |
| 164 | Vildagliptin with metformin |
| 165 | Zidovudine |

Schedule 2—Repeals

National Health (Continued Dispensing) Determination 2012

1 The whole of the instrument

Repeal the instrument.

National Health (Continued Dispensing – Emergency Measures) Determination 2020

2 The whole of the instrument

Repeal the instrument.

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 | o = order(s) |
| am = amended | Ord = Ordinance |
| amdt = amendment | orig = original |
| c = clause(s) | par = paragraph(s)/subparagraph(s) |
| C[x] = Compilation No. x | /sub‑subparagraph(s) |
| Ch = Chapter(s) | pres = present |
| def = definition(s) | prev = previous |
| Dict = Dictionary | (prev…) = previously |
| disallowed = disallowed by Parliament | Pt = Part(s) |
| Div = Division(s) | r = regulation(s)/rule(s) |
| ed = editorial change | reloc = relocated |
| exp = expires/expired or ceases/ceased to have | renum = renumbered |
| effect | rep = repealed |
| F = Federal Register of Legislation | rs = repealed and substituted |
| gaz = gazette | s = section(s)/subsection(s) |
| LA = *Legislation Act 2003* | Sch = Schedule(s) |
| LIA = *Legislative Instruments Act 2003* | Sdiv = Subdivision(s) |
| (md) = misdescribed amendment can be given | SLI = Select Legislative Instrument |
| effect | SR = Statutory Rules |
| (md not incorp) = misdescribed amendment | Sub‑Ch = Sub‑Chapter(s) |
| cannot be given effect | SubPt = Subpart(s) |
| mod = modified/modification | underlining = whole or part not |
| No. = Number(s) | 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 2(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) | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| **Part 1** |  |
| s 1.02  | rep LA s 48D |
| s 1.04  | rep LA s 48C |
| **Schedule 1** |  |
| s 1  | am F2022L01306 |
| **Schedule 2** |  |
| Schedule 2  | rep LA s48C |