National Health (Pharmaceutical Benefits) Regulations 2017

made under the

National Health Act 1953

Compilation No. 14

Compilation date: 14 October 2024

Includes amendments: F2024L01299

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Pharmaceutical Benefits) Regulations 2017* that shows the text of the law as amended and in force on 14 October 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

Division 1—General

1 Name

This instrument is the *National Health (Pharmaceutical Benefits) Regulations 2017*.

3 Authority

This instrument is made under the *National Health Act 1953*.

5 Interpretation

Note: A number of expressions used in this instrument are defined in the Act, including the following:
(a) Chief Executive Medicare;
(b) public hospital;
(c) public hospital authority.

(1) In this instrument:

Act means the *National Health Act 1953*.

additional patient charge means the further additional patient charge referred to in clause 6.2.1(c) of the Eighth Community Pharmacy Agreement, as in force on 1 July 2024.

Note: The charge is based on a formula that takes into account whichever of the general patient charge, general patient reduced charge or concessional beneficiary charge is applicable to a supply under Part VII of the Act.

applicable amount has the same meaning as in Part VII of the Act.

approved hospital means a hospital in respect of which the hospital authority is approved under section 94 of the Act.

approved hospital authority has the same meaning as in Part VII of the Act.

approved information technology requirements means information technology requirements of a kind approved by the Secretary under section 12 for the purposes of the provision in which the expression is used.

approved medical practitioner has the same meaning as in Part VII of the Act.

approved pharmacist has the same meaning as in Part VII of the Act.

approved supplier has the same meaning as in Part VII of the Act.

authorised midwife has the same meaning as in Part VII of the Act.

authorised nurse practitioner has the same meaning as in Part VII of the Act.

authorised optometrist has the same meaning as in Part VII of the Act.

authority approval number, for an authority prescription, means the number allotted to the prescription when the prescription is authorised by the Minister or the Chief Executive Medicare.

authority prescription means a prescription that prescribes a pharmaceutical benefit and that:

(a) has been written in accordance with an authorisation under section 30; or

(b) has been authorised in accordance with authority required procedures that:

(i) are part of the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or

(ii) are part of the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit; or

(c) if neither paragraph (a) or (b) applies—has been authorised as part of the circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act.

brand, of a pharmaceutical item, has the same meaning as in Part VII of the Act.

Commonwealth price has the same meaning as in Part VII of the Act.

concessional beneficiary has the same meaning as in Part VII of the Act.

concession card has the same meaning as in Part VII of the Act.

CTS claim has the same meaning as in Part VII of the Act.

data collection period, for a brand of a pharmaceutical item, has the meaning given by section 67.

deferred supply authorisation means a deferred supply authorisation prepared under paragraph 53(3)(a).

delisted brand, of a pharmaceutical item: a listed brand of a pharmaceutical item becomes a ***delisted brand*** when a determination made under subsection 85(6) of the Act is no longer in force for that brand.

dependant, in relation to a concessional beneficiary, has the same meaning as in Part VII of the Act.

drug in a pharmaceutical item has the same meaning as in Part VII of the Act.

drug is on F2 has the same meaning as in Part VII of the Act.

electronic communication has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

electronic medication chart has the meaning given by subsection 41(6).

electronic medication chart system means a software system that:

(a) is used for prescribing, and recording the administration of, pharmaceutical benefits to a person receiving treatment in or at:

(i) a residential care service at which the person is receiving residential care; or

(ii) an approved hospital; and

(b) is accessible in real time by approved suppliers for the purposes of:

(i) viewing electronic prescriptions written in electronic medication charts within the system; and

(ii) recording the supply information mentioned in paragraph 45(2)(d) in such electronic prescriptions; and

(c) meets any electronic medication chart system functionality requirements approved by the Secretary under section 12A.

electronic order form means a form that is approved by the Secretary under subparagraph 33(1)(b)(ii) for the purposes of lodging an order under paragraph 33(1)(b).

electronic prescription means a prescription that is prepared and submitted:

(a) in accordance with approved information technology requirements (if any), by means of an eligible electronic communication; and

(b) in accordance with:

(i) for prescriptions other than medication chart prescriptions—the form approved by the Secretary under subparagraph 40(2)(c)(ii); or

(ii) for medication chart prescriptions—either the form approved by the Secretary under paragraph 41(5)(a), or the information requirements approved by the Secretary under paragraph 41(5)(b), for the purpose of writing an electronic prescription.

eligible electronic communication means:

(a) an electronic communication of a kind approved by the Secretary under section 11 for the purposes of the provision in which the expression is used; or

(b) if no such approval is in force for the purposes of the provision in which the expression is used—any electronic communication.

entitlement card has the same meaning as in Part VII of the Act.

exempt item has the same meaning as in Part VII of the Act.

final day, of a data collection period, means the last day of the data collection period.

healthcare identifier has the same meaning as in the *Healthcare Identifiers Act 2010*.

healthcare provider organisation has the same meaning as in the *Healthcare Identifiers Act 2010*.

incentive, for a brand of a pharmaceutical item, includes anything given as an incentive to take supply of the brand (including a delisted brand before it was delisted) whether the incentive is given:

(a) before the supply of the brand, but on condition of taking supply; or

(b) at, or after, the time of the supply of the brand; or
(c) over a period of time; or
(d) directly for the brand; or
(e) indirectly for the brand (for example, for a group of brands of pharmaceutical items or other products).

information technology requirements has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

initial month, for a brand of a pharmaceutical item that was not a listed brand immediately before the brand's start day, means the first month of the brand's first data collection period.

last listed brand, of a pharmaceutical item, means the brand of the pharmaceutical item that was the last to become a delisted brand before the final day of the data collection period for the brand of the pharmaceutical item.

listed brand has the same meaning as in Part VII of the Act.

maximum quantity, of a pharmaceutical item or a pharmaceutical benefit, means the maximum quantity or number of units of the pharmaceutical item or pharmaceutical benefit that may, in one prescription, be directed to be supplied on any one occasion, as determined by the Minister under subsection 85A(2) of the Act.

Medicare/DVA copy, for a paper-based prescription, means the part of the prescription on which the words "Medicare /DVA copy" appear.

medicare number has the same meaning as in Part VII of the Act.

medication chart has the meaning given by subsection 41(4).

medication chart prescription has the meaning given by subsection 41(1).

optometrist has the same meaning as in Part VII of the Act.

originator brand has the same meaning as in Division 3B of Part VII of the Act.

out-patient medication has the same meaning as in Part VII of the Act.

paper-based prescription means a prescription that is prepared in duplicate in accordance with paragraph 40(2)(a), (b) or (d).

participating dental practitioner has the same meaning as in Part VII of the Act.

PBS prescriber has the same meaning as in Part VII of the Act.

pharmaceutical benefit has the same meaning as in Part VII of the Act.

pharmaceutical benefit has a drug has the same meaning as in Part VII of the Act.

pharmaceutical item has the same meaning as in Part VII of the Act.

pharmacist/patient copy, for a paper-based prescription, means the part of the prescription on which the words "pharmacist/patient copy" appear.

practitioner:

(a) in Division 1 of Part 4—has the meaning given by section 29; and

(b) in Division 2 of Part 4—has the meaning given by section 31.

price adjustment means an adjustment under:

(a) a price agreement; or

(b) a price determination; or

(c) Division 3A of Part VII of the Act.

price agreement has the same meaning as in Part VII of the Act.

price determination has the same meaning as in Part VII of the Act.

price disclosure requirements has the same meaning as in Division 3B of Part VII of the Act.

price sampling day has the meaning given by section 68.

pricing quantity has the same meaning as in Part VII of the Act.

ready-prepared pharmaceutical benefit means a pharmaceutical benefit in respect of which a determination made under subsection 85(6) of the Act is in force.

record form has the same meaning as in Part VII of the Act.

related brand, of a brand of a pharmaceutical item, means a brand of a pharmaceutical item that has the same drug and manner of administration as the first-mentioned pharmaceutical item (including another brand of the same pharmaceutical item), but does not include a brand of an exempt item.

relevant day has the same meaning as in Division 3B of Part VII of the Act.

relevant entitlement period has the same meaning as in Part VII of the Act.

relevant streamlined authority code, for a pharmaceutical benefit that is prescribed, means the streamlined authority code that is part of:

(a) the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or

(b) the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit.

repatriation pharmaceutical benefit has the same meaning as in Part VII of the Act.

repeat authorisation means a repeat authorisation prepared under subparagraph 52(3)(a)(i).

repeat authorisation form means the form referred to in subparagraph 52(3)(a)(i).

residential care has the same meaning as in the *Aged Care Act 1997*.

residential care service has the same meaning as in the *Aged Care Act 1997*.

responsible person has the same meaning as in Part VII of the Act.

Schedule equivalent has the same meaning as in Part VII of the Act.

special patient contribution has the same meaning as in Part VII of the Act.

start day, for a brand of a pharmaceutical item, means the day on which the brand was first required to comply with the price disclosure requirements under section 99ADD of the Act.

value for safety net purposes has the same meaning as in Part VII of the Act.

WADP brand has the meaning given by subsection 83(2).

weighted average disclosed price has the same meaning as in Division 3B of Part VII of the Act.

(2) In this instrument, a reference to prescribing, or to the writing of a prescription, is a reference to the writing of a prescription for the supply of a pharmaceutical benefit under Part VII of the Act.

(3) In this instrument:
  (a) a reference to the holder of a concession card or an entitlement card is a reference to a person who is, under section 84G of the Act, taken to be a holder of the card; and
  (b) a reference to the original holder of a concession card is a reference to the person to whom a concession card has been issued under section 84DA of the Act; and
  (c) a reference to the original holder of an entitlement card is a reference to the person to whom an entitlement card has been issued under section 84E of the Act; and
  (d) a reference to a member of the family of a person is a reference to a person who is a member of that family within the meaning of section 84B of the Act.

Division 2—Application of this instrument to electronic prescriptions and electronic orders

7 Preparing electronic prescriptions

A reference in this instrument to writing or preparing a prescription, a repeat authorisation or a deferred supply authorisation, whether the expression ***writing***, ***preparing*** or any other expression is used, is taken to include:

(a) for an electronic prescription—preparing the electronic prescription; and

(b) for a repeat authorisation that relates to an electronic prescription—writing or preparing the authorisation by means of an electronic form approved by the Secretary under subparagraph 52(3)(a)(i) for the supply of a pharmaceutical benefit under an electronic prescription; and

(c) for a deferred supply authorisation that relates to an electronic prescription—writing or preparing the authorisation by means of an electronic form approved by the Secretary under paragraph 53(3)(a) for deferring the supply of a pharmaceutical benefit under an electronic prescription.

8 Date when a prescription is written or a pharmaceutical benefit is prescribed

A reference in this instrument to the day or date on which a prescription is written by a PBS prescriber or the day or date on which a pharmaceutical benefit is prescribed is, in relation to an electronic prescription, a reference to the day or date on which the prescription is signed by the PBS prescriber.

9 Requirement to give information in writing

(1) If, under this instrument, a person is required to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, that requirement is taken to have been met in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form, if the person gives the information:

(a) in accordance with approved information technology requirements (if any); and

(b) by means of an eligible electronic communication.

(2) This section applies to a requirement to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, whether the expression ***write***, ***certify***, ***endorse***, ***identify***, ***indicate***, ***mark***, ***specify***, ***state***, or any other expression is used.

10 Requirement to give a prescription

If, under this instrument, a prescription is required to be given or presented to an approved supplier for the purpose of supplying a pharmaceutical benefit to the

person for whom the prescription was written, that requirement is taken to have been met in relation to an electronic prescription if:

(a) the person who will receive the pharmaceutical benefit (whether or not for the person's own use) requests the approved supplier to supply the pharmaceutical benefit; and

(b) the approved supplier consents, within the meaning of subsection 5(1) of the *Electronic Transactions Act 1999*, to the prescription being given or presented, in accordance with approved information technology requirements (if any), by means of an eligible electronic communication; and

(c) the prescription is accessible by the approved supplier.

11 Approval of kinds of electronic communications

The Secretary may, in writing, approve a kind of electronic communication for one or more of the following purposes:

(a) preparing or submitting an electronic prescription;

(b) giving information, for the purposes of this instrument, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;

(c) giving or presenting an electronic prescription to an approved supplier under this instrument;

(d) submitting a prescription to the Minister in accordance with paragraph 30(3)(b);

(e) lodging an order with an approved pharmacist under paragraph 33(1)(b);

(f) submitting a receipt for a pharmaceutical benefit under paragraph 33(4)(c);

(g) giving an acknowledgement under this instrument for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;

(h) doing any other thing that is required or permitted to be done for the purposes of this instrument.

12 Approval of information technology requirements

The Secretary may, in writing, approve information technology requirements for one or more of the following purposes:

(a) preparing and submitting an electronic prescription;

(b) giving information, for the purposes of this instrument, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;

(c) giving or presenting an electronic prescription to an approved supplier under this instrument;

(d) lodging an order with an approved pharmacist under paragraph 33(1)(b);

(e) submitting a receipt for a pharmaceutical benefit under paragraph 33(4)(c);

(f) giving an acknowledgement under this instrument for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;

(g) doing any other thing that is required or permitted to be done for the purposes of this instrument.

12A Electronic medication chart system functionality requirements

For the purposes of paragraph (c) of the definition of ***electronic medication chart system*** in subsection 5(1), the Secretary may, in writing, approve electronic medication chart system functionality requirements to facilitate the safe and effective prescribing and supplying of pharmaceutical benefits using electronic medication charts.

Part 2—Approvals under Part VII of the Act

13 Purpose of this Part

This Part is made for the purposes of section 140 of the Act.

14 Application for certain approvals to be in approved form

(1) The Secretary may refuse to consider:

(a) an application for approval of a pharmacist under section 90 of the Act; or

(b) an application for approval of a medical practitioner under section 92 of the Act;

if the application is not in a form approved, in writing, by the Secretary.

(2) The Minister may refuse to consider an application for approval of a hospital authority under section 94 of the Act if the application is not in a form approved, in writing, by the Secretary.

15 Application for approval as authorised optometrist, authorised midwife or authorised nurse practitioner

The following applications must be made in a form approved, in writing, by the Secretary:

(a) an application for approval as an authorised optometrist under subsection 84AAB(1) of the Act;

(b) an application for approval as an authorised midwife under subsection 84AAF(1) of the Act;

(c) an application for approval as an authorised nurse practitioner under subsection 84AAJ(1) of the Act.

16 Numbering of approvals

(1) If the Secretary approves:

(a) a dental practitioner under section 84A of the Act; or

(b) an optometrist under section 84AAB of the Act; or

(c) an eligible midwife under section 84AAF of the Act; or

(d) an eligible nurse practitioner under section 84AAJ of the Act; or

(e) a pharmacist under section 90 of the Act; or

(f) a medical practitioner under section 92 of the Act;

the Secretary may allot a number to that approval.

(2) If, under section 90A of the Act, the Minister substitutes for a decision of the Secretary a decision approving a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises, the Minister may allot a number to that approval.

(3) If the Secretary grants permission to a person to supply pharmaceutical benefits under subsection 91(1) of the Act, the Secretary may allot a number to the approval that, under paragraph 91(7)(a) of the Act, is treated as having been granted to the person under section 90 of the Act.

(3A) If the Secretary grants permission to an applicant to supply pharmaceutical benefits under subsection 91B(1), (2) or (3) of the Act, the Secretary may allot a number to the approval that, under paragraph 91B(10)(a) of the Act, is treated as having been granted to the person under section 90 of the Act.

(4) If the Minister approves a hospital authority under section 94 of the Act, the Minister may allot a number to that approval.

17 Certain requirements to be met after cancellation etc. of approval—approved pharmacists

(1) A person commits an offence if:

(a) the person's approval as an approved pharmacist is suspended, revoked or cancelled; and

(b) the person, in any way, indicates that he or she has been, or is, approved to supply pharmaceutical benefits.

Penalty: 1 penalty unit.

(2) An offence against subsection (1) is an offence of strict liability.

Part 3—Safety net concession cards and pharmaceutical benefits entitlement cards

Division 1A—Value for safety net purposes

17A Value for safety net purposes

(1) For the purposes of subsection 84C(1E) of the Act, this section prescribes the value for safety net purposes of the supply of a pharmaceutical benefit.

(2) If the supply is one to which subsection 99(2A), (2AB) or (2B) of the Act applies and the amount charged for the supply is in accordance with the Act, the value for safety purposes is the lesser of the following:

(a) the price of the pharmaceutical benefit worked out in accordance with a determination in force under subsection 84C(7) of the Act at the time of the supply, minus any additional patient charge (or part thereof) included in the amount charged for the supply;

(b) the amount charged for the supply.

(3) If subsection (2) does not apply and the amount charged for the supply is in accordance with the Act, the value for safety net purposes is the amount charged under whichever of paragraphs 87(2)(a), (b) and (e) of the Act applies (not including any amount charged under other subsections of section 87).

(4) If the amount charged for the supply is not in accordance with the Act, the value for safety net purposes is zero.

Division 1—Pharmaceutical benefits prescription record forms etc.

18 Pharmaceutical benefits prescription record forms etc.

(1) For the purposes of paragraph 84D(3)(b) of the Act, the following particulars of the person to whom a record form is issued are prescribed particulars:

(a) the given name and the surname of the person;

(b) the address of the person.

(2) For the purposes of subsection 84D(4) of the Act, the following particulars of a person (the ***family member***) who is a member of the family of a person to whom a record form is issued are prescribed particulars:

(a) the given name and the surname of the family member;

(b) the relationship of the family member to the person to whom the record form is issued.

(3) For the purposes of paragraph 84D(7)(c) of the Act, the following particulars in relation to the supply of a pharmaceutical benefit or repatriation pharmaceutical benefit are prescribed:

(a) the item code number by which the pharmaceutical benefit or repatriation pharmaceutical benefit is identified as a pharmaceutical benefit or repatriation pharmaceutical benefit (as the case may be);

(b) the number allotted under section 16 to the approval of the approved pharmacist, approved medical practitioner or approved hospital authority supplying the pharmaceutical benefit or repatriation pharmaceutical benefit;

(c) the value for safety net purposes of the pharmaceutical benefit or repatriation pharmaceutical benefit.

(4) For the purposes of paragraph 84D(11)(c) of the Act, the following particulars in relation to the supply of an out-patient medication are prescribed:

(a) particulars that identify the medication;

(b) particulars that identify the public hospital at which the medication was supplied;

(c) the value for safety net purposes of the medication.

Division 2—Issue of safety net concession cards

19 Application for safety net concession card

(1) For the purposes of paragraph 84DA(3)(b) of the Act, the following particulars are prescribed in relation to an application under subsection 84DA(1) or (2) of the Act:

(a) the given name and surname of the applicant;

(b) the residential address of the applicant;

(c) the given name and surname of each person who is a member of the applicant's family;

(d) the relationship of each person referred to in paragraph (c) to the applicant;

(e) the date on which the application is made;

(f) the medicare number of the applicant.

(2) For the purposes of paragraph 84DA(3)(b) of the Act, the following documents are prescribed in relation to an application under subsection 84DA(1) or (2) of the Act:

(a) record forms issued to the applicant or to a member of the applicant's family that:

(i) record the value for safety net purposes of the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and

(ii) include a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the form were so supplied;

(b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value for safety net purposes of the pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

20 Prescribed offices

For the purposes of subsection 84DA(5) of the Act, each office referred to in an item in the table in Schedule 1 is a prescribed office.

Division 3—Issue of pharmaceutical benefits entitlement card

21 Application for pharmaceutical benefits entitlement card

(1) For the purposes of paragraph 84E(3)(b) of the Act, the following particulars are prescribed in relation to an application under subsection 84E(1) or (2) of the Act:

(a) the given name and surname of the applicant;

(b) the residential address of the applicant;

(c) the given name and surname of each person who is a member of the applicant's family;

(d) the relationship of each person referred to in paragraph (c) to the applicant;

(e) the date on which the application is made;

(f) the medicare number of the applicant.

(2) For the purposes of paragraph 84E(3)(b) of the Act, the following documents are prescribed in relation to an application under subsection 84E(1) or (2) of the Act:

(a) record forms issued to the applicant or to a member of the applicant's family that:

(i) record the value for safety net purposes of the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and

(ii) include a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the form were so supplied;

(b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value for safety net purposes of that pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

22 Prescribed offices

For the purposes of subsection 84E(5) of the Act, each office referred to in an item in the table in Schedule 1 is a prescribed office.

Division 4—Additional and replacement concession cards and entitlement cards

23 Purpose of this Division

For the purposes of subsections 84H(1) and (3) of the Act, this Division sets out matters relating to the issue of additional and replacement concession cards and entitlements cards.

24 Application for, and issue of, additional concession cards and entitlement cards

(1) A person whose concession card, or entitlement card, has been lost, stolen, damaged or destroyed may apply to the Secretary for an additional card.

(2) A person who is a holder of a concession card, or an entitlement card, other than a person referred to in subsection (1), may apply for an additional card to:
  (a) the Secretary; or
  (b) if the original card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority.

(3) An application under subsection (1) or (2) for an additional card must:
  (a) be in accordance with the form approved, in writing, by the Secretary; and
  (b) set out:
    (i) the given name and surname of the applicant; and
    (ii) the residential address of the applicant; and
    (iii) the given name and surname of each person (other than the applicant) who is a member of the family of the original holder of the card and the relationship of that person to the original holder; and
    (iv) for an additional concession card—the number (if known to the applicant) of any other concession card held by a member of the family of the original holder of the concession card; and
    (v) for an additional entitlement card—the number (if known to the applicant) of any other entitlement card held by a member of the family of the original holder of the entitlement card; and
    (vi) for an application that is made under subsection (1)—the number (if known to the applicant) of the concession card, or entitlement card, that the applicant holds; and
    (vii) the medicare number of the applicant; and
  (c) be signed and dated by the applicant; and
  (d) be accompanied by the original card unless the application is made under subsection (1).

(4) Where, on an application to a person for the issue of an additional card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

(b) any other relevant matters;

that an additional card should be issued to the applicant, the person must issue an additional card to the applicant.

25 Application for, and issue of, replacement concession cards and entitlement cards

(1) An original card holder (within the meaning of subsection 84H(3) of the Act) may apply for the issue of a replacement card.

(2) An application under subsection (1) must:

(a) be made, in accordance with the form approved in writing by the Secretary, to:

(i) the Secretary; or

(ii) where the original card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority; and

(b) set out:

(i) the given name and surname of the applicant; and

(ii) the residential address of the applicant; and

(iii) the given name and surname of any new family member (within the meaning of subsection 84H(3) of the Act) and his or her relationship to the applicant; and

(iv) the medicare number of the applicant; and

(c) be signed and dated by the applicant; and

(d) be accompanied by the original card unless the application is made to the Secretary.

(3) Where, on an application to a person for the issue of a replacement card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

(b) any other relevant matters;

that:

(c) the applicant is the original card holder (within the meaning of subsection 84H(3) of the Act); and

(d) each person identified in the application in accordance with subparagraph (2)(b)(iii) became, after the issue of that card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder's family;

the person must issue a replacement card to the applicant.

26 Refusal to issue additional or replacement cards by person other than the Secretary

Where an approved pharmacist, an approved medical practitioner, a public hospital authority or an approved hospital authority makes:

(a) a decision under section 24 refusing to issue an additional card; or

(b) a decision under section 25 refusing to issue a replacement card;

the applicant may apply to the Secretary under subsection 24(2) or 25(1) for the issue of the additional card or replacement card, as the case requires.

27 Refusal to issue additional or replacement cards by the Secretary

(1) Where the Secretary makes:

(a) a decision under section 24 refusing to issue an additional card; or

(b) a decision under section 25 refusing to issue a replacement card;

the Secretary must, by notice in writing, inform the applicant of the making of, and reasons for, the decision.

(2) A notice under subsection (1) must include a statement to the effect that:

(a) applications may be made, subject to the *Administrative Review Tribunal Act 2024*, by or on behalf of a person whose interests are affected by the decision, to the Administrative Review Tribunal for review of the decision; and

(b) a person whose interests are affected by the decision may, except where subsection 269(7) of that Act applies, request a statement of reasons for the decision under section 268 of that Act.

(3) A failure to comply with subsection (2) in relation to a decision does not affect the validity of the decision.

28 Review of decisions

Applications may be made to the Administrative Review Tribunal for review of the following decisions of the Secretary:

(a) a decision under section 24 to refuse to issue an additional card;

(b) a decision under section 25 to refuse to issue a replacement card.

Part 4—Supply of pharmaceutical benefits

Division 1—General matters relating to supply

29 Meaning of *practitioner*

In this Division:

practitioner means any of the following:

(a) an authorised optometrist;
(b) a medical practitioner;
(c) an authorised midwife;
(d) an authorised nurse practitioner.

30 Variation of application of determination of maximum number of repeats or maximum number of quantity of units

(1) For the purposes of subsection 85A(3) of the Act, this section makes provision for authorising the variation of the application, in relation to persons included in a class of persons, of a determination under paragraph 85A(2)(a) or (b) of the Act.

(2) If:

(a) a practitioner included in a class of persons to which the determination applies proposes to write a prescription of one of the following kinds that is not in accordance with the determination:

(i) a prescription other than a medication chart prescription;

(ii) a medication chart prescription for a person who is receiving treatment in or at an approved hospital; and

(b) the practitioner provides the details of the proposed prescription to the Minister;

the Minister may authorise the variation of the application of the determination in relation to that practitioner and that prescription.

(3) If the Minister decides to authorise the variation, the Minister must allot a number to the prescription and tell the practitioner that number.

Note: For requirements to write the allotted number on the prescription, see sections 40 and 41.

Division 2—Supply by particular PBS prescribers

31 Meaning of *practitioner*

In this Division:

practitioner means any of the following:

(a) a medical practitioner;

(b) an authorised midwife;

(c) an authorised nurse practitioner.

32 Prescriber bag supplies—practitioners on ships

For the purposes of sections 93, 93AA and 93AB of the Act, a practitioner who is practising his or her profession on a ship is not authorised to supply pharmaceutical benefits.

33 Prescriber bag supplies—practitioners other than approved medical practitioners

Application

(1A) This section applies to a practitioner who is not an approved medical practitioner.

How benefits to be obtained—lodging order with approved pharmacist

(1) For the purposes of sections 93, 93AA and 93AB of the Act and subject to this section, a practitioner may obtain a pharmaceutical benefit only if he or she lodges with an approved pharmacist:

(a) an order, in duplicate, signed by the practitioner, in accordance with a form approved, in writing, by the Secretary; or

(b) an order, in accordance with subsection (2), that is:

(i) signed by the practitioner; and

(ii) in accordance with an electronic form approved, in writing, by the Secretary.

(2) For the purposes of paragraph (1)(b), an order is lodged with an approved pharmacist if:

(a) it is lodged in accordance with any approved information technology requirements and by an eligible electronic communication; and

(b) the practitioner, or an agent of the practitioner, who will receive the pharmaceutical benefit asks the approved pharmacist to supply the pharmaceutical benefit under the order; and

(c) the approved pharmacist consents, within the meaning of subsection 5(1) of the *Electronic Transactions Act 1999*, to the order being lodged in accordance with any approved information technology requirements and by an eligible electronic communication; and

(d) the order is accessible by the approved pharmacist.

Restriction—one order per month

(3) A practitioner may obtain a pharmaceutical benefit under subsection (1) only once in a calendar month.

Restriction—stockpiling

(3A) A practitioner may obtain a pharmaceutical benefit that has a drug mentioned in an item of Schedule 1 to the *National Health (Prescriber Bag Supplies) Determination 2024* in the form mentioned in that item at a particular time only if, at that time:

(a) the quantity (if any) of pharmaceutical benefits that have that drug in that form that the practitioner has in the practitioner's possession and that the practitioner has previously obtained under this section is less than the maximum quantity set out in that item; and

(b) if the group number mentioned in that item is the same as the group number mentioned in another item—the quantity (if any) of pharmaceutical benefits that have the drug mentioned in the other item in the form mentioned in the other item that the practitioner has in the practitioner's possession and that the practitioner has previously obtained under this section is less than the maximum quantity set out in the other item.

Receipt for order

(4) A practitioner, or an agent of a practitioner, who receives a pharmaceutical benefit under subsection (1), must:

(a) prepare a receipt for the benefit supplied, using the part of the order form identified for that purpose, that includes the following information:

(i) the date of supply of the benefit;

(ii) if the benefit is received by an agent of the practitioner—the agent's address; and

(b) if the order is lodged in accordance with paragraph (1)(a)—give the receipt to the approved pharmacist supplying the benefit; and

(c) if the order is lodged in accordance with paragraph (1)(b):

(i) submit the receipt, in accordance with any approved information technology requirements and by an eligible electronic communication; and

(ii) ensure the receipt is accessible by the approved pharmacist supplying the benefit.

34 Prescriber bag supplies—supply of pharmaceutical benefits by approved pharmacists

(1) This section is made for the purposes of section 140 of the Act.

(2) An approved pharmacist commits an offence if:

(a) the pharmacist supplies a pharmaceutical benefit on an order lodged under section 33; and
(b) neither of the circumstances referred to in subsection (3) apply.

Penalty: 0.4 penalty units.

(3) For the purposes of paragraph (2)(b), the circumstances are as follows:
(a) the pharmacist knows the practitioner whose signature appears on the order;
(b) if the pharmacist does not know the practitioner, the pharmacist:
(i) is given the given name, surname and address of the practitioner by the person who lodged the order; and
(ii) if the practitioner is a medical practitioner—is given the medical registration number of the practitioner by the person who lodged the order; and
(iii) for any other practitioner—is given the number allotted to the approval for the practitioner by the Secretary under subsection 16(1) by the person who lodged the order; and
(iv) writes on the order form the details referred to in subparagraphs (i), (ii) and (iii).

(4) An offence against subsection (2) is an offence of strict liability.

35 Prescriber bag supplies—payment for pharmaceutical benefits

(1) This section is made for the purposes of subsections 93(3), 93AA(4) and 93AB(4) of the Act.

(2) An approved pharmacist who supplies a pharmaceutical benefit to a practitioner on an order under section 33 is entitled to be paid, by the Commonwealth for the supply, the sum of:
(a) the Commonwealth price of the pharmaceutical benefit; and
(b) the special patient contribution for a brand of the pharmaceutical item that is the pharmaceutical benefit (if any).

(3) Payment by the Commonwealth under subsection (2) is subject to the conditions set out in a determination under paragraph 98C(1)(b) of the Act that is in force at the time the benefit is supplied, as if the benefit had been supplied other than under section 93, 93AA, or 93AB of the Act.

36 Pharmaceutical benefits obtained by approved medical practitioners for the purposes of section 93 of the Act

(1) This section is made for the purposes of section 140 of the Act.

Offence—obtaining pharmaceutical benefit for purposes of section 93 of the Act by lodging order under section 33 of this instrument

(2) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purposes of section 93 of the Act by lodging with an approved pharmacist an order under section 33 of this instrument.

Penalty: 0.2 penalty units.

Offence—obtaining pharmaceutical benefit for purposes of section 93 of the Act more than once each month

(3) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purposes of section 93 of the Act more than once in each month.

Penalty: 0.2 penalty units.

Offence—not giving notice of obtaining pharmaceutical benefit for purposes of section 93 of the Act (manual claim)

(4) An approved medical practitioner commits an offence if he or she:
(a) obtains a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act; and
(b) makes a claim for a payment under section 99AAA of the Act, in relation to obtaining the benefit for such a supply, using the manual system referred to in that section; and
(c) does not, when making the claim, give notice to the Secretary that he or she has obtained the benefit.

Penalty: 0.2 penalty units.

(5) For the purposes of paragraph (4)(c), the notice must be:
(a) in a form approved, in writing, by the Secretary; and
(b) signed and dated by the practitioner.

(6) An approved medical practitioner commits an offence if he or she:
(a) gives a notice to the Secretary under subsection (4); and
(b) does not retain a copy of the notice for at least 2 years from the date on which he or she gives the notice to the Secretary.

Penalty: 0.2 penalty units.

Offence—not creating record of obtaining pharmaceutical benefit for purposes of section 93 of the Act (CTS claim)

(7) An approved medical practitioner commits an offence if he or she:
(a) obtains a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act; and
(b) makes a CTS claim in relation to obtaining the benefit for such a supply; and

(c) does not create a written record of having obtained the benefit as soon as practicable after obtaining it.

Penalty: 0.2 penalty units.

(8) For the purposes of paragraph (7)(c), the record must be:
(a) in a form approved, in writing, by the Secretary; and
(b) signed and dated by the practitioner.

(9) An approved medical practitioner commits an offence if he or she:
(a) creates a record under subsection (7); and
(b) does not retain the record for at least 2 years from the date on which it was created.

Penalty: 0.2 penalty units.

Strict liability applies to offences

(10) An offence against subsection (2), (3), (4), (6), (7) or (9) is an offence of strict liability.

37 Payment for pharmaceutical benefits obtained by approved medical practitioners for the purposes of section 93 of the Act

(1) This section is made for the purposes of subsection 93(3) of the Act.

(2) An approved medical practitioner is entitled to payment from the Commonwealth for obtaining a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act if:
(a) the pharmaceutical benefit is obtained in accordance with this instrument; and
(b) the approved medical practitioner makes a claim for a payment under section 99AAA of the Act in relation to obtaining the benefit for such a supply; and
(c) if the claim is made using the manual system referred to in that section—the approved medical practitioner gives a notice to the Secretary in accordance with subsection 36(4) of this instrument.

(3) The approved medical practitioner is entitled to payment under subsection (2) at the rate applicable under section 35 for the supply of the same benefit on an order under section 33.

Part 5—Prescriptions and supply

38 Purpose of this Part

(1) Unless otherwise specified, this Part is made for the purposes of sections 105 and 140 of the Act.

(2) This Part:

(a) prescribes terms and conditions relating to the supply of pharmaceutical benefits; and

(b) provides rules about writing prescriptions.

39 Writing prescriptions—general

A prescription for the supply of a pharmaceutical benefit must be written in accordance with:

(a) either:

(i) section 40 (prescriptions other than medication chart prescriptions); or

(ii) section 41 (medication chart prescriptions); and

(b) if the prescription is an electronic prescription—section 41A (additional requirements for all electronic prescriptions).

Note: Other provisions of this instrument may also contain requirements for the writing of prescriptions.

40 Writing prescriptions—prescriptions other than medication chart prescriptions

Requirements for writing prescriptions

(1) A PBS prescriber writes a prescription in accordance with this section if the PBS prescriber:

(a) if the PBS prescriber is a participating dental practitioner, an authorised optometrist, an authorised midwife or an authorised nurse practitioner—states in the prescription the number allotted to his or her approval under section 16; and

(b) states in the prescription the name of the person for whom the pharmaceutical benefit is prescribed and the residential address of that person; and

(c) prepares the prescription in accordance with subsection (2); and

(d) identifies in the prescription the pharmaceutical benefit in accordance with subsection (2A); and

(e) states in the prescription:

(i) the quantity or number of units of the pharmaceutical benefit to be supplied; and

(ii) if the supply of the benefit is to be repeated—the number of times it is to be repeated; and

(f) if the pharmaceutical benefit to be supplied is not a ready-prepared pharmaceutical benefit—indicates in the prescription the manner in which the pharmaceutical benefit is to be administered; and

(g) signs the prescription after it is prepared; and

(h) specifies on the prescription the date on which the prescription is written; and

(i) if the prescription is covered by paragraph (a) or (b) of the definition of ***authority prescription***—writes on it:

(i) each authority approval number for the prescription; or

(ii) the relevant streamlined authority code for the pharmaceutical benefit that is prescribed; and

(j) if, under section 49, the medical practitioner, authorised midwife or authorised nurse practitioner directs in the prescription the supply on the one occasion of a quantity or number of units of a pharmaceutical benefit exceeding the quantity or number of units that could otherwise be prescribed—writes on the prescription "Reg 24", "Regulation 24", "Reg 49", "Regulation 49", "Section 49", "one supply" or "1 supply".

Note 1: For paragraph (i), an authority prescription covered by paragraph (c) of the definition does not require an authority approval number to be a valid prescription, but an authority approval number may be needed for the special patient contribution to be payable by the Commonwealth under section 85B of the Act.

Note 2: For paragraph (j), section 49 of this instrument was previously regulation 24 of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

(2) For the purposes of paragraph (1)(c), the prescription must be prepared:

(a) in duplicate, by handwriting the prescription in ink on a prescription form:

(i) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and

(ii) on which the name and address of the PBS prescriber, and the letters "PBS", appear; and

(iii) on one part of which the words "pharmacist/patient copy" appear; and

(iv) on one part of which the words "Medicare/DVA copy" appear; or

(b) in duplicate, by means of a computer on a prescription form:

(i) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and

(ii) on which the name and address of the PBS prescriber, and the letters "PBS", appear; and

(iii) on one part of which the words "pharmacist/patient copy" appear; and

(iv) on one part of which the words "Medicare/DVA copy" appear; and

(v) that is approved in writing for the purpose by the Secretary; or

(c) by means of a form:

(i) on which the name and address of the PBS prescriber and the letters "PBS" appear; and

(ii) that is approved, in writing, by the Secretary for the purpose of writing an electronic prescription; or

(d) by another method approved in writing by the Secretary.

(2A) For the purposes of paragraph (1)(d), the PBS prescriber must identify in the prescription:

(a) if:

(i) the prescription is prepared in accordance with paragraph (2)(a); or

(ii) the prescription is for the supply of a pharmaceutical benefit that has 4 or more drugs; or

(iii) the prescription is for the supply of a pharmaceutical benefit that is specified by the Secretary, in writing, for the purposes of this subparagraph;

the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit; or

(b) otherwise:

(i) each drug that the pharmaceutical benefit has; and

(ii) if the PBS prescriber considers that it is necessary for the medical treatment of the person for whom the pharmaceutical benefit is to be supplied to identify a brand of the pharmaceutical item that the pharmaceutical benefit has—the brand of the pharmaceutical item.

(2B) If subparagraph (2A)(b)(ii) applies, the brand of the pharmaceutical item must be listed after the drugs that the pharmaceutical benefit has.

(2C) Subsection (2A) does not apply to the extent that it would be contrary to a law of a State or Territory that would otherwise apply.

(3) A prescription written in accordance with this section must not provide for the supply of a pharmaceutical benefit (the ***prescribed benefit***) to:

(a) a person if the PBS prescriber has written, on the same day, another prescription for the supply of a pharmaceutical benefit to the person that is:

(i) the same pharmaceutical benefit as the prescribed benefit; or

(ii) another brand of the same pharmaceutical benefit as the prescribed benefit; or

(iii) a pharmaceutical benefit that is a Schedule equivalent to the prescribed benefit; or

(b) more than one person.

(4) For the purposes of paragraphs (2)(b), (c) and (d), a prescription must not be prepared using a computer program that:

(a) operates, or may operate, to indicate on a prescription by default, for the purposes of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied; or

(b) if paragraph (2A)(b) of this section applies to the prescription—operates, or may operate, to indicate on a prescription by default a brand of the pharmaceutical item that the pharmaceutical benefit has.

41 Writing prescriptions—medication chart prescriptions

Writing prescription by completing section of medication chart

(1) A PBS prescriber writes a prescription (a ***medication chart prescription***) for a pharmaceutical benefit in accordance with this section if:

(a) the person for whom the pharmaceutical benefit is prescribed is receiving treatment in or at:

(i) a residential care service at which the person is receiving residential care; or

(ii) an approved hospital; and

(b) the PBS prescriber completes a section of a medication chart for the person in relation to the pharmaceutical benefit in accordance with:

(i) subsection (2); and

(ii) if the prescription would be covered by paragraph (a) or (b) of the definition of ***authority prescription***—subsection (3); and

(c) if the prescription is an electronic prescription—the electronic prescription is written in an electronic medication chart using an electronic medication chart system.

Note: For subparagraph (b)(ii), an authority prescription covered by paragraph (c) of the definition does not require an authority approval number to be a valid prescription, but an authority approval number may be needed for the special patient contribution to be payable by the Commonwealth under section 85B of the Act.

Completing section of medication chart—general

(2) A PBS prescriber completes a section of a medication chart in accordance with this subsection for a person (the ***patient***) in relation to a pharmaceutical benefit if:

(a) the PBS prescriber writes in the section of the chart:

(i) particulars to identify the pharmaceutical benefit in accordance with subsection (2A); and

(ii) the date on which the pharmaceutical benefit is prescribed; and

(iii) the pharmaceutical benefit's dose, frequency of administration and route of administration; and

(iv) the letters "PBS" or "RPBS"; and

(b) the chart contains the following information:

(i) the PBS prescriber's given name, surname, address and PBS prescriber number;

(ii) the patient's full name;

(iii) the name of the residential care service or approved hospital in or at which the patient is receiving treatment;

(iv) if the patient is receiving treatment in or at a residential care service—the Residential Aged Care Service ID for the residential care service;

(v) if the patient is receiving treatment in or at an approved hospital—the patient's address; and

(c) the PBS prescriber writes his or her signature:

(i) in the section of the chart; and

(ii) except in the case of an electronic prescription—on the cover page of the chart; and

(d) the section of the chart does not provide for the supply of a pharmaceutical benefit to more than one person; and

(e) the section of the chart is not completed using a computer program that operates, or may operate, to indicate on a prescription by default, for the purpose of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied; and

(ea) if paragraph (2A)(b) of this section applies to the prescription—the section of the chart is not completed using a computer program that operates, or may operate, to indicate on a prescription by default a brand of the pharmaceutical item that the pharmaceutical benefit has; and

(f) if the patient is receiving treatment in or at an approved hospital—the chart specifies the day on which the chart's period of validity ends under subsection 45(4), which must be the day after the last day of one of the following periods starting on the day the first prescription for a pharmaceutical benefit is written in the chart:

(i) 1 month;

(ii) 4 months;

(iii) 12 months; and

(g) if the patient is receiving treatment in or at a residential care service and the chart is not an electronic medication chart—the pharmaceutical benefit is not referred to in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*); and

(h) in any case—the section of the chart is completed before the end of the chart's period of validity under subsection 45(3) or (4).

Note: A section in a medication chart may set out fields that only need to have information filled in if the information is relevant to the particular prescription concerned.

Example: For the purposes of paragraph (f), the first prescription is written in a medication chart on 11 June in a particular year. The day specified in the chart as the day on which the chart's period of validity ends must be 11 July or 11 October in that year, or 11 June in the following year.

(2A) For the purposes of subparagraph (2)(a)(i), the PBS prescriber must write in the section of the chart:

(a) if:

(i) the prescription is prepared by handwriting the prescription on the section of the chart; or

(ii) the prescription is for the supply of a pharmaceutical benefit that has 4 or more drugs; or

(iii) the patient is receiving treatment in or at a residential care service and the medication chart is not an electronic medication chart; or

(iv) the prescription is for the supply of a pharmaceutical benefit that is specified by the Secretary, in writing, for the purposes of this subparagraph;

particulars sufficient to identify the pharmaceutical benefit; or

(b) otherwise:

(i) each drug that the pharmaceutical benefit has; and

(ii) if the PBS prescriber considers that it is necessary for the medical treatment of the patient to identify a brand of the pharmaceutical item that the pharmaceutical benefit has—the brand of the pharmaceutical item.

(2B) If subparagraph (2A)(b)(ii) applies, the brand of the pharmaceutical item must be listed after the drugs that the pharmaceutical benefit has.

(2C) Subsection (2A) does not apply to the extent that it would be contrary to a law of a State or Territory that would otherwise apply.

Completing section of medication chart—authority prescriptions

(3) A PBS prescriber completes a section of a medication chart in accordance with this subsection for a person for the purpose of writing an authority prescription if:

(a) the section of the chart contains:

(i) each authority approval number for the prescription; or

(ii) the relevant streamlined authority code for the pharmaceutical benefit that is prescribed; and

(b) if the person is receiving treatment in or at a residential care service and subparagraph (a)(ii) does not apply—the chart is an electronic medication chart.

Medication charts

(4) A ***medication chart*** is a chart:

(a) in a form (if any) approved under paragraph (5)(a); or

(b) that meets the information requirements (if any) approved under paragraph (5)(b);

that is used for prescribing, and recording the administration of, pharmaceutical benefits to persons receiving treatment in or at a residential care service or a hospital, whether or not the chart:

(c) is used for any other purpose; or

(d) contains any other information.

Note: For the purposes of paragraph (a), the chart may also be used (for example) to prescribe, and record the administration of, drugs, medicines and other substances that are not pharmaceutical benefits.

(5) For the purposes of subsection (4), the Secretary may, in writing:

(a) approve one or more forms for a medication chart; or

(b) approve information requirements that must be met in relation to a medication chart.

Electronic medication charts

(6) An ***electronic medication chart*** is a medication chart that:

(a) is in a form approved under subsection (5); or

(b) meets the information requirements approved under subsection (5);

for the purpose of writing an electronic prescription.

41A Writing prescriptions—additional requirements for all electronic prescriptions

A PBS prescriber writes an electronic prescription in accordance with this section if the PBS prescriber:

(a) includes in the metadata of the prescription:

(i) the conformance identifier provided to the Australian Digital Health Agency in relation to the software used to prepare the prescription; and

(ii) a unique identifier for the prescription generated by that software; and

(b) states in the prescription:

(i) the healthcare identifier (if any) assigned to the PBS prescriber; and

(ii) the healthcare identifier assigned to a healthcare provider organisation to which the PBS prescriber is linked (within the meaning of the *Healthcare Identifiers Act 2010*).

41B Writing prescriptions—additional information that may be included in electronic prescriptions

An electronic prescription may include either or both of the following:

(a) the date of birth of the person for whom the pharmaceutical benefit is prescribed;

(b) the reason why the pharmaceutical benefit is prescribed to that person.

42 Information about status of person

(1) This section does not apply in relation to a medication chart prescription.

Note: See section 47 for information about the status of a person for a medication chart prescription and for a supply of a pharmaceutical benefit under subsection 89A(1) of the Act.

(2) For the purposes of subsections 84AA(1), (1A), (2) and (3) of the Act, the following information is prescribed:

(a) in relation to a person who is a concessional beneficiary:

(i) information that the person is a concessional beneficiary; and

(ii) the number specified on a card held by the person (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person;

(b) in relation to a person who is a holder of a concession card:

(i) information that the person is the holder of a concession card; and

(ii) the number of the card;

(c) in relation to a person who is a holder of an entitlement card:

(i) information that the person is the holder of an entitlement card; and
(ii) the number of the card;

(d) in relation to a person who is a dependant of a concessional beneficiary:
(i) information that the person is a dependant of a concessional beneficiary; and
(ii) the number specified on a card held by that concessional beneficiary (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person.

(3) For the purposes of subsections 84AA(1) and (1A) of the Act, prescribed information must be written or marked on a prescription by:
(a) making provision on the prescription for the supply of that information, in accordance with a form approved, in writing, by the Secretary for the purposes of this subsection; and
(b) inserting:
(i) in the case of information that the person to whom the prescription relates is a concessional beneficiary or a dependant of a concessional beneficiary—a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person; and
(ii) in the case of information that the person to whom the prescription relates is a holder of a concession card or an entitlement card—a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person; and
(iii) in a case where the information is the entitlement number referred to in subparagraph (2)(a)(ii), (2)(b)(ii), (2)(c)(ii) or (2)(d)(ii) (as the case may be) in relation to the person to whom the prescription relates—the letters and digits forming that number, in the appropriate sequence, in the squares provided on the prescription for the supply of such information.

(4) For a prescription to which subsection 84AA(1) or (1A) of the Act applies, subsections (2) and (3) do not apply if:
(a) the claim for a payment from the Commonwealth in relation to the supply of the pharmaceutical benefit to which the prescription relates is a CTS claim; and
(b) the claim includes the card number that, under subsection (2) would, except for this subsection, be required.

(5) For the purposes of subsections 84AA(2) and (3) of the Act, prescribed information must be communicated to a pharmacist orally or in writing.

43 Restriction on using PBS forms

(1) A person commits an offence if:
(a) he or she writes a prescription on a form bearing the letters “PBS”; and
(b) the prescription is not written in accordance with, or for a purpose authorised by, this instrument; and

(c) the letters “PBS” are not clearly struck out, or obliterated.

Penalty: 0.4 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

44 Supply of pharmaceutical benefit on first presentation of prescription

(1) This section does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

Note: See section 45 for the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

(2) An approved pharmacist or an approved medical practitioner must not supply a pharmaceutical benefit to a person on the first presentation of a prescription for the supply of that benefit to the person, unless:

(a) subject to sections 48, 52 and 53, the prescription is:

(i) written in accordance with this instrument; and

(ii) given to the pharmacist or practitioner; and

(b) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written; and

(c) the pharmacist or practitioner writes on the prescription (including, for a paper-based prescription, both the pharmacist/patient copy and the Medicare/DVA copy):

(i) the pharmacist’s or practitioner’s name and approval number under section 16; and

(ii) a number that identifies the prescription.

(3) An approved hospital authority must not supply a pharmaceutical benefit to a person on the first presentation of a prescription for the supply of that benefit to that person, unless:

(a) subject to sections 48, 52 and 53, the prescription is:

(i) written in accordance with this instrument; and

(ii) given to the pharmacist or practitioner by whom, or under whose supervision, the benefit will be dispensed; and

(b) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written; and

(c) the prescription (including, for a paper-based prescription, both the pharmacist/patient copy and the Medicare/DVA copy) is marked, for the hospital authority, with:

(i) the hospital authority’s name and approval number under section 16; and

(ii) a number that identifies the prescription.

(4) In this section, a reference to the ***first presentation*** of a prescription is taken to mean, in relation to an electronic prescription, the first occasion when the prescription is accessed by an approved pharmacist or an approved medical

practitioner for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written.

45 Supply of pharmaceutical benefit on basis of medication chart prescription

Who may supply pharmaceutical benefit

(1) A pharmaceutical benefit may only be supplied on the basis of a medication chart prescription by:

(a) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at a residential care service—an approved pharmacist or an approved medical practitioner; or

(b) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at an approved hospital—an approved pharmacist or the approved hospital authority.

Requirements for supply of pharmaceutical benefit

(2) An approved supplier may supply a pharmaceutical benefit on the basis of a medication chart prescription only if:

(a) if the medication chart by which the prescription was written is not an electronic medication chart—the approved supplier has seen:

(i) the medication chart by which the prescription was written; or

(ii) a copy of so much of the chart as would indicate that subsection 41(2), and subsection 41(3) (if applicable), have been complied with; and

(aa) if the medication chart by which the prescription was written is an electronic medication chart—the approved supplier:

(i) if subparagraph (ii) does not apply and subject to subsection (8)—has seen the electronic medication chart by which the prescription was written in an electronic medication chart system; or

(ii) in a case of urgency—has seen a copy of the electronic medication chart that complies with subsection (2A) and supplies the pharmaceutical benefit in accordance with subsection (2B); and

(b) the date on which the pharmaceutical benefit is supplied is:

(i) during the period of validity of the medication chart; and

(ii) no later than the stop date (if any) indicated in the prescription; and

(c) if the medication chart by which the prescription was written is not an electronic medication chart—the approved supplier writes on the medication chart, or the copy of the chart, the following for the supply:

(i) the approved supplier's name and approval number under section 16;

(ii) an identification number for the supply;

(iii) the date on which the pharmaceutical benefit is supplied; and

(d) if the medication chart by which the prescription was written is an electronic medication chart—the approved supplier writes on the electronic prescription written in the electronic medication chart the following information for the supply:

(i) the approved supplier's name and approval number under section 16;
(ii) an identification number for the supply;
(iii) the date on which the pharmaceutical benefit is supplied.

(2A) For the purposes of subparagraph (2)(aa)(ii), a copy of an electronic medication chart complies with this subsection if the copy of the chart:
(a) meets so much of the information requirements approved for the electronic medication chart under paragraph 41(5)(b) as are specified, in writing, by the Secretary under subsection (9) of this section; and
(b) contains a date stamp showing the date and time when the copy was generated.

(2B) For the purposes of subparagraph (2)(aa)(ii), the approved supplier:
(a) must supply the pharmaceutical benefit within 72 hours of the date and time stamped on the copy of the electronic medication chart in accordance with paragraph (2A)(b); and
(b) despite subsections (5), (6) and (7), must not:
(i) supply the pharmaceutical benefit more than once; or
(ii) supply more than the maximum quantity of the pharmaceutical benefit.

(3) For the purposes of paragraph (2)(b), the period of validity of a medication chart for a person receiving treatment in or at a residential care service:
(a) if the chart is an electronic medication chart:
(i) starts on the day when the first prescription for a pharmaceutical benefit is written in the medication chart; and
(ii) ends 6 months after the day mentioned in subparagraph (i); or
(b) otherwise:
(i) starts on the day in a calendar month (the ***first calendar month***) when the first prescription for a pharmaceutical benefit is written in the medication chart; and
(ii) ends on the last day of the third calendar month that starts after the first calendar month.

Example: The first prescription is written in a medication chart on 11 June. The period of validity of the medication chart starts on 11 June and, if it is written in an electronic medication chart, ends on 11 December. Otherwise, it ends on 30 September.

(4) For the purposes of paragraph (2)(b), the period of validity of a medication chart for a person receiving treatment in or at a hospital:
(a) starts on the day when the first prescription for a pharmaceutical benefit is written in the chart; and
(b) ends at the end of the day specified in the chart as the day on which the chart's period of validity ends (see paragraph 41(2)(f)).

Quantity that may be supplied

(5) An approved supplier may supply up to a maximum quantity of a pharmaceutical item or pharmaceutical benefit more than once on the basis of a particular medication chart prescription for the pharmaceutical benefit only if:

(a) the prescription indicates either of the following:

(i) that an ongoing supply of the pharmaceutical benefit is authorised for the period of validity of the chart;

(ii) a stop date for the supply of the pharmaceutical benefit and, based on the dose and frequency of administration of the pharmaceutical benefit indicated in the prescription, more than one supply of a maximum quantity of the pharmaceutical item or pharmaceutical benefit is needed before the stop date is reached; and

(b) the prescription is not for the supply of a pharmaceutical benefit referred to in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*) to a person receiving treatment in or at a residential care service.

(6) If paragraphs (5)(a) and (b) do not apply, an approved supplier may only supply the quantity of the pharmaceutical benefit needed to give effect to the prescription, up to a maximum quantity of the pharmaceutical item or pharmaceutical benefit.

Note: The following information entered in the prescription may also indicate the quantity of the pharmaceutical benefit that is needed:

(a) the dose and frequency of administration of the pharmaceutical benefit;

(b) the date of prescribing, or the start date (if any) for administration of the pharmaceutical benefit;

(c) the stop date (if any) for administration of the pharmaceutical benefit.

(7) However, for a supply:

(a) on the basis of a prescription referred to in subparagraph (5)(a)(i); or

(b) referred to in subsection (6);

an approved supplier may supply up to a maximum quantity of the pharmaceutical item or pharmaceutical benefit even if the period of validity of the medication chart will end before administration of that quantity in accordance with the prescription would finish.

Matters in relation to electronic medication charts

(8) For the purposes of subparagraph (2)(aa)(i), the electronic medication chart seen by the approved supplier:

(a) must include the information mentioned in subparagraph 41(2)(a)(iii) (about dose, frequency of administration and route of administration) that is written in the chart in respect of the person for whom the pharmaceutical benefit is prescribed; but

(b) does not need to include other information in the electronic medication chart about the administration of the pharmaceutical benefit to the person.

Information requirements for copies of electronic medication charts

(9) The Secretary may, in writing, specify information requirements for the purposes of paragraph (2A)(a).

46 Continued dispensing supply of pharmaceutical benefit

(1) This section applies in relation to the supply of a pharmaceutical benefit to a person by an approved pharmacist under subsection 89A(1) of the Act.

(2) The approved pharmacist must not supply the pharmaceutical benefit unless the approved pharmacist writes on a repeat authorisation form for the supply:
   (a) the approved pharmacist's name and approval number under section 16; and
   (b) an identification number for the supply; and
   (c) the date on which the pharmaceutical benefit is supplied by the approved pharmacist.

47 Information about status of person—continued dispensing supplies and medication chart prescriptions

(1) This section applies in relation to:
   (a) the supply of a pharmaceutical benefit to a person (the ***patient***) by an approved pharmacist (the ***supplier***) under subsection 89A(1) of the Act; and
   (b) the supply of a pharmaceutical benefit by an approved supplier (the ***supplier***) on the basis of a medication chart prescription written for a person (the ***patient***).

(2) The supplier must collect the following information at the time of supply:
   (a) information about whether the patient is, at the time of the supply:
      (i) a concessional beneficiary or a dependant of a concessional beneficiary; or
      (ii) the holder of a concession card or entitlement card;
   (b) for a person referred to in subparagraph (a)(i)—the number specified on a card, issued by the Commonwealth, as an entitlement number (however described) in relation to the person;
   (c) for a person referred to in subparagraph (a)(ii)—the number of the concession card or entitlement card.

(3) The supplier must include the information collected under subsection (2) in the claim for a payment from the Commonwealth in relation to the supply using the Claims Transmission System, within the meaning given by subsection 99AAA(1) of the Act.

48 Supply of pharmaceutical benefits before surrender of written prescription

Supply in cases of urgency

(1) Subject to this section, a pharmaceutical benefit may be supplied to a person, in a case of urgency, by an approved pharmacist or an approved medical practitioner (the ***supplier***) before the prescription for that pharmaceutical benefit is given to the supplier if:

(a) a PBS prescriber advises the supplier of the details of the prescription; or

(b) a PBS prescriber has given the supplier a copy of the prescription.

Authority prescriptions

(2) If the prescription is or would be an authority prescription, the supplier may supply the pharmaceutical benefit under subsection (1) only if:

(a) if the pharmaceutical benefit prescribed has a relevant streamlined authority code—the PBS prescriber informs the supplier of that code before the pharmaceutical benefit is supplied; or

(b) otherwise:

(i) the Minister or the Chief Executive Medicare has notified the PBS prescriber (orally or by other means) that each relevant authorisation will be given; and

(ii) the PBS prescriber informs the supplier of that notification before the pharmaceutical benefit is supplied.

Requirement for prescription to be received or accessible after supply

(3) A PBS prescriber referred to in subsection (1) must ensure that, for a paper-based prescription, the pharmacist/patient copy and the Medicare/DVA copy of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

(4) A PBS prescriber referred to in subsection (1) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

(5) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subsection (2) must ensure that, for a paper-based prescription, the pharmacist/patient copy and the Medicare/DVA copy of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

(6) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subsection (2) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

(7) A PBS prescriber commits an offence if he or she contravenes subsection (3), (4), (5) or (6).

Penalty: 0.2 penalty units.

(8) An offence against subsection (7) is an offence of strict liability.

Section does not apply to certain pharmaceutical benefits

(9) This section does not apply to:

(a) a pharmaceutical benefit if:

(i) the pharmaceutical benefit would be supplied under this section by an approved pharmacist; and

(ii) the relevant prescription must be in writing under a law in force in the State or Territory in which the premises, at or from which the pharmaceutical benefit would be supplied, are located; or

(b) a pharmaceutical benefit if:

(i) the pharmaceutical benefit would be supplied under this section by an approved medical practitioner; and

(ii) the relevant prescription must be in writing under a law in force in the area in respect of which the medical practitioner is approved; or

(c) in any case—a pharmaceutical benefit to be supplied on the basis of a medication chart prescription.

49 Circumstances in which quantity of repeated supply can be directed to be supplied on one occasion

(1) This section does not apply in relation to the writing of a medication chart prescription.

(2) For the purposes of subsection 88(6) of the Act, a medical practitioner may, instead of directing a repeated supply of a pharmaceutical benefit in accordance with Part VII of the Act, direct in a prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under that subsection if he or she is satisfied that:

(a) the maximum quantity of the pharmaceutical benefit is insufficient for the medical treatment of the person for whom the prescription is written; and

(b) that person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to that person's place of residence; and

(c) that person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.

(3) For the purposes of subsection 88(6B) of the Act, an authorised midwife or authorised nurse practitioner may, instead of directing a repeated supply of a pharmaceutical benefit, direct in a prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under subsection 88(6A) of the Act if he or she is satisfied that:

(a) the maximum quantity of the pharmaceutical benefit is insufficient for the treatment of the person for whom the prescription is written; and

(b) the person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to the person's place of residence; and

(c) the person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.

Note 1: Subsection (3) does not apply in relation to a pharmaceutical benefit if the authorised midwife or authorised nurse practitioner is not authorised to write a prescription for the supply of the pharmaceutical benefit under subsection 88(1D) or (1E) of the Act.

Note 2: This section was previously regulation 24 of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

50 Continued dispensing supplies—repeated supply not to be supplied on one occasion

(1) This section applies in relation to the supply (the ***continued dispensing supply***) of a pharmaceutical benefit by an approved pharmacist under subsection 89A(1) of the Act on the basis of a previous prescription from a PBS prescriber.

(2) If, instead of directing a repeated supply, the PBS prescriber directed in the prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under subsection 88(6) of the Act, the direction does not apply for the purposes of the continued dispensing supply.

51 Repeated supplies of pharmaceutical benefits

(1) A pharmaceutical benefit must not be supplied a number of times greater than the number specified in the prescription.

(2) Subsection (3) applies to a pharmaceutical benefit in relation to which:

(a) the Minister determines, under paragraph 85A(2)(b) of the Act, that the maximum number of occasions on which the supply of the benefit may, in one prescription, be directed to be repeated is more than 4; and

(b) the Minister determines, under paragraph 85A(2)(c) of the Act, that the manner of administration that may, in a prescription, be directed to be used in relation to the benefit is administration otherwise than by application to the eye.

(3) A pharmaceutical benefit to which this subsection applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:

(a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit or another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit:

(i) in the period specified under subsection 84AAA(2) of the Act for the pharmaceutical benefit immediately preceding the day on which it is to be supplied to the person; or

(ii) if no period is so specified—in the period of 20 days immediately preceding the day on which it is to be supplied to the person; or

(b) the supplier of the benefit:

(i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and

(ii) writes the words "immediate supply necessary" on the Medicare /DVA copy (for a paper-based prescription) or on the prescription (for an electronic prescription); and

(iii) signs the Medicare/DVA copy or the electronic prescription, as the case requires; or

(c) the supplier of the benefit:

(i) reasonably believes that, having regard to the person's circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and

(ii) writes the words "immediate supply necessary" on the Medicare /DVA copy (for a paper-based prescription) or on the prescription (for an electronic prescription); and

(iii) signs the Medicare/DVA copy or the electronic prescription, as the case requires.

(4) A pharmaceutical benefit other than a benefit to which subsection (3) applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:

(a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit or another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit:

(i) in the period specified under subsection 84AAA(2) of the Act for the pharmaceutical benefit immediately preceding the day on which it is to be supplied to the person; or

(ii) if no period is so specified—in the period of 4 days immediately preceding the day on which it is to be supplied to the person; or

(b) the supplier of the benefit:

(i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and

(ii) writes the words "immediate supply necessary" on the Medicare /DVA copy (for a paper-based prescription) or on the prescription (for an electronic prescription); and

(iii) signs the Medicare/DVA copy or the electronic prescription, as the case requires; or

(c) the supplier of the benefit:

(i) reasonably believes that, having regard to the person's circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and

(ii) writes the words "immediate supply necessary" on the Medicare /DVA copy (for a paper-based prescription) or on the prescription (for an electronic prescription); and

(iii) signs the Medicare/DVA copy or the electronic prescription, as the case requires.

Continued dispensing supplies

(5) Subject to subsection (2), if the pharmaceutical benefit is supplied to a person by an approved pharmacist (the ***supplier***) under subsection 89A(1) of the Act, subsection (3) or (4) applies as if:

(a) the person had presented the supplier with a prescription that:

(i) had been written by a PBS prescriber in accordance with the Act and this instrument; and

(ii) did not include a medicare number; and

(iii) did not direct a repeated supply of the pharmaceutical benefit; and

(b) subparagraphs (3)(b)(ii) and (c)(ii) or (4)(b)(ii) and (c)(ii) were omitted, and the words "immediate supply necessary" were required to be written on the repeat authorisation form for the supply; and

(c) subparagraphs (3)(b)(iii) and (c)(iii) or (4)(b)(iii) and (c)(iii) were omitted, and the supplier were required to sign the repeat authorisation form referred to in paragraph (b).

Medication chart prescriptions

(6) Subject to subsection (2), if the pharmaceutical benefit is supplied by an approved supplier on the basis of a medication chart prescription:

(a) subsection (1) does not apply; and

(b) subsection (3) or (4) applies as if the words "immediate supply necessary" and the supplier's signature were required to be written by the approved supplier on the part of the medication chart, or the part of the copy of that chart, that contains the completed section by which the prescription was written.

52 Repeat authorisations

(1) This section does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

Circumstances of supply

(2) Subsection (3) applies if:

(a) an approved pharmacist, an approved medical practitioner or an approved hospital authority supplies a pharmaceutical benefit under:

(i) a Medicare/DVA copy of a paper-based prescription that contains a direction to supply the benefit more than once; or

(ii) a pharmacist/patient copy of a paper-based prescription to which is attached a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(iii) a pharmacist/patient copy of a paper-based prescription to which is attached a repeat authorisation that contains a direction to supply the benefit more than once; or

(iv) an electronic prescription that contains a direction to supply the benefit more than once; or

(v) an electronic prescription to which is attached or linked, by electronic means, a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(vi) an electronic prescription to which is attached or linked, by electronic means, a repeat authorisation that contains a direction to supply the benefit more than once; and

(b) subsequent supplies of the pharmaceutical benefit can be made under the prescription at the time of supply under paragraph (a).

Requirement to prepare repeat authorisation

(3) The approved pharmacist, approved medical practitioner or approved hospital authority must:

(a) on or before supplying the pharmaceutical benefit:

(i) prepare a repeat authorisation in accordance with a form (including a paper-based or an electronic form) approved, in writing, by the Secretary for the supply of the pharmaceutical benefit; and

(ii) if the prescription for the pharmaceutical benefit is written on an authority prescription—mark the number of the authority prescription on the repeat authorisation; and

(iii) if the prescription for the pharmaceutical benefit is a paper-based prescription—attach the repeat authorisation to the pharmacist/patient copy and give the repeat authorisation and pharmacist/patient copy to the person to whom the pharmaceutical benefit is supplied; and

(iv) if the prescription for the pharmaceutical benefit is an electronic prescription—attach or link, by electronic means, the repeat authorisation to the electronic prescription and ensure that the person to whom the pharmaceutical benefit is supplied is given a print-out of the repeat authorisation and prescription or is able to access the repeat authorisation and prescription; and

(b) for the supply of the pharmaceutical benefit on the first occasion—mark on the repeat authorisation:

(i) the name and address of the approved supplier; and

(ii) the approval number given to the approved supplier under section 16; and

(iii) the identifying number given to the prescription by the approved supplier; and

(iv) if the pharmaceutical benefit is a substitute benefit for the purposes of subsection 103(2A) of the Act—the brand name of the substitute benefit; and

(c) for the supply of the pharmaceutical benefit on a subsequent occasion—mark on the repeat authorisation:

(i) the date on which the most recent supply was made; and

(ii) the identifying number given to the prescription under subparagraph (b)(iii).

(4) An approved pharmacist, approved medical practitioner or approved hospital authority commits an offence if the pharmacist, medical practitioner or hospital authority (as the case may be) contravenes subsection (3).

Penalty: 0.2 penalty units.

(5) An offence against subsection (4) is an offence of strict liability.

Supply with pharmacist/patient copy of paper-based prescription only

(6) An approved pharmacist, approved medical practitioner or approved hospital authority is not authorised to supply a pharmaceutical benefit upon presentation of only the pharmacist/patient copy of a paper-based prescription unless:

(a) the approved pharmacist, approved medical practitioner or approved hospital authority is given a repeat authorisation or a deferred supply authorisation that:

(i) is related to that pharmacist/patient copy by a number or numbers; and

(ii) indicates that the pharmaceutical benefit to be supplied has not been supplied for the number of times directed in the prescription; and

(b) there is written on the repeat authorisation or deferred supply authorisation the approval number given to the supplier under section 16; and

(c) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written.

Supply by approved hospital authority

(7) If a pharmaceutical benefit is supplied by an approved hospital authority in the circumstances set out in subsection (2), the approved hospital authority must cause the requirements in subsection (3) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the pharmaceutical benefit is supplied.

53 Deferred supply authorisations

(1) This section does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

(2) Where a prescription contains a direction to supply more than one pharmaceutical benefit, the approved pharmacist, approved medical practitioner or approved hospital authority to whom the prescription is presented may, at the

request of the person for whom the prescription is written, defer the supply of one or more of the pharmaceutical benefits.

(3) An approved pharmacist, approved medical practitioner or approved hospital authority that defers the supply of a pharmaceutical benefit must:

(a) prepare a deferred supply authorisation, on and in accordance with a form (including a paper-based or an electronic form) approved, in writing, by the Secretary, in respect of each pharmaceutical benefit for which the deferral of supply is requested; and

(b) mark on the deferred supply authorisation the approval number given to the pharmacist, medical practitioner or hospital authority under section 16; and

(c) if the prescription is a paper-based prescription:

(i) mark on the pharmacist/patient copy and the Medicare/DVA copy of the prescription, across the wording relating to the pharmaceutical benefit the supply of which is being deferred, the words "original supply deferred"; and

(ii) attach the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the pharmacist/patient copy; and

(iii) give the authorisation and pharmacist/patient copy to the person for whom the prescription is written at the same time as the benefit on the original prescription is supplied; and

(d) if the prescription is an electronic prescription:

(i) mark on the prescription, in relation to the pharmaceutical benefit the supply of which is being deferred, the words "original supply deferred"; and

(ii) attach or link, by electronic means, the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the prescription; and

(iii) give a print-out of the deferred supply authorisation and prescription to the person to whom the pharmaceutical benefit is supplied or ensure that the deferred supply authorisation and prescription are accessible by that person.

(4) If an approved hospital authority defers the supply of a pharmaceutical benefit in the circumstance set out in subsection (2), the authority must cause the requirements in subsection (3) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the other pharmaceutical benefit to which the prescription refers is supplied.

54 Presentation of prescriptions in trading hours

(1) An approved pharmacist must, at all times, keep prominently displayed at each of the premises in respect of which he or she is approved, so as to be readily visible to persons who enter the premises, a notice setting out the normal trading hours during which services for the supply of pharmaceutical benefits are available.

(2) Subject to section 55, a person is entitled to be supplied with a pharmaceutical benefit from an approved pharmacist during normal trading hours only.

55 Presentation of urgent prescriptions

(1) If:

(a) a prescription for the supply of a pharmaceutical benefit is marked "Urgent"; and

(b) in the case of a paper-based prescription—that marking is initialled by the PBS prescriber writing the prescription;

the prescription may be presented at any time to an approved pharmacist at the premises in respect of which he or she is approved.

(2) An approved pharmacist must supply a pharmaceutical benefit as soon as practicable if:

(a) a prescription is presented to the pharmacist under subsection (1); and

(b) any charge lawfully demanded for the prescription is paid.

(3) An approved pharmacist commits an offence if he or she contravenes subsection (2).

Penalty: 0.2 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

(5) It is a defence to a prosecution for an offence against subsection (3) if the pharmacist had a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter referred to in subsection (5) (see section 13.3 of the *Criminal Code*).

56 Special charge for delivery

For the purposes of subsection 87(4) of the Act, when a pharmaceutical benefit is supplied by delivery at or to a place other than premises in respect of which an approved pharmacist is approved or the premises at which an approved medical practitioner carries on his or her practice, as the case may be, the pharmacist or medical practitioner may make a special charge equal to the cost of delivery.

Part 6—Other matters relating to prescriptions and supply etc.

58 Purpose of this Part

Unless otherwise specified, this Part is made for the purposes of sections 105 and 140 of the Act.

59 Keeping documents—other than for continued dispensing supplies or medication chart prescriptions

(1) An approved supplier commits an offence if:

(a) the approved supplier supplies a pharmaceutical benefit, other than a pharmaceutical benefit that is:

(i) a dangerous drug; or

(ii) supplied under subsection 89A(1) of the Act; or

(iii) supplied on the basis of a medication chart prescription; and

(b) the approved supplier does not keep a document required by subsection (3), (4) or (5) that relates to the supply for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

Penalty: 0.2 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

Note 1: For a pharmaceutical benefit supplied as referred to in subparagraph (1)(a)(ii) or (iii), see sections 60 and 61.

Note 2: The document may be kept in an electronic form (see subsection 12(2) of the *Electronic Transactions Act 1999*).

Electronic prescriptions

(3) For the purposes of subsection (1), if the supply was on the basis of an electronic prescription, the approved supplier must keep:

(a) the electronic prescription, or a copy of the electronic prescription; and

(b) any repeat authorisation or deferred supply authorisation on the basis of which the supply was made.

Paper-based prescriptions

(4) For the purposes of subsection (1), the approved supplier must keep a document referred to in an item in the following table if:

(a) the supply was on the basis of a paper-based prescription; and

(b) the supply is of a kind referred to in that item.

Note: If a supply is covered by more than one item in the table, then documents must be kept under each of those items.

Documents to be kept for paper-based prescriptions		
Item	**Kind of supply**	**Document**
1	Both of the following apply in relation to the supply: (a) the supply was the first or only supply of a pharmaceutical benefit authorised by the prescription; (b) a CTS claim is made for the supply.	The Medicare/DVA copy.
2	Both of the following apply in relation to the supply: (a) the supply was on the basis of a repeat authorisation or a deferred supply authorisation; (b) a CTS claim is made for the supply.	The repeat authorisation or deferred supply authorisation.
3	After the supply, there are no remaining supplies of pharmaceutical benefits that are authorised by the prescription.	The pharmacist/patient copy.

Orders lodged under section 33

(5) For the purposes of subsection (1), if the supply is on the basis of an order lodged under section 33, the approved supplier must keep:
  (a) if a CTS claim is made for the supply—the order; and
  (b) if a claim is made for the supply using the manual system referred to in section 99AAA of the Act—the duplicate of the order.

Definition

(6) In this section:

dangerous drug means a drug or medicinal preparation in respect of which the law of the State or Territory in which the prescription is written provides that a pharmacist who dispenses that drug or medicinal preparation, or who dispenses it on the last of a number of occasions of supply indicated in a prescription for its supply, must take possession of the prescription and cancel it or deliver it to the authority administering that law.

60 Keeping documents—continued dispensing supplies

(1) An approved pharmacist commits an offence if:
  (a) the approved pharmacist supplies a pharmaceutical benefit to a person under subsection 89A(1) of the Act; and
  (b) the approved pharmacist does not keep the following information for at least 2 years from the date the pharmaceutical benefit was supplied by the approved pharmacist:

(i) information that supports the claim for payment made under section 99AAA of the Act in relation to the supply of the pharmaceutical benefit, including the repeat authorisation form;

(ii) information, about the supply of the pharmaceutical benefit, that the approved pharmacist gives to the PBS prescriber who most recently prescribed the pharmaceutical benefit to the person.

Penalty: 0.2 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

Note: The information may be kept in an electronic form (see subsection 12(2) of the *Electronic Transactions Act 1999*).

61 Keeping documents—medication chart prescriptions

Supplying a pharmaceutical benefit on the basis of a medication chart prescription if the medication chart is not an electronic medication chart

(1) An approved supplier commits an offence if:

(a) the approved supplier supplies a pharmaceutical benefit on the basis of a medication chart prescription; and

(aa) the medication chart is not an electronic medication chart; and

(b) the approved supplier does not keep the medication chart, or the copy of the medication chart, on which the approved supplier wrote the details referred to in paragraph 45(2)(c) in relation to the prescription, for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

Penalty: 0.2 penalty units.

Supplying a pharmaceutical benefit on the basis of a medication chart prescription if the medication chart is an electronic medication chart

(1A) An approved supplier commits an offence if:

(a) the approved supplier supplies a pharmaceutical benefit on the basis of a medication chart prescription; and

(b) the medication chart is an electronic medication chart; and

(c) the approved supplier does not keep the electronic prescription written in the electronic medication chart, or a copy of the electronic prescription, on which the approved supplier wrote the details referred to in paragraph 45(2)(d) in relation to the electronic prescription, for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

Penalty: 0.2 penalty units.

Strict liability offences

(2) An offence against subsection (1) or (1A) is an offence of strict liability.

Note: The medication chart, or copy of the medication chart, may be kept in an electronic form (see subsection 12(2) of the *Electronic Transactions Act 1999*).

62 Proper stocks to be kept

(1) An approved pharmacist commits an offence if he or she does not, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits.

Penalty: 0.2 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

63 Standards of composition and purity of pharmaceutical benefits and ingredients

(1) This section is made for the purposes of paragraph 103(5)(f) of the Act.

(2) If:

(a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and

(b) the drug, medicine or substance is to be supplied as a pharmaceutical benefit;

the standard of composition or purity of the drug, medicine or substance is the standard for the purposes of the Act.

(3) If:

(a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and

(b) the drug, medicine or substance is used as an ingredient in another drug, medicine or substance (the ***finished product***); and

(c) the finished product is to be supplied as a pharmaceutical benefit;

the standard of composition or purity of the drug, medicine or substance used as an ingredient is the standard for the purposes of the Act.

64 Labelling of pharmaceutical benefits—full cost

(1) A pharmaceutical benefit supplied by an approved supplier must be labelled with the words “full cost” followed by the full cost of the pharmaceutical benefit.

(2) Subsection (1) does not apply to:

(a) an approved supplier to which section 99AAB of the Act applies; or

(b) an approved hospital authority; or

(c) a pharmaceutical benefit obtained under subsection 93(2), 93AA(2) or 93AB(2) of the Act; or

(d) a pharmaceutical benefit to which subsection 99(2A), (2AB) or (2B) of the Act applies; or

(e) the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

(3) For the purposes of subsection (1), the ***full cost*** of a pharmaceutical benefit is the sum of:

(a) the Commonwealth price of the pharmaceutical benefit; and

(b) the special patient contribution charged under subsection 87(2A) of the Act.

65 Surrender of forms

(1) The Secretary may, by notice in writing served on a person (the ***first person***), require the first person to surrender to the Secretary or to a person specified in the notice, within a time specified in the notice, any forms that:

(a) have been supplied to the first person by, or on behalf of, the Commonwealth under, or for the purposes of:

(i) Part VII of the Act; or

(ii) this instrument; and

(b) are in the possession of the first person.

(2) A person commits an offence if:

(a) a notice is served on the person under subsection (1); and

(b) the person does not comply with the notice.

Penalty: 0.2 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

Part 7—Price reduction, price disclosure and stockholding

Division 1—Price reduction

65A Price reductions for single brands of combination items

(1) This section sets out, for the purposes of subsection 99ACC(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of a single brand of a combination item on the reduction day mentioned in that subsection.

(2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{Reduction day component AEMPs} \times \frac{\text{Day before combination item AEMP}}{\text{Day before component AEMPs}}$$

where:

component drug, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug.

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

differential reduction percentage means:

(a) if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day—the difference between 100% and the percentage by which the approved ex-manufacturer price of any one brand of the listed component item in the combination item has been so reduced; or

(b) if there are 2 or more listed component items for which the approved ex-manufacturer price of any one brand of each of those listed component items has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day—the difference between 100% and the average of the percentages by which the approved ex-manufacturer price of any one brand of each of those listed component items has been so reduced.

listed component drug means a component drug in relation to which a declaration under subsection 85(2) is in force.

listed component item, for each listed component drug contained in the combination item, means the pharmaceutical item that has:

(a) the listed component drug; and

(b) the same manner of administration as the combination item as referred to in subsection 99ACC(7) of the Act; and

(c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the sum of the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3).

reduction day component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

(3) For the purposes of the definitions of ***day before component AEMPs***, ***non-listed component price*** and ***reduction day component AEMPs*** in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:

(a) any difference in quantity or amount; and

(b) any difference in pricing quantity;

of the listed component drug in the listed component item.

(4) For the purposes of paragraph (c) of the definition of ***listed component item*** in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that:

(a) is not an exempt item; and

(b) results in the smallest reduction under this section to the approved ex-manufacturer price of the brand of the combination item;

is taken to be the listed component item for the purposes of this section.

66 Reduction day

For the purposes of paragraph 99ADH(2)(b) of the Act, 1 August and 1 December in any year are prescribed.

Division 2—Price disclosure

Subdivision A—Interpretation

67 Meaning of *data collection period*

Start of first data collection period

(1) The first ***data collection period*** for a brand of a pharmaceutical item starts on the brand's start day.

End of first data collection period

(2) If, on the day before the start day for the brand (the ***starting brand***) the price disclosure requirements apply to a related brand of the starting brand, the starting brand's first ***data collection period*** ends when the data collection period for any of the related brands ends.

(3) Otherwise, the starting brand's first ***data collection period*** ends on:
  (a) if the start day occurs between 2 April and 1 October—the next 31 March; or
  (b) if the start day occurs between 2 October and 1 April—the next 30 September.

Start and end of subsequent data collection periods

(4) After the first data collection period for a listed brand of a pharmaceutical item, each subsequent ***data collection period*** for the brand:
  (a) starts immediately after the end of the previous data collection period; and
  (b) ends on the next 31 March or 30 September, whichever is sooner.

Example 1: If a brand to which subsection (2) applies has a start day of 1 July 2014, and the data collection period for a related brand ends on 30 September 2014:
  (a) the first data collection period starts on 1 July 2014; and
  (b) the first data collection period ends on 30 September 2014; and
  (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2014, 1 April 2015, 1 October 2015 and so on.

Example 2: If a brand to which subsection (3) applies has a start day of 1 August 2014:
  (a) the first data collection period starts on 1 August 2014; and
  (b) the first data collection period ends on 31 March 2015; and
  (c) subsequent data collection periods will be the 6 month periods that start on 1 April 2015, 1 October 2015, 1 April 2016 and so on.

Example 3: If a brand to which subsection (3) applies has a start day of 1 December 2014:
  (a) the first data collection period starts on 1 December 2014; and
  (b) the first data collection period ends on 30 September 2015; and
  (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2015, 1 April 2016, 1 October 2016 and so on.

68 Meaning of *price sampling day*

A day is a ***price sampling day*** for a data collection period for a brand of a pharmaceutical item if the day:

(a) is the first day of a calendar month; and

(b) the day is within whichever of the following periods commenced earlier:

(i) the data collection period;

(ii) the data collection period for another brand of the same pharmaceutical item.

69 Special rules for certain listed brands

(1) Subsections (3), (4) and (5) apply to a listed brand of a pharmaceutical item if:

(a) paragraphs 99ADB(3B)(a) and (b) of the Act apply to the listed brand; and

(b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

(2) Subsections (4) and (5) apply to a listed brand of a pharmaceutical item if:

(a) the start day for the listed brand is the relevant day; and

(b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

Approved ex-manufacturer price on relevant day

(3) For the purposes of paragraph 99ADB(3B)(c) of the Act, the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the relevant day is the approved ex-manufacturer price of the brand on the start day minus any amount that would have been added, and plus any amount that would have been deducted, because of a price adjustment, had the brand been a listed brand in the period:

(a) starting on the relevant day; and

(b) ending immediately before the brand's start day.

Deemed data collection period and approved ex-manufacturer price for determining weighted average disclosed price

(4) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision B, the brand is taken to have had a data collection period:

(a) beginning on the earliest day on which the data collection period began for any related brand of the listed brand; and

(b) ending on the day before the relevant day.

(5) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision B, the approved ex-manufacturer price of the listed brand on a price sampling day is taken to have been the approved ex-manufacturer price of the listed brand on the brand's start day minus any amount that would have been added, and plus any amount that would have been

deducted, because of a price adjustment, had the brand been a listed brand in the period:

(a) starting on the price sampling day; and

(b) ending immediately before the brand's start day.

Note: This enables an average approved ex-manufacturer price to be worked out for the purpose of determining the weighted average disclosed price.

Subdivision B—Weighted average disclosed price

70 Method for determining weighted average disclosed price of listed brand of pharmaceutical item

(1) This Subdivision is made for the purposes of subsection 99ADB(6) of the Act.

(2) Sections 71 to 81 prescribe the method for determining the weighted average disclosed price of a listed brand of a pharmaceutical item in respect of a data collection period for the listed brand.

(3) When using the method, the Minister may disregard information provided under section 85 for a data collection period if the information is incomplete.

Note 1: Section 99ADA of the Act provides that Division 3B (Price disclosure) of Part VII of the Act does not apply to brands of exempt items.

Note 2: Subdivision C prescribes information that must not be taken into account in determining a weighted average disclosed price.

71 Step 1—net revenue for brand

(1) Work out the net revenue for the listed brand of the pharmaceutical item for the data collection period for the brand.

(2) The ***net revenue*** is the revenue from sales of the listed brand for the data collection period, other than for the listed brand's initial month, minus the value of any incentive given in relation to sales of the listed brand for the data collection period, other than for the listed brand's initial month.

72 Step 2—adjusted volume for brand

(1) Work out the adjusted volume of the listed brand of the pharmaceutical item sold for the data collection period for the brand.

(2) The ***adjusted volume*** is the number of packs of the listed brand sold for the data collection period, other than for the listed brand's initial month, worked out as if the size of the pack equals the pricing quantity of the listed brand on the final day.

73 Step 3—average approved ex-manufacturer price for brand

(1) Work out the average approved ex-manufacturer price of the listed brand of the pharmaceutical item for the data collection period for the brand.

(2) The ***average approved ex-manufacturer price*** is the amount worked out by:

(a) adding together, for each price sampling day for the listed brand for the data collection period:

(i) if the listed brand had an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price; or

(ii) if the listed brand did not have an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price of a listed brand of the same pharmaceutical item; and

(b) dividing that amount by the number of price sampling days for the listed brand for the data collection period.

Note: A price sampling day may be within the data collection period for another brand of the same pharmaceutical item (see section 68).

Adjustment for variation in pricing quantity

(3) If the pricing quantity of a brand on a price sampling day is different from the pricing quantity of the brand on the final day, for the purposes of subsection (2) the approved ex-manufacturer price of the brand on the price sampling day is taken to be:

$$\frac{\text{AEMP}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP means the approved ex-manufacturer price of the brand on the price sampling day (for the pricing quantity of the brand on the price sampling day).

PQ1 means the pricing quantity of the brand on the price sampling day.

PQ2 means the pricing quantity of the brand on the final day.

73A Step 3A—adjusted net revenue for brand

(1) Work out the adjusted net revenue of the listed brand of the pharmaceutical item for the data collection period.

Where average approved ex-manufacturer price is $4 or less

(2) If the average approved ex-manufacturer price (see step 3) of the listed brand of the pharmaceutical item for the data collection period for the brand is $4 or less, the ***adjusted net revenue*** is the amount worked out by multiplying:

(a) the adjusted volume of the listed brand of the pharmaceutical item sold for the data collection period (see step 2); by

(b) the average approved ex-manufacturer price of the listed brand of the pharmaceutical item for the data collection period (see step 3).

Example: A responsible person has one listed brand (***brand A***) of a pharmaceutical item that has an average approved ex-manufacturer price of $3.50 and the net revenue obtained for a sale of 1,000 packs of that brand was $3,000. The adjusted net revenue of brand A is $3,500.

Where average approved ex-manufacturer price is more than $4

(3) If the average approved ex-manufacturer price (see step 3) of the listed brand (the ***relevant brand***) of the pharmaceutical item for the data collection period is more than $4, the ***adjusted net revenue*** is the amount worked out by:

(a) working out the sum of the net revenue worked out under step 1 for all listed brands of pharmaceutical items to which both of the following apply for the data collection period:

(i) the responsible person for the brand of the pharmaceutical item is the same as the responsible person for the relevant brand;

(ii) the average approved ex-manufacturer price of the brand of the pharmaceutical item is $4 or less; and

(b) working out what would have been the sum of the net revenue of all listed brands of pharmaceutical items to which paragraph (a) applies for the data collection period if each of those listed brands had instead been sold for the average approved ex-manufacturer prices by:

(i) multiplying the adjusted volume worked out under step 2 for each of those listed brands by the average approved ex-manufacturer price for each of those brands worked out under step 3; and

(ii) adding up the amounts worked out under subparagraph (i); and

(c) reducing (but not below zero) the amount worked out under paragraph (b) by the amount worked out under paragraph (a); and

(d) working out the ***net revenue adjustment percentage*** (expressed as a percentage to 2 decimal places) by dividing the amount worked out under paragraph (c) by the sum of the net revenue (worked out under step 1) of all listed brands of pharmaceutical items to which both of the following apply for the data collection period:

(i) the responsible person for the brand of the pharmaceutical item is the same as the responsible person for the relevant brand;

(ii) the average approved ex-manufacturer price of the brand of pharmaceutical item is more than $4; and

(e) reducing the net revenue for the relevant brand for the data collection period by the net revenue adjustment percentage.

Note: The effect of this subsection is that any difference between net revenue and the revenue that would have been obtained by a responsible person had they supplied brands of pharmaceutical items with approved ex-manufacturer prices of $4 or less at the average approved ex-manufacturer prices for those brands will be apportioned to the net revenue for the responsible person's brands of pharmaceutical items that have approved ex-manufacturer prices of more than $4.

Example: The responsible person for brand A is also the responsible person for two listed brands of pharmaceutical items that have approved ex-manufacturer prices of more than $4. The net revenue for one of those brands (***brand B***) is $2,000 and for the other (***brand C***) is $3,000. The net revenue adjustment percentage is obtained by dividing $500 (the difference between the adjusted net revenue and the net revenue of brand A) by $5,000 (the sum of the net revenue of brand B and brand C) which equals 10%. The adjusted net revenue of brand B is $1,800 ($2,000 reduced by 10%) and the adjusted net revenue of brand C is $2,700 ($3,000 reduced by 10%).

74 Step 4—disclosed price for brand

(1) Work out the disclosed price of the listed brand of the pharmaceutical item for the data collection period for the brand.

(2) The ***disclosed price*** is:
  (a) if the adjusted volume (see step 2) of the listed brand is zero or less—zero; or
  (b) if the adjusted volume (see step 2) of the listed brand is more than zero:
    (i) the amount worked out by dividing the adjusted net revenue for the listed brand (see step 3A) by the adjusted volume; or
    (ii) if the amount worked out under subparagraph (i) is more than the average approved ex-manufacturer price for the listed brand for the data collection period—the average approved ex-manufacturer price of the listed brand.

75 Step 5—price percentage difference of brand

(1) Work out the price percentage difference of the listed brand of the pharmaceutical item for the data collection period.

(2) The ***price percentage difference*** of the listed brand is the amount (expressed as a percentage to 2 decimal places) worked out as follows:
  (a) subtract the listed brand's disclosed price for the data collection period (see step 4) from the listed brand's average approved ex-manufacturer price for the data collection period (see step 3); and
  (b) divide that amount by the listed brand's average approved ex-manufacturer price for the data collection period.

76 Step 6—repeat steps for each brand of pharmaceutical item

(1) For each other brand of the same pharmaceutical item (including delisted brands) work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.

(2) The price percentage difference of the other brand is worked out using steps 1 to 5, reading references to the listed brand as references to the other brand.

(3) If the other brand of the pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:
  (a) if there is a listed brand of the same pharmaceutical item on the final day—the pricing quantity of the listed brand; or
  (b) if there is no listed brand of the same pharmaceutical item on the final day—the pricing quantity of the last listed brand immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

77 Step 7—total adjusted volume of brands of pharmaceutical item

(1) Work out the total adjusted volume of the brands of the pharmaceutical item.

(2) The ***total adjusted volume*** is the amount worked out by adding together the adjusted volume for each brand of the pharmaceutical item for the brand's data collection period.

78 Step 8—weighted average percentage difference of brands of pharmaceutical item

(1) Work out the weighted average percentage difference of the brands of the pharmaceutical item.

(2) The ***weighted average percentage difference*** is:
  (a) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is zero or less—zero; or
  (b) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is more than zero—the amount (expressed as a percentage to 2 decimal places) worked out by:
    (i) for each brand of the pharmaceutical item, multiplying the adjusted volume of the brand for the brand's data collection period (see step 2) by the price percentage difference of the brand for the data collection period (see step 5); and
    (ii) adding up each of those amounts; and
    (iii) dividing that amount by the total adjusted volume of the brands of the pharmaceutical item.

79 Step 9—repeat steps for each pharmaceutical item with related brands

(1) For each brand (including delisted brands) of a pharmaceutical item with the same drug and manner of administration as the listed brand but a different form (the ***other pharmaceutical item***), other than an exempt item, work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.

(2) The price percentage difference of a brand of the other pharmaceutical item is worked out using steps 1 to 5, reading references to the listed brand as references to the brand of the other pharmaceutical item.

(3) If a brand of the other pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:
  (a) if there is a listed brand of the other pharmaceutical item on the final day—the pricing quantity of the listed brand of the other pharmaceutical item; or
  (b) if there is no listed brand of the other pharmaceutical item on the final day—the pricing quantity of the last listed brand of the other pharmaceutical item immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

(4) For each pharmaceutical item with the same drug and manner of administration as the listed brand but a different form, other than an exempt item, work out the weighted average percentage difference of the brands of the pharmaceutical item (using steps 7 and 8).

80 Step 10—weighted average percentage difference for listed brand and all related brands

(1) Work out the weighted average percentage difference for the listed brand and all related brands.

(2) The ***weighted average percentage difference*** is the amount (expressed as a percentage to 2 decimal places) worked out as follows:

(a) for each pharmaceutical item with the same drug and manner of administration as the listed brand (including the pharmaceutical item of the listed brand):

(i) multiply the total adjusted volume for the brands of the pharmaceutical item (see step 7) by the average approved ex-manufacturer price for a brand of the pharmaceutical item (see step 3); and

(ii) multiply that amount by the weighted average percentage difference of the brands of the pharmaceutical item (see step 8);

(b) add up the amounts worked out under subparagraph (a)(ii);

(c) add up the amounts worked out under subparagraph (a)(i);

(d) divide the amount worked out under paragraph (b) by the amount worked out under paragraph (c).

(3) However:

(a) if the amount worked out under paragraph (2)(c) is zero or less, the ***weighted average percentage difference*** is zero; and

(b) if the amount worked out under paragraph (2)(d) is 99% or more, the ***weighted average percentage difference*** is 99%.

81 Step 11—weighted average disclosed price for listed brand of pharmaceutical item

(1) Work out the weighted average disclosed price of the listed brand of the pharmaceutical item for the data collection period.

(2) The ***weighted average disclosed price*** of the listed brand of the pharmaceutical item is the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).

(3) However, if the pricing quantity of the listed brand of the pharmaceutical item on the final day is different from the pricing quantity of the listed brand on the relevant day, the ***weighted average disclosed price*** is:

$$\frac{WR}{PQ1} \times PQ2$$

where:

PQ1 means the pricing quantity of the listed brand on the final day.

PQ2 means the pricing quantity of the listed brand on the relevant day.

WR means the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).

Note: See section 99ADHA of the Act for price reductions for brands listed after the end of the data collection period.

(4) This section has effect subject to section 82.

82 When weighted average disclosed price is the same as the applicable approved ex-manufacturer price

Despite section 81, if all of the following apply, the ***weighted average disclosed price*** of the listed brand of the pharmaceutical item for the data collection period is taken to be the amount of the applicable approved ex-manufacturer price of the listed brand of the pharmaceutical item:

(a) the total adjusted volume worked out for brands of the pharmaceutical item under section 77:
  (i) is more than zero; and
  (ii) is no more than 10% of the sum of the total adjusted volumes for the brands of each pharmaceutical item with the same drug and manner of administration as the listed brand (including the pharmaceutical item of the listed brand);

(b) the weighted average percentage difference worked out for brands of the pharmaceutical item under section 78 is not more than 3%;

(c) there is not a related brand of the listed brand of the pharmaceutical item:
  (i) that is bioequivalent or biosimilar to the listed brand of the pharmaceutical item; and
  (ii) to which paragraphs (a) and (b) do not apply;

(d) the Pharmaceutical Benefits Advisory Committee has not advised the Minister that the pharmaceutical item does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies.

Subdivision C—Information that must not be taken into account

83 Information that must not be taken into account

(1) This Subdivision is made for the purposes of subsection 99ADB(6A) of the Act.

(2) Section 84 prescribes information that must not be taken into account in determining the weighted average disclosed price of a listed brand of a pharmaceutical item (the ***WADP brand***) in respect of a data collection period.

(3) However, section 84 does not apply in relation to determining a weighted average disclosed price for the purposes of section 82.

(4) To avoid doubt, this Subdivision has effect:
  (a) despite Subdivision B (weighted average disclosed price); and
  (b) even if the information relates to the WADP brand.

84 Originator brands

(1) Information provided under section 85 about an originator brand must not be taken into account if:
  (a) on the first day of each calendar month in the data collection period (from its beginning in relation to the originator brand) on which the originator brand is a listed brand, there is another listed brand of pharmaceutical item that:
    (i) is not an originator brand; but
    (ii) has the same pharmaceutical item as the originator brand; and
  (b) at the end of the previous data collection period either:
    (i) the drug in the WADP brand had been on F2 for at least 18 months and during that period there has been no price reduction under Division 3B of Part VII of the Act to any brand of pharmaceutical item that has the same drug and manner of administration as the WADP brand; or
    (ii) the drug in the WADP brand had been on F2 for at least 30 months; and
  (c) on a day at least as many months as mentioned in subparagraph (b)(i) or (ii) (whichever is applicable) before the end of the previous data collection period:
    (i) there was a related brand of the WADP brand that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the WADP brand; or
    (ii) there were 2 or more related brands of the WADP brand that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.

(2) Paragraph (1)(a) has effect even if the other listed brand is different from month to month.

(3) However, subsection (1) does not apply if taking the information into account would result in a higher weighted average percentage difference under section 80 (weighted average percentage difference for the WADP brand and all related brands).

Subdivision D—Price disclosure requirements

85 Price disclosure requirements

(1) This section is made for the purposes of subsection 99ADC(1) of the Act.

Prescribed information

(2) The responsible person must provide the following information in relation to the supply of a brand of a pharmaceutical item:
  (a) the start and end dates of the period to which the information relates;
  (b) the name of the brand;
  (c) the name of the responsible person;
  (d) the name of the drug in the pharmaceutical item;
  (e) the form of the drug, including its strength;
  (f) the manner of administration of the form of the drug;
  (g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
  (h) the number of packs sold;
  (i) the revenue from sales of the brand, excluding GST;
  (j) if any incentive is given in relation to the brand:
    (i) the kind of incentive; and
    (ii) the value of the incentive, excluding GST.

(2A) Subsection (2) does not apply to a supply of a brand of a pharmaceutical item during a data collection period for the brand if:
  (a) the supply is to a public hospital; and
  (b) the drug in the pharmaceutical item had not been on F2 for at least 42 months at the end of the previous data collection period for the brand.

(3) If information is provided under paragraph (2)(i), the information must not also be provided under paragraph (2)(j).

(4) The information referred to in each of paragraphs (2)(h), (i) and (j), to the extent that the information relates to the brand's initial month, must be provided separately.

(5) An amount provided under paragraph (2)(i) or (j) must be:
  (a) expressed in Australian dollars; and
  (b) rounded to the nearest whole dollar, rounding 50 cents upwards.

Prescribed person

(6) The responsible person must provide the information to:
  (a) Australian Healthcare Associates Pty Ltd (ABN 82 072 790 848); or
  (b) if the responsible person receives written notice from the Department to provide the information to the Secretary—the Secretary.

Prescribed manner and form

(7) The responsible person must provide the information in a form approved, in writing, by the Secretary.

(8) The completed form must:
  (a) include all the statements and information required by the form; and
  (b) be signed (or authorised for electronic transmission) by a person who is authorised by the responsible person to provide the information.

Prescribed times

(9) Subject to subsection (10), the responsible person must provide the information:
  (a) for each period between 1 April and 30 September in a year—before the end of 11 November in that year; and
  (b) for each period between 1 October and the next 31 March—before the end of the next 12 May.

(10) However, for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person must provide the information:
  (a) if the start day happens between 1 April and 30 September in a year—before the end of 11 November in that year; or
  (b) if the start day happens between 1 October and the next 31 March—before the end of the next 12 May.

Subdivision E—Price reduction

85A Flow on price reductions for brands of combination items

(1) This section sets out, for the purposes of subsection 99ADHB(2) of the Act, the method for calculating the reduced approved ex-manufacturer price of an existing brand of a combination item on the reduction day mentioned in that subsection.

(2) The reduced approved ex-manufacturer price of the brand of the combination item is the amount worked out by the following formula:

$$\text{Reduction day component AEMPs} \times \frac{\text{Day before combination item AEMP}}{\text{Day before component AEMPs}}$$

where:

component drug, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug.

day before combination item AEMP means the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

day before component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

differential reduction percentage means:

(a) if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision in Division 3B of Part VII of the Act on the reduction day—the difference between 100% and the percentage by which the approved ex-manufacturer price of any one brand of the listed component item in the combination item has been so reduced; or

(b) if there are 2 or more listed component items for which the approved ex-manufacturer price of any one brand of each of those listed component items has been reduced under a provision in Division 3B of Part VII of the Act on the reduction day—the difference between 100% and the average of the percentages by which the approved ex-manufacturer price of any one brand of each of those listed component items has been so reduced.

listed component drug means a component drug in relation to which a declaration under subsection 85(2) is in force.

listed component item, for each listed component drug that is in the combination item and in a non-combination item as mentioned in paragraph 99ADHB(1)(d) of the Act, means the pharmaceutical item that has:

(a) the same listed component drug as the non-combination item; and

(b) the same manner of administration as the combination item as referred to in subsection 99ADHB(7) of the Act; and

(c) subject to subsection (4) of this section, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

non-listed component price means the day before combination item AEMP reduced (but not below zero) by the sum of the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3).

reduction day component AEMPs means the sum of:

(a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3); and

(b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

(3) For the purposes of the definitions of ***day before component AEMPs***, ***non-listed component price*** and ***reduction day component AEMPs*** in subsection (2), adjust the approved ex-manufacturer price of a brand of a listed component item so that the value attributed to the listed component drug in the combination item reflects:

(a) any difference in quantity or amount; and

(b) any difference in pricing quantity;

of the listed component drug in the listed component item.

(4) For the purposes of paragraph (c) of the definition of ***listed component item*** in subsection (2), if there is more than one pharmaceutical item that has the smallest difference as referred to in that paragraph, the pharmaceutical item that:

(a) is not an exempt item; and

(b) results in the smallest reduction under this section to the approved ex-manufacturer price of the brand of the combination item;

is taken to be the listed component item for the purposes of this section.

Division 3—Stockholding requirements

85B Usual demand for a brand

(1) For the purposes of subsection 99AEKC(5) of the Act, the ***usual demand*** for a brand of a pharmaceutical item for a month in a data collection period for that brand is the number of packs of the brand supplied during the data collection period (the ***reference period***) before the previous data collection period for the brand divided by the number of months in the reference period.

(2) For the purposes of subsection (1) the number of packs of the brand supplied during a data collection period is taken to be:
  (a) the number provided in accordance with paragraph 85(2)(h) for that brand for that period; and
  (b) adjusted as if the size of the pack equals the pricing quantity of the brand.

(3) If a brand of a pharmaceutical item is not a listed brand in the reference period referred to in subsection (1), the usual demand for the brand for the month referred to in that subsection is taken to be zero.

85C Stockholding disclosure requirements

(1) This section is made for the purposes of subsection 99AEKF(1) of the Act.

Prescribed information

(2) The responsible person for a brand of a pharmaceutical item must provide the following information in relation to the quantity of the brand of pharmaceutical item kept in stock in Australia:
  (a) the start and end dates of the period to which the information relates;
  (b) the name of the brand;
  (c) the name of the responsible person;
  (d) the name of the drug in the pharmaceutical item;
  (e) the form of the drug, including its strength;
  (f) the manner of administration of the form of the drug;
  (g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
  (h) the number of packs held in stock at the end of each month in the period.

Prescribed person

(3) The responsible person must provide the information to the same person to whom the responsible person must give information under subsection 85(6).

Prescribed manner and form

(4) The responsible person must provide the information in a form approved, in writing, by the Secretary.

(5) The completed form must:
  (a) include all the statements and information required by the form; and
  (b) be signed (or authorised for electronic transmission) by a person who is authorised by the responsible person to provide the information.

Prescribed times

(6) Subject to subsection (7), the responsible person must provide the information:
  (a) for each period between 1 April and 30 September in a year—before the end of 11 November in that year; and
  (b) for each period between 1 October and the next 31 March—before the end of the next 12 May.

(7) However, for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person must provide the information:
  (a) if the start day happens between 1 April and 30 September in a year—before the end of 11 November in that year; or
  (b) if the start day happens between 1 October and the next 31 March—before the end of the next 12 May.

Part 8—Arrangements for the Pharmaceutical Benefits Advisory Committee

Division 1—Matters relating to the appointment of members of the Committee

86 Nominating bodies

Industry organisations

(1) For the purposes of paragraph 100B(1AA)(a) of the Act, the following industry organisations are prescribed:
  (a) Medicines Australia Limited;
  (b) Generic Medicines Industry Association Pty Ltd trading as the Generic and Biosimilar Medicines Association;
  (c) Ausbiotech Ltd.

Consumer organisations

(2) For the purposes of paragraph 100B(1AB)(a) of the Act, the following consumer organisations are prescribed:
  (a) the Consumers Health Forum of Australia Ltd;
  (b) the Australian Federation of AIDS Organisations Incorporated;
  (c) the Australian Consumers' Association.

Professional associations

(3) For the purposes of paragraph 100B(1A)(b) of the Act, the following professional associations of health economists are prescribed:
  (a) the Australian Health Economics Society Inc;
  (b) the Economic Society of Australia Inc.

(4) For the purposes of paragraph 100B(1A)(c) of the Act, the following professional associations of pharmacists are prescribed:
  (a) the Pharmacy Guild of Australia;
  (b) the Pharmaceutical Society of Australia;
  (c) the Society of Hospital Pharmacists of Australia.

(5) For the purposes of paragraph 100B(1A)(d) of the Act, the following professional associations of medical practitioners are prescribed:
  (a) the Australian Medical Association Limited;
  (b) the Royal Australian College of General Practitioners;
  (c) the Doctors Reform Society—Australia Inc;
  (d) the Australian Federation of Medical Women Inc.

(6) For the purposes of paragraph 100B(1A)(e) of the Act, the following professional associations of clinical pharmacologists are prescribed:
  (a) the Royal Australasian College of Physicians;
  (b) the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

(7) For the purposes of paragraph 100B(1A)(f) of the Act, the following professional associations of specialists are prescribed:
  (a) the Australian Medical Association Limited;
  (b) the Royal Australasian College of Physicians;
  (c) the Committee of Presidents of Medical Colleges.

87 Number of nominations for appointment

For the purposes of subsection 100B(1B) of the Act, each body prescribed for the purposes of subsection 100B(1AA), (1AB) or (1A) of the Act must be asked to nominate at least 3 persons for selection for appointment as members of the Pharmaceutical Benefits Advisory Committee.

88 Resignation

A member of the Pharmaceutical Benefits Advisory Committee may resign by notice in writing given to the Minister.

Division 2—Matters relating to the procedure of the Committee

89 Purpose of this Division

For the purposes of subsection 101(5) of the Act, this Division makes provision for and in relation to the procedure of the Pharmaceutical Benefits Advisory Committee.

90 Presiding member

(1) The Chairperson of the Pharmaceutical Benefits Advisory Committee must preside at a meeting of the Committee if the Chairperson is present.

(2) If the Chairperson is absent and there is a Deputy Chairperson of the Committee present, the Deputy Chairperson must preside at the meeting.

(3) If:
  (a) the Chairperson is absent; and
  (b) there is no Deputy Chairperson present;

the members of the Committee attending the meeting must elect a member to preside at the meeting.

91 Meetings of the Committee

(1) The Chairperson of the Pharmaceutical Benefits Advisory Committee may, at any time, by notice in writing to all members of the Committee, convene a meeting of the Committee.

(2) The Committee must keep minutes of its meetings.

92 Quorum

At a meeting of the Pharmaceutical Benefits Advisory Committee, a quorum is the number of members who constitute a majority of the membership of the Committee.

93 Voting

(1) At a meeting of the Pharmaceutical Benefits Advisory Committee, the members present each have a deliberative vote.

(2) A matter requiring a decision at a meeting must be determined by a majority of the votes of the members present and voting.

(3) If an equal number of votes is cast for and against a matter at a meeting:
  (a) the member presiding at the meeting may exercise a casting vote; and
  (b) if that member declines to exercise a casting vote—the matter is resolved in the negative.

(4) Decisions of the Committee must be recorded in the minutes of the meeting.

94 Disclosure of pecuniary interests by members

(1) Each member of the Pharmaceutical Benefits Advisory Committee must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the member has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with the member's duties.

(2) If a member does not have an interest of the kind referred to in subsection (1), the member must give a statement to that effect to the Minister.

(3) If the member presiding at a meeting of the Committee has a direct or indirect pecuniary interest in a matter that is to be considered at the meeting, the presiding member:
  (a) must disclose the interest to the other members present at the meeting; and
  (b) must not take part in the meeting during the consideration of that matter unless the other members present at the meeting agree that the presiding member may take part in the meeting.

(4) If the presiding member is precluded from taking part in a meeting or part of a meeting because of paragraph (3)(b):
  (a) if the presiding member is the Chairperson of the Committee and a Deputy Chairperson of the Committee is present—the Deputy Chairperson must act in the place of the Chairperson for the duration of the Committee's consideration of the matter; or
  (b) if:
    (i) the presiding member is the Chairperson of the Committee and no Deputy Chairperson of the Committee is present; or
    (ii) the Deputy Chairperson is the presiding member;

  the other members attending the meeting must elect a member who is present to act in the place of the presiding member for the duration of the Committee's consideration of the matter.

(5) If a member (other than the presiding member) of the Committee has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting of the Committee, the member:
  (a) must disclose the interest to the presiding member at the commencement of the meeting; and
  (b) must not take part in the meeting during the consideration of that matter unless the presiding member allows the member to take part in the meeting.

(6) The following matters must be recorded in the minutes of a meeting of the Committee:
  (a) a disclosure made under subsection (3) or (5);
  (b) an agreement under paragraph (3)(b);
  (c) consent of the presiding member under paragraph (5)(b).

95 Resolutions without a formal meeting

If a majority of the members of the Pharmaceutical Benefits Advisory Committee sign a document that includes a statement that they are in favour of a resolution in the terms set out in the document, the resolution is taken to have been passed at a meeting of the Committee:

(a) on the day on which the document is signed; or

(b) if the members sign the document on different days—on the day on which the document is signed by the member who completes the majority.

96 Reports and recommendations

(1) A report or a recommendation made to the Minister by the Pharmaceutical Benefits Advisory Committee as part of its consideration of a matter must be in writing.

(2) If:

(a) the members of the Committee are not unanimous in agreeing to a report or a recommendation; and

(b) a member who is not part of the majority asks the Chairperson of the Committee to include, as part of the report or recommendation:

(i) a statement that the members are not unanimous; or

(ii) an explanation of the opinion of the member; or

(iii) a separate report or recommendation made by the member;

the report or recommendation must include the matter requested by the member.

Division 3—Matters relating to sub-committees

97 Remuneration for chair and members of sub-committees

Fees and allowances payable to chairs

(1) For the purposes of paragraph 140(a) of the Act, the fees and allowances payable to the Chair of the Drug Utilisation Sub-Committee and the Chair of the Economics Sub-Committee are the amounts payable to the Chairperson of the Pharmaceutical Services Federal Committee of Inquiry in accordance with a determination made by the Remuneration Tribunal.

Fees and allowances payable to other members

(2) For the purposes of paragraph 140(a) of the Act, the fees and allowances payable to a member (other than the Chair) of the Drug Utilisation Sub-Committee or the Economics Sub-Committee are the amounts payable to a member (other than the Chairperson) of the Pharmaceutical Services Federal Committee of Inquiry in accordance with a determination made by the Remuneration Tribunal.

Definitions

(3) In this section:

Drug Utilisation Sub-Committee means the sub-committee of that name established under section 101A of the Act.

Economics Sub-Committee means the sub-committee of that name established under section 101A of the Act.

Part 9—Application, savings and transitional provisions

98 Definitions

In this Part:

old regulations means the *National Health (Pharmaceutical Benefits) Regulations 1960*.

99 Things done under old regulations

(1) If:

(a) a thing was done for a particular purpose under the old regulations as in force immediately before those regulations were repealed; and

(b) the thing could be done for that purpose under this instrument;

the thing has effect for the purposes of this instrument as if it had been done under this instrument.

(2) Without limiting subsection (1), a reference in that subsection to a thing being done includes a reference to a notice, approval or other instrument being given or made.

102 Transitional provision relating to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*

(1) This section applies in relation to a prescription for the supply of a pharmaceutical benefit that is written before 1 February 2021.

(2) Despite the amendments of section 40 made by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*, a prescription that is not a medication chart prescription is taken to have been written in accordance with section 40 if the prescription is written in accordance with that section as in force immediately before 31 October 2019.

(3) Despite the amendments of section 41 made by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*, a prescription that is a medication chart prescription is taken to have been written in accordance with section 41 if the prescription is written in accordance with that section as in force immediately before 31 October 2019.

103 Application provision relating to the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*

(1) Sections 65A and 85A, as inserted by Part 1 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*, apply in relation to reduction days occurring on or after 1 July 2022.

(2) The amendments made to section 84 by Part 2 of Schedule 1 to those Regulations apply to data collection periods beginning on or after 1 April 2022.

(3) Section 73A, as inserted by Part 3 of Schedule 1 to those Regulations, and the amendments made to section 74 by Part 3 of Schedule 1 to those Regulations, apply to data collection periods beginning on or after 1 October 2022.

(4) The amendments made to section 85 by Part 3 of Schedule 1 to those Regulations apply to information in relation to supplies of brands of pharmaceutical items occurring on or after 1 October 2022.

(5) Sections 85B and 85C, as inserted by Part 4 of Schedule 1 to those Regulations, apply to information in relation to supplies of brands of pharmaceutical items occurring on or after 1 July 2023.

104 Transitional provision relating to the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*

(1) This section applies in relation to prescriptions for the supply of pharmaceutical benefits written before 1 July 2024.

(2) Despite the repeal and substitution of section 30 by the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*:

(a) a practitioner may submit a prescription to the Minister in accordance with subsection 30(3) as in force immediately before 1 April 2024; and

(b) the Minister may make a variation under subsection 30(1) as in force immediately before 1 April 2024 in relation to the practitioner; and

(c) the prescription is taken to have been written in accordance with an authorisation under section 30 if the prescription is authorised in accordance with subsection 30(4) as in force immediately before 1 April 2024.

(3) If the Minister makes a variation in accordance with paragraph 30(4)(a), (b) or (c) as in force immediately before 1 April 2024, the practitioner is not required to comply with the following provisions in relation to the authorised prescription:

(a) paragraph 40(1)(i);

(b) paragraph 41(3)(a).

105 Application provisions relating to the *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024*

(1) The amendment made by item 4 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024*

(the ***amending regulations***) applies in relation to an electronic prescription written on or after the commencement of the amending regulations.

(2) The amendments made by items 5 to 9 and item 12 of Schedule 1 to the amending regulations apply in relation to the supply of a pharmaceutical benefit occurring on or after the commencement of the amending regulations.

(3) The amendments made by items 10 and 11 of Schedule 1 to the amending regulations apply in relation to an electronic medication chart where the first prescription for a pharmaceutical benefit is written in the chart on or after the commencement of the amending regulations.

(4) The amendments made by items 13 to 15 of Schedule 1 to the amending regulations apply in relation to the supply of a pharmaceutical benefit occurring on or after the commencement of the amending regulations.

Schedule 1—Prescribed offices

Note: See sections 20 and 22.

1 Table of prescribed offices

The following table sets out offices that are prescribed offices.

Prescribed offices

Item	Office
1	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 SYDNEY NSW 2000
2	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 MELBOURNE VIC 3000
3	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 BRISBANE QLD 4000
4	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 PERTH WA 6000
5	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 ADELAIDE SA 5000
6	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 HOBART TAS 7000

Clause 1

Prescribed offices	
Item	**Office**
7	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 CANBERRA ACT 2600
8	Pharmaceutical Benefits Scheme Claims Section Department of Human Services GPO Box 9826 DARWIN NT 0800

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 (Pharmaceutical Benefits) Regulations 2017	27 Mar 2017 (F2017L00313)	1 Apr 2017 (s 2(1) item 1)	
National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018	16 May 2018 (F2018L00621)	1 June 2018 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019	16 Aug 2019 (F2019L01072)	31 Oct 2019 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019	9 Oct 2019 (F2019L01312)	31 Oct 2019 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Supply of Pharmaceutical Benefits Following Bankruptcy or External Administration) Regulations 2019	29 Nov 2019 (F2019L01530)	5 Dec 2019 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020	9 July 2020 (F2020L00898)	10 July 2020 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2020	25 Aug 2020 (F2020L01055)	26 Aug 2020 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Electronic Prescribing) Regulations 2021	3 June 2021 (F2021L00687)	4 June 2021 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021	16 Dec 2021 (F2021L01797)	Sch 1 (items 1–3): 1 July 2022 (s 2(1) item 2) Sch 1 (items 4–7): 1 Oct 2022 (s 2(1) item 3) Sch 1 (items 8–12): 1 Apr 2023 (s 2(1) item 4) Sch 1 (items 13–15): 1 July 2023 (s 2(1) item 5)	—
National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024	28 Mar 2024 (F2024L00380)	1 Apr 2024 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024	28 June 2024 (F2024L00830)	1 July 2024 (s 2(1) item 1)	—
National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024	1 Oct 2024 (F2024L01241)	2 Oct 2024 (s 2(1) item 1)	—
Administrative Review Tribunal Legislation Consequential Amendments (2024 Measures No. 1) Regulations 2024	11 Oct 2024 (F2024L01299)	Sch 7 (items 13–16): 14 Oct 2024 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Division 1	
s 2	rep LA s 48D
s 4	rep LA s 48C
s 5	am F2018L00621; F2019L01072; F2019L01312; F2020L00898; F2021L00687; F2024L00380; F2024L00830; F2024L01241
s 6	rep F2018L00621
Division 2	
s 9	am F2019L01072
s 10	am F2019L01072
s 12A	ad F2024L01241
Part 2	
s 16	am F2019L01530
Part 3	
Division 1A	
Division 1A	ad F2018L00621
s 17A	ad F2018L00621
Division 1	
s 18	am F2018L00621
Division 2	
s 19	am F2018L00621
Division 3	
s 21	am F2018L00621
Division 4	
s 27	am F2024L01299
s 28	am F2024L01299
Part 4	
Division 1	
s 30	am F2019L01072
	rs F2024L00380
Division 2	
s 33	am F2019L01072; F2024L00380
Part 5	
s 39	am F2019L01072
s 40	am F2019L01072; F2019L01312; F2024L00380
s 41	am F2019L01072; F2019L01312; F2021L00687; F2024L00380; F2024L01241
s 41A	ad F2019L01072

Endnote 4—Amendment history

Provision affected	How affected
s 41B	ad F2019L01072
s 45	am F2021L00687; F2024L01241
s 57	am F2019L01072
	rep F2024L00380
Part 6	
s 59	am F2019L01072
s 61	am F2024L01241
Part 7	
Part 7 heading	rs F2021L01797
Division 1	
s 65A	ad F2021L01797
Division 2	
Subdivision B	
s 73A	ad F2021L01797
s 74	am F2021L01797
Subdivision C	
s 84	am F2021L01797
Subdivision D	
s 85	am F2021L01797
Subdivision E	
Subdivision E	ad F2021L01797
s 85A	ad F2021L01797
Division 3	
Division 3	ad F2021L01797
s 85B	ad F2021L01797
s 85C	ad F2021L01797
Part 9	
s 100	rep 1 Apr 2019 (s 100(3))
s 101	rep 1 Apr 2019 (s 101(3))
s 102	ad F2019L01312
	am F2020L01055
s 103	ad F2021L01797
	am F2021L01797
s 104	ad F2024L00380
s 105	ad F2024L01241
Schedule 2	rep LA s 48C