National Health (Continued Dispensing) Determination 2012

made under subsection 89A(3) of the

National Health Act 1953

Compilation No. 2

Compilation date:	1 October 2020
Includes amendments up to:	PB 98 of 2020
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About this compilation

This compilation

This is a compilation of the *National Health (Continued Dispensing) Determination 2012* that shows the text of the law as amended and in force on 1 October 2020 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1.01 Name of determination

This determination is the *National Health (Continued Dispensing) Determination 2012*.

1.03 Definitions

(1) In this determination:

Act means the *National Health Act 1953*.

PSA Guidelines means the document titled *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists*, issued by the Pharmaceutical Society of Australia.

requested supply: see subsection 2.01(1).

(2) In this determination, the following terms have the same meaning as in Part VII of the Act:

- approved pharmacist
- listed brand
- PBS prescriber
- pharmaceutical benefit
- pharmaceutical item.
- Schedule equivalent

1.04 Purpose

This determination specifies the pharmaceutical benefits that may be supplied, and the conditions that must be satisfied when those pharmaceutical benefits are supplied, by an approved pharmacist without a current prescription, but on the basis of a previous prescription from a PBS prescriber.

Part 2—Conditions

2.01 General

(1) For paragraph 89A(3)(b) of the Act, this Part sets out the conditions that must be satisfied when making a supply (the ***requested supply***) of a pharmaceutical benefit to a person under subsection 89A(1) of the Act.

(2) An approved pharmacist must consider the PSA Guidelines when:
  (a) satisfying the conditions set out in this Part; or
  (b) deciding whether those conditions are satisfied.

(3) In this Part:
  (a) a reference to the person is a reference to the person who requested the supply of a pharmaceutical benefit under subsection 89A(1) of the Act; and
  (b) 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 person.
  (c) a reference to "the pharmaceutical benefit" in sections 2.03, 2.05, 2.06 and 2.07 includes a pharmaceutical benefit that is Schedule equivalent.

2.02 Not practicable to obtain prescription

A condition *is* that the approved pharmacist is satisfied that it is not practicable for the person to obtain a prescription for the pharmaceutical benefit from a PBS prescriber before the person needs the supply of the pharmaceutical benefit.

2.03 Previous supply of pharmaceutical benefit

A condition is that the approved pharmacist is satisfied that:
  (a) the person 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 person 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.

2.04 Stability of therapy

A condition is that the approved pharmacist is satisfied that the person's therapy is stable.

2.05 Prior clinical review by PBS prescriber

A condition is that the approved pharmacist is satisfied that:

(a) the person 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 person's condition and decided that there is a need for ongoing treatment with the pharmaceutical benefit.

Note: See paragraph 2.01(3)(b) for references to the PBS prescriber.

2.06 Prescription for last supply of pharmaceutical benefit

A condition is that the approved pharmacist is satisfied that the person had a valid prescription under Part VII of the Act for the last supply of the pharmaceutical benefit to the person before the requested supply.

2.07 No continued dispensing in previous 12 months

A condition is that the approved pharmacist is satisfied that the person was not supplied with the pharmaceutical benefit under subsection 89A(1) of the Act in the 12 months before the requested supply.

2.08 Declaration by person supplied with pharmaceutical benefit

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

2.09 Maximum quantity of supply

A condition is that the approved pharmacist supplies a maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit determined under paragraph 85A(2)(a) of the Act.

2.10 Preparing and recording information

(1) A condition is that, when the pharmaceutical benefit is supplied, the approved pharmacist:

(a) records the information that the pharmacist used to support his or her decision to supply the pharmaceutical benefit; and

(b) prepares information about the supply that the pharmacist will send to the PBS prescriber.

Note: See the PSA Guidelines for guidance about when the information should be sent to the PBS prescriber.

(2) The information that must be recorded and prepared includes the following:

(a) a statement that the pharmaceutical benefit supplied is a pharmaceutical benefit determined under paragraph 89A(3)(a) of the Act;

(b) a statement that the conditions mentioned in sections 2.02 to 2.05 are satisfied;

(c) a statement that the approved pharmacist is satisfied that the pharmaceutical benefit needs to be supplied to the person to facilitate continuity of treatment.

Part 3—Pharmaceutical benefits

3.01 Pharmaceutical benefits

(1) For subsection 89A(3)(a) of the Act, an approved pharmacist may supply without a prescription a pharmaceutical benefit, being any listed brand of a pharmaceutical item mentioned in Schedule 1.

(2) For subsection (1), the pharmaceutical item is the listed drug mentioned in Schedule 1:

(a) in the form mentioned in Schedule 1 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Schedule 1—Pharmaceutical benefits

(section 3.01)

Part 1—Oral hormonal contraceptives

Listed Drug	Form	Manner of Administration
Levonorgestrel	Tablets 30 micrograms, 28	Oral
Levonorgestrel with ethinylestradiol	Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets	Oral
	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets	Oral
	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	Oral
	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	Oral
Norethisterone	Tablets 350 micrograms, 28	Oral
Norethisterone with ethinylestradiol	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	Oral
	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	Oral
Norethisterone with Mestranol	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets	Oral

Part 2—Lipid modifying agents

Listed Drug	Form	Manner of Administration
Atorvastatin	Tablet 10 mg (as calcium)	Oral
	Tablet 20 mg (as calcium)	Oral
	Tablet 40 mg (as calcium)	Oral
	Tablet 80 mg (as calcium)	Oral
Fluvastatin	Tablet (prolonged release) 80 mg (as sodium)	Oral
Pravastatin	Tablet containing pravastatin sodium 10 mg	Oral
	Tablet containing pravastatin sodium 20 mg	Oral
	Tablet containing pravastatin sodium 40 mg	Oral
	Tablet containing pravastatin sodium 80 mg	Oral
Rosuvastatin	Tablet 5 mg (as calcium)	Oral
	Tablet 10 mg (as calcium)	Oral
	Tablet 20 mg (as calcium)	Oral

Listed Drug	Form	Manner of Administration
	Tablet 40 mg (as calcium)	Oral
Simvastatin	Tablet 5 mg	Oral
	Tablet 10 mg	Oral
	Tablet 20 mg	Oral
	Tablet 40 mg	Oral
	Tablet 80 mg	Oral

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 the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in 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 2012	29 June 2012 (F2012L01465)	1 July 2012 (s 1.02)	
National Health (Continued Dispensing) Amendment Determination 2013 (No. 1) (PB 45 of 2013)	9 Aug 2013 (F2013L01561)	10 Aug 2013 (s 2)	—
National Health (Continued Dispensing) Amendment Determination 2020 (No. 1) (PB 98 of 2020)	30 Sept 2020 (F2020L01252)	1 Oct 2020 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 1.02	rep LA s 48D
s 1.03	am PB 45 of 2013; PB 98 of 2020
Part 2	
s 2.01	am PB 45 of 2013
Part 3	
s 3.01	rs PB 45 of 2013
Schedule 1	
Schedule 1	rs PB 45 of 2013
Part 1	
Part 1	am PB 98 of 2020
Part 2	
Part 2	am PB 98 of 2020