National Health Act 1953

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Authorised Version C2026C00283 registered 13/07/2026

About this compilation

This compilation

This is a compilation of the *National Health Act 1953* that shows the text of the law as amended and in force on 1 July 2026 (the ***compilation date***).

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

Uncommenced amendments

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

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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.

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

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

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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An Act relating to the provision of pharmaceutical, sickness and hospital benefits, and of medical and dental services

Part I—Preliminary

1 Short title

This Act may be cited as the *National Health Act 1953*.

2 Commencement

(1) Parts I and II shall come into operation on the day on which this Act receives the Royal Assent.

(2) The remaining provisions of this Act shall come into operation on such dates as are respectively fixed by Proclamation.

4 Interpretation

(1) In this Act, unless the contrary intention appears:

Chief Executive Medicare has the same meaning as in the *Human Services (Medicare) Act 1973*.

civil penalty provision has the same meaning as in the Regulatory Powers Act.

Committee of Inquiry means a Committee of Inquiry established under Part VIII.

complying health insurance policy has the meaning given by section 63-10 of the *Private Health Insurance Act 2007*.

de facto partner of a person means:

(a) another person (whether of the same sex or a different sex) with whom the person has a relationship that is registered

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under a law of a State or Territory prescribed for the purposes of section 2E of the *Acts Interpretation Act 1901* as a kind of relationship prescribed for the purposes of that section; or

(b) another person (whether of the same sex or a different sex) who is living with the person on a genuine domestic basis although not legally married to the person.

designated vaccine has the meaning given by subsection 9B(2).

disclose, in relation to information, includes divulge or communicate.

entrusted public official means any of the following:

(a) the Minister;
(b) the Chief Executive Medicare;
(c) the Secretary of a relevant Department;
(d) an APS employee in a relevant Department;
(e) a Departmental employee within the meaning of the *Human Services (Medicare) Act 1973*;
(f) any other person employed or engaged by the Commonwealth to provide services to the Commonwealth in connection with a relevant Department or Services Australia;
(g) any other person employed or engaged (however described) by a person described in paragraph (f) to provide services in connection with the services mentioned in that paragraph.

Finance Minister means the Minister administering the *Public Governance, Performance and Accountability Act 2013*.

friendly society means:

(a) a body that is a friendly society for the purposes of the *Life Insurance Act 1995*; or
(b) a body that is registered or incorporated as a friendly society under a law of a State or Territory; or
(c) a body that is permitted, by a law of a State or Territory, to assume or use the expression ***friendly society***; or
(d) a body that, immediately before the date that is the transfer date for the purposes of the *Financial Sector Reform*

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(Amendments and Transitional Provisions) Act (No. 1) 1999, was registered or incorporated as a friendly society under a law of a State or Territory.

hospital has the meaning given by subsection 121-5(5) of the *Private Health Insurance Act 2007*.

hospital-substitute treatment has the same meaning as in the *Private Health Insurance Act 2007*.

hospital treatment has the meaning given by section 121-5 of the *Private Health Insurance Act 2007*.

medicare program has the same meaning as in the *Human Services (Medicare) Act 1973*.

midwife means a person who is registered as a midwife, or authorised (however described) to practise midwifery, by or under a law of a State or an internal Territory that provides for the registration of midwives, or the authorisation of persons to practise midwifery.

nurse practitioner means a person who is registered, or authorised (however described) to practise, as a nurse practitioner by or under a law of a State or an internal Territory that provides for the registration of nurse practitioners, or the authorisation of persons to practise as nurse practitioners.

pharmacist means a person registered as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists, and includes a friendly society or other body of persons (whether corporate or unincorporate) carrying on business as a pharmacist.

premises includes a part of premises.

private health insurer has the same meaning as in the *Private Health Insurance Act 2007*.

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public hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a public hospital.

public hospital authority means the governing body of a public hospital.

Regulatory Powers Act means the *Regulatory Powers (Standard Provisions) Act 2014*.

relevant Department means any of the following:

(a) the Department administered by the Minister who administers this Act;

(b) the Department administered by the Minister who administers the *Dental Benefits Act 2008*;

(c) the Department administered by the Minister who administers the *Health Insurance Act 1973*;

(d) the Department administered by the Minister who administers the *Human Services (Centrelink) Act 1997*;

(e) the Department administered by the Minister who administers the *Human Services (Medicare) Act 1973*.

rules, in relation to a private health insurer, has the same meaning as in the *Private Health Insurance Act 2007*.

Secretary means the Secretary of the Department.

spouse includes a de facto partner.

Territory means an internal Territory.

use, in relation to information, includes make a record of.

vaccine means a preparation, including a vaccine or immunising agent, that confers protection to persons through active or passive immunity against disease.

Veterans' Affairs Department means the Department administered by the Veterans' Affairs Minister.

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Veterans' Affairs Minister means the Minister administering section 1 of the *Military Rehabilitation and Compensation Act 2004*.

(1A) In this Act, unless the contrary intention appears, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act.

(2) A reference in this Act to a prescription for the supply of a pharmaceutical benefit is a reference to a prescription written in accordance with subsection 88(1), (1A), (1C), (1D) or (1E).

(3) A reference in this Act to the supply of pharmaceutical benefits at premises is a reference to the supply of pharmaceutical benefits to people who are at the premises when the supply is made.

6 Delegation

(1) The Minister may, either generally or as otherwise provided by the instrument of delegation, by writing signed by the Minister, delegate to a person (including the Secretary) all or any of the Minister's powers under this Act, the regulations or another legislative instrument under this Act, other than:

(a) this power of delegation; or

(aa) the Minister's power under subsection 90(10); or

(ab) the Minister's powers under section 90A and subsection 90B(5); or

(b) the Minister's powers under section 95.

(2) A power so delegated under subsection (1), when exercised by the delegate, shall, for the purposes of this Act, the regulations or another legislative instrument under this Act, be deemed to have been exercised by the Minister.

(3) A delegate under subsection (1) is, in the exercise of a power so delegated, subject to the directions (if any) of the Minister.

(4) A delegation under subsection (1) does not prevent the exercise of a power by the Minister.

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(5) The Secretary may, either generally or as otherwise provided by the instrument of delegation, by writing signed by the Secretary, delegate to a person all or any of the Secretary's powers under this Act, the regulations or another legislative instrument under this Act other than:

(a) this power of delegation; or

(b) the Secretary's powers under section 95.

(6) A power so delegated under subsection (5), when exercised by the delegate, shall, for the purposes of this Act, the regulations or another legislative instrument under this Act, be deemed to have been exercised by the Secretary.

(7) A delegate under subsection (5) is, in the exercise of a power so delegated, subject to the directions (if any) of the Secretary.

(8) A delegation under subsection (5) does not prevent the exercise of a power by the Secretary.

(9) The Chief Executive Medicare may, either generally or as otherwise provided by the instrument of delegation, by writing signed by the Chief Executive Medicare, delegate to a person all or any of the Chief Executive Medicare's powers under this Act, the regulations or another legislative instrument under this Act, other than this power of delegation.

(10) A power so delegated under subsection (9), when exercised by the delegate, is, for the purposes of this Act, the regulations or another legislative instrument under this Act, taken to have been exercised by the Chief Executive Medicare.

(11) A delegate under subsection (9) is, in the exercise of a power so delegated, subject to the directions (if any) of the Chief Executive Medicare.

(12) A delegation under subsection (9) does not prevent the exercise of a power by the Chief Executive Medicare.

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6A External Territories

This Act extends to Norfolk Island, to the Territory of Cocos (Keeling) Islands and to the Territory of Christmas Island.

7A Application of the *Criminal Code*

Chapter 2 (other than Part 2.5) of the *Criminal Code* applies to all offences against this Act.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

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Part II—National health services

8 Interpretation

In this Part, ***Territory*** includes an external Territory to which this Act extends.

9 Provision of certain medical and dental services

(1) The Governor-General may provide, or arrange for the provision of:

(a) aerial medical and dental services;

(b) diagnostic and therapeutic services for medical practitioners and hospitals, and for patients of medical practitioners or hospitals;

(c) teaching, research and advisory services in relation to maternal and child health;

(d) teaching, research and advisory services for or in relation to the improvement of health or the prevention of disease; and

(e) anything incidental to a service referred to in paragraph (a), (b), (c) or (d).

(2) The Minister may disseminate information relating to health or the prevention of disease.

9A Provision of medical and surgical aids and appliances etc. by the Commonwealth

(1) The Minister may, on behalf of the Commonwealth, arrange for:

(a) the supply by the Commonwealth of such medical or surgical aids, equipment or appliances as are prescribed to persons who require them;

(b) the making of any modifications to a building, vehicle or equipment that are necessary for the treatment or rehabilitation of a sick or disabled person.

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(2) Subject to the provisions of an arrangement made under subsection 9C(1), a hearing aid, or any other medical or surgical aid, equipment or appliance of a kind prescribed for the purposes of this subsection, that is supplied under this section remains the property of the Commonwealth notwithstanding any purported disposition or pledging of the aid, equipment or appliance by any person.

(3) The Minister may impose such conditions as the Minister thinks fit on the use or possession of aids, equipment or appliances supplied, or to be supplied, under subsection (1).

(4) The regulations may make provision with respect to the supply of aids, equipment or appliances, or the making of modifications, under subsection (1), including provision for offences with respect to the use or possession of aids, equipment or appliances so supplied.

9B Provision of vaccines

(1) The Minister may provide, or arrange for the provision of:
  (a) designated vaccines; and
  (b) goods or services that are associated with, or incidental to, the provision or administration of designated vaccines.

Designated vaccines

(2) The Minister may, by legislative instrument, determine that a specified vaccine is a ***designated vaccine*** for the purposes of this Act.

Note: For variation and revocation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

(3) A vaccine may be specified by reference to any or all of the following:
  (a) brand;
  (b) formulation;
  (c) active ingredient;

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(d) strength;
(e) number and timing of doses in a course of immunisation.

(4) Subsection (3) does not limit the ways in which a vaccine may be specified.

(5) In addition to specifying a vaccine, a determination under subsection (2) may specify the circumstances in which the vaccine may be provided.

(6) If any such circumstances are specified, subsection (1) only authorises the provision of the vaccine in those circumstances.

(7) A vaccine must not be specified in a determination under subsection (2) unless:
(a) the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that the vaccine be a designated vaccine; or
(b) at any time during the 60-day period ending immediately before the commencement of this subsection, the vaccine was provided under repealed section 9B of this Act.

(8) Before:
(a) revoking a determination under subsection (2); or
(b) varying a determination under subsection (2) in such a way that a vaccine ceases to be a designated vaccine;
the Minister must obtain the written advice of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

(9) An advice under subsection (8) is to be tabled in each House of the Parliament with the revocation or variation to which the advice relates.

(10) This section does not limit the vaccine-related powers that may be exercised by the Minister under the *Biosecurity Act 2015*.

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9C Arrangements with States for provision of surgical aids and appliances etc.

(1) The Minister may, on behalf of the Commonwealth, enter into an arrangement with a State, a Territory or a body corporate established for a public purpose under a law of a State or Territory for and in relation to:

(a) the supply of medical or surgical aids, equipment or appliances prescribed for the purposes of paragraph 9A(1)(a) to persons who require them; and

(b) the making of any modifications to a building, vehicle or equipment that are necessary for the treatment or rehabilitation of a sick or disabled person.

(2) Without limiting the generality of subsection (1), an arrangement entered into under that subsection with a State, a Territory or a body corporate may provide for:

(a) the payment by the Commonwealth of amounts to the State, Territory or body corporate, as the case may be, in connection with the carrying out of the arrangement; and

(b) the transfer to the State, Territory or body corporate, as the case may be, of medical or surgical aids, equipment or appliances owned by the Commonwealth.

(4) An arrangement entered into under subsection (1) may be expressed to have taken effect from a day earlier than the day on which the arrangement was entered into.

10 Arrangements with other Ministers

The Minister may make an arrangement with any other Minister for the performance by that other Minister of a service in connexion with a service, matter or thing for which provision is made by or under this Part.

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11 Arrangements with States

(1) The Governor-General may enter into an arrangement with the Governor of a State or the Administrator of a Territory for the performance by that State or Territory of a service in connexion with a service, matter or thing for which provision is made by or under this Part.

(2) An arrangement entered into under this section may provide for payments by the Commonwealth to the State or Territory in respect of capital expenditure or maintenance expenditure incurred by the State or Territory at the request of the Commonwealth in connexion with the service performed by the State or Territory.

(3) Any arrangement entered into under this section which provides for payments by the Commonwealth to a State or Territory in respect of expenditure referred to in subsection (2) shall provide for information to be supplied to the Minister by such persons, at such times and in such manner and form as the Minister requires.

(4) An arrangement entered into under this section shall provide:

(a) that property the cost of which, or part of the cost of which, has been paid by the Commonwealth to the State or Territory under the arrangement shall not, except with the approval of the Minister, be used otherwise than for the purpose for which the property was acquired; and

(b) for the indemnification of the Commonwealth:

(i) in the event of the acquisition by the Commonwealth of property the cost of which has been paid by the Commonwealth to the State or Territory under the arrangement—against payment by way of compensation for the acquisition of that property; and

(ii) in the event of the acquisition by the Commonwealth of property the cost of which was paid in part by the Commonwealth to the State or Territory under the arrangement—against payment by way of compensation proportionate to the cost so paid.

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Part III—Continence Aids Payment Scheme

12 Continence Aids Payment Scheme

(1) The Minister may, by legislative instrument, formulate a Continence Aids Payment Scheme, under which the Commonwealth makes payments as a contribution towards the cost of buying products that help manage incontinence.

(2) A person who satisfies the eligibility criteria that are stated in the legislative instrument is eligible to participate in the scheme.

(3) Without limiting subsection (1), the legislative instrument may provide for:

(a) applications by persons who want to participate in the scheme; and

(b) the conditions that must be complied with in order for a person to participate in the scheme; and

(c) the amount of the contribution that is payable in each financial year in relation to a person who is participating in the scheme; and

(d) investigations to be conducted in order to ensure that persons who are participating in the scheme are eligible to do so; and

(e) the functions and powers of the Chief Executive Medicare in relation to the scheme.

(4) Without limiting subsection (1), the legislative instrument may provide that applications may be made to the Administrative Review Tribunal for review of decisions made in the exercise of powers conferred by the instrument.

(5) Subsections 14(5) and 15(5) do not, by implication, limit subsection (4) of this section.

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13 Secretary or Chief Executive Medicare may request information

(1) This section applies if the Secretary or Chief Executive Medicare (the ***official***) believes, on reasonable grounds, that a person is capable of giving information that is relevant to deciding:

(a) whether a contribution is payable to a person under the Continence Aids Payment Scheme; or

(b) the amount of a contribution that is payable to a person under the Continence Aids Payment Scheme.

(2) The official may request the person to give the information to the official.

(3) The request:

(a) must be made in writing; and

(b) must state what information must be given to the official; and

(c) may require the information to be verified by statutory declaration; and

(d) must specify a day on or before which the information must be given, which day must be at least 28 days after the day on which the request is made; and

(e) must contain a statement to the effect that a failure to comply with the request is an offence.

(4) The person commits an offence if the person fails to comply with the request.

Penalty: 30 penalty units.

(5) However, an individual is excused from complying with the request if the giving of the information might tend to:

(a) incriminate the individual; or

(b) expose the individual to a penalty.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5). See subsection 13.3(3) of the *Criminal Code*.

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

Note: For strict liability, see section 6.1 of the *Criminal Code*.

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14 Reviewing decision whether applicant is eligible for the scheme

(1) This section applies if the Chief Executive Medicare decides that a person who has applied to participate in the scheme is not eligible to participate in the scheme.

(2) The Chief Executive Medicare must give the person a signed notice that states:

(a) the decision; and

(b) the day when the decision has effect; and

(c) the reasons for the decision; and

(d) that, within 28 days after receiving the notice, the person may apply to the Chief Executive Medicare for a review of the decision; and

(e) how the person may apply for the review.

(3) A person who is aggrieved by the Chief Executive Medicare's decision may apply for a review of the decision in the way stated in the legislative instrument that sets out the scheme.

(4) If an application is made under subsection (3), the Chief Executive Medicare must review the decision and give the person a signed notice that states:

(a) the decision; and

(b) the day when the decision has effect; and

(c) if the decision is that the person is not eligible to participate in the scheme:

(i) the reasons for the decision; and

(ii) that the person may apply to the Administrative Review Tribunal for a review of the Chief Executive Medicare's decision.

(5) An application may be made to the Administrative Review Tribunal for the review of the Chief Executive Medicare's decision mentioned in subsection (4).

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15 Reviewing decision whether participant is eligible for the scheme

(1) This section applies if the Chief Executive Medicare decides that a person who is participating in the scheme is not eligible to participate in the scheme.

(2) The Chief Executive Medicare must give the person a signed notice that states:

(a) the decision; and

(b) the day when the decision has effect; and

(c) the reasons for the decision; and

(d) that, within 28 days after receiving the notice, the person may apply to the Chief Executive Medicare for a review of the decision; and

(e) how the person may apply for the review.

(3) A person who is aggrieved by the Chief Executive Medicare's decision may apply for a review of the decision in the way stated in the legislative instrument that sets out the scheme.

(4) If an application is made under subsection (3), the Chief Executive Medicare must review the decision and give the person a signed notice that states:

(a) the decision; and

(b) the day when the decision has effect; and

(c) if the decision is that the person is not eligible to participate in the scheme:

(i) the reasons for the decision; and

(ii) that the person may apply to the Administrative Review Tribunal for a review of the Chief Executive Medicare's decision.

(5) An application may be made to the Administrative Review Tribunal for the review of the Chief Executive Medicare's decision mentioned in subsection (4).

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Part VII—Pharmaceutical benefits

Division 1—Preliminary

83Z Repeal and saving

(1) The *Pharmaceutical Benefits Act 1947*, the *Pharmaceutical Benefits Act 1949*, the *Pharmaceutical Benefits Act (No. 2) 1949* and the *Pharmaceutical Benefits Act 1952* are repealed.

(2) The National Health (Medicines for Pensioners) Regulations made under the *National Health Service Act 1948–1949* are repealed.

(3) Notwithstanding the repeal effected by subsection (1):

(a) where immediately before the commencement of this Part, a person or body was under the *Pharmaceutical Benefits Act 1947–1952*:

(i) an approved pharmaceutical chemist approved in respect of one or more premises;

(ii) an approved medical practitioner approved in respect of an area; or

(iii) an approved hospital authority approved in respect of one or more hospitals;

that person or body shall be deemed to be an approved pharmacist in respect of those premises, an approved medical practitioner in respect of that area or an approved hospital authority in respect of that hospital or those hospitals under section 90, 92 or 94, as the case requires, and the provisions of this Act apply to and in relation to that person or body accordingly; and

(b) a special arrangement made in pursuance of section 15 of the *Pharmaceutical Benefits Act 1947–1952* which was in force immediately before the commencement of this Part shall continue in force as if made in pursuance of section 100.

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(4) The reference in subparagraph (3)(a)(i) to an approved pharmaceutical chemist includes a reference to a person who:

(a) owned, or was about to own, a business for the supply of pharmaceutical benefits at or from particular premises; and

(b) was purportedly approved under the *Pharmaceutical Benefits Act 1947–1952* as an approved pharmaceutical chemist.

84 Interpretation

(1) In this Part, unless the contrary intention appears:

12.5% price reduction: see subsection 99ACA(2).

16% price reduction: see subsection 99ACA(2A).

25% price reduction: see subsection 99ACA(2B).

ACSS eligible supply (short for additional community supply support payment eligible supply): a supply of a pharmaceutical benefit is an ***ACSS eligible supply*** if the supply is of a kind determined under subparagraph 98B(1)(b)(i).

ACSS payment (short for additional community supply support payment), for an ACSS eligible supply, means the amount for that supply determined under, or worked out in the manner determined under, subparagraph 98B(1)(b)(ii).

additional member means an additional member of the Tribunal.

agreed price means the amount in force under a price agreement.

allowable discount, for a supply of a pharmaceutical benefit, has the meaning given by subsection 87(2AAAA).

applicable amount has the meaning given by subsection 84BA(4).

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approved ex-manufacturer price of a listed brand of a pharmaceutical item means:

(a) if a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item; or

(b) if a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item.

Note: See also section 85BA (effect of deemed reductions of, or increases to, the approved ex-manufacturer price).

approved hospital authority means a hospital authority for the time being approved, or deemed to be approved, under section 94.

approved medical practitioner means a medical practitioner for the time being approved, or deemed to be approved, under section 92.

approved pharmacist means a person for the time being approved under section 90 and includes:

(a) a person treated as having been so approved under any provision of a law of the Commonwealth other than section 91 or 91B; and

(b) except so far as subsection 90(3) is concerned—a person treated as having been so approved under section 91 or 91B.

approved supplier means an approved pharmacist, an approved medical practitioner or an approved hospital authority.

authorised midwife means an eligible midwife in relation to whom an approval is in force under section 84AAF.

authorised nurse practitioner means an eligible nurse practitioner in relation to whom an approval is in force under section 84AAJ.

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authorised optometrist means an optometrist in relation to whom an approval is in force under section 84AAB.

Authority means the Australian Community Pharmacy Authority established under section 99J.

brand of a pharmaceutical item means:

(a) the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or

(b) if there is no trade name—the name of the person who is or will be the responsible person.

Chairperson means the Chairperson of the Tribunal.

child, in relation to a member of a friendly society, means:

(a) a child under the age of 16 years of that member; or

(b) a child of that member who:

(i) has attained the age of 16 years;

(ii) is receiving full-time education at a school, college or university;

(iii) is wholly or substantially dependent on that member or on the spouse of that member; and

(iv) is a person who is to be treated as a child of that member in accordance with the rules of the friendly society.

Note: See also subsection (3B).

claimed price means the amount specified in a determination in force under subsection 85B(3).

co-marketed brands has the meaning given by section 84AE.

combination item means a pharmaceutical item that has a drug that contains at least 2 other drugs or medicinal preparations, at least one of which is a listed drug.

combination item has a drug: see subsection 84ABA(2).

Commonwealth officer means:

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(a) the Governor-General; or

Note: See also section 16A of the *Acts Interpretation Act 1901*.

(b) a Minister; or

(c) a member of the Parliament of the Commonwealth; or

(e) a person who is in the employment of the Commonwealth; or

(f) a person who holds or performs the duties of any office or position established by or under a law of the Commonwealth; or

(g) a member of the Australian Defence Force; or

(h) the Commissioner of the Australian Federal Police, a Deputy Commissioner of the Australian Federal Police, an AFP employee, a special member or a special protective service officer (all within the meaning of the *Australian Federal Police Act 1979*).

Commonwealth price means:

(a) in relation to a pharmaceutical benefit supplied by an approved pharmacist—the Commonwealth price for the particular quantity or number of units of the pharmaceutical benefit worked out in accordance with a determination in force under paragraph 98B(1)(a); or

(b) in relation to a pharmaceutical benefit supplied by an approved medical practitioner—the Commonwealth price for the particular quantity or number of units of the pharmaceutical benefit worked out in accordance with a determination in force under subsection 98C(1); or

(c) in relation to a pharmaceutical benefit supplied by an approved hospital authority to a patient receiving treatment in or at a hospital in respect of which the authority is approved—the amount of the payment to which the authority is entitled under subsection 99(4) in respect of the supply of the particular quantity or number of units of the pharmaceutical benefit.

communicated, in relation to a prescription, means communicated directly or indirectly.

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communicated prescription means a prescription that is communicated to an approved pharmacist in the circumstances and manner set out in regulations made for the purposes of paragraph 89(a).

concessional beneficiary means:

(a) a person who is the holder of a pensioner concession card, a seniors health card or a health care card under the *Social Security Act 1991*; or

(b) a person (other than the holder of the card) whose name is included in a card referred to in paragraph (a); or

(c) a person:

(i) who is an Australian resident within the meaning of the *Health Insurance Act 1973*; and

(ii) who is eligible for fringe benefits under section 53A of the *Veterans' Entitlements Act 1986*; or

(d) a person who is:

(i) an Australian resident within the meaning of the *Health Insurance Act 1973*; and

(ii) eligible, under subsection 86(1), (2) or (3) of the *Veterans' Entitlements Act 1986*, to be provided with treatment under Part V of the last-mentioned Act; or

(da) a person who is:

(i) an Australian resident within the meaning of the *Health Insurance Act 1973*; and

(ii) entitled to treatment under section 284 of the *Military Rehabilitation and Compensation Act 2004*; or

(e) a person who is:

(i) an Australian resident within the meaning of the *Health Insurance Act 1973*; and

(ii) the holder of a seniors health card within the meaning of the *Veterans' Entitlements Act 1986*.

Note: See also subsection (3C) (effect of a person's death on status as a concessional beneficiary).

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concessional benefit prescription means a prescription that, in accordance with section 84AA, is a prescription in respect of a concessional beneficiary or of a person who, in relation to the concessional beneficiary, is a dependant within the meaning of subsection (4) or (7).

concession card means a safety net concession card issued under section 84DA and includes an additional concession card, or a replacement concession card, issued under section 84H.

concession card prescription means a prescription that, in accordance with section 84AA, is a prescription for the supply of a pharmaceutical benefit to a person who is a holder of a concession card.

CTS claim means a claim made to the Chief Executive Medicare using the procedures of the Claims Transmission System provided for in section 99AAA.

dependant has the meaning given by subsections (4) and (7).

Note: See also subsection (7A) (effect of a person's death on status as a dependant of a concessional beneficiary).

determined price means the amount specified in a determination in force under subsection 85B(2).

determined quantity of a listed brand of a pharmaceutical item: see subsection 84AK(3).

drug in a combination item means the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item that is the combination item.

drug in a pharmaceutical item means the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item.

drug is on F1 has the meaning given by section 84AC.

drug is on F2 has the meaning given by section 84AC.

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early supply of a specified pharmaceutical benefit has the meaning given by subsection 84AAA(1).

eligible for increased discounting: see section 87AA.

eligible midwife has the meaning given by section 84AAE.

eligible nurse practitioner has the meaning given by section 84AAI.

entitlement card means a pharmaceutical benefits entitlement card issued under section 84E and includes an additional entitlement card, or a replacement entitlement card, issued under section 84H.

entitlement card prescription means a prescription that, in accordance with section 84AA, is a prescription for the supply of a pharmaceutical benefit to a person who is a holder of an entitlement card.

exempt item means a pharmaceutical item determined by the Minister under section 84AH to be an exempt item.

expiry date, in relation to a medicare number, means:

(a) if the number is recorded on a medicare card that specifies a particular date on which the card expires—that date; and

(b) if the number is recorded on a medicare card that does not specify a particular date on which the card expires but that has recorded on it the month at the end of which the card expires—the last day of that month; and

(c) if the number is not of a kind referred to in paragraph (a) or (b)—such date as the Minister specifies, in writing, in respect of the number.

friendly society body means a body (whether corporate or unincorporate) carrying on business for the benefit of members of a friendly society or friendly societies.

general benefit prescription means a prescription other than:

(b) a concessional benefit prescription; or

(c) an entitlement card prescription; or

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(d) a concession card prescription.

general patient means a person who is an eligible person within the meaning of the *Health Insurance Act 1973*, but who is not a concessional beneficiary.

general patient charge amount means $25.00.

Note: The figure in this definition is adjusted annually under section 99G.

hospital means premises in which patients are received and lodged for the purpose of hospital treatment.

hospital authority means the governing body of a public hospital or the proprietor of a private hospital.

listed brand of a pharmaceutical item means a brand of the pharmaceutical item in relation to which a determination under subsection 85(6) is in force.

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

medicare card means:

(a) a card issued by the Chief Executive Medicare and commonly known as a medicare card; or

(b) a card or written authorisation provided to a person that evidences a person's eligibility for pharmaceutical benefits under:

(i) the scheme known as the Repatriation Pharmaceutical Benefits Scheme established under the *Veterans' Entitlements Act 1986*; or

(ii) a scheme that applies under section 18 of the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006*; or

(iii) a scheme that applies under section 20 of the *Treatment Benefits (Special Access) Act 2019*; or

(c) any other card that is prescribed for the purposes of this definition.

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medicare number means:

(a) in relation to a particular person covered by a medicare card—the particular combination of numbers, or letters and numbers, on the card that is applicable only to that person as a person covered by that card; and

(b) in relation to a person who the Chief Executive Medicare is satisfied is, or is entitled to be treated as, an eligible person within the meaning of the *Health Insurance Act 1973* but who is not covered by a medicare card—the particular combination of numbers, or letters and numbers, that would be applicable to that person if that person were covered by a medicare card.

member means a member of the Tribunal, and includes the Chairperson.

nurse practitioner treatment, in relation to a nurse practitioner, means treatment that the nurse practitioner is authorised (however described) to provide under a law of a State or an internal Territory.

optometrist means a person registered or licensed as an optometrist or optician under a law of a State or an internal Territory that provides for the registration or licensing of optometrists or opticians.

out-patient medication means a drug or medicinal preparation supplied through the out-patient department of a public hospital.

pack quantity of a listed brand of a pharmaceutical item: see subsection 84AK(2).

participating dental practitioner means a dental practitioner in relation to whom an approval is in force under section 84A.

PBS prescriber means:

(a) a medical practitioner; or

(b) a participating dental practitioner; or

(c) an authorised optometrist; or

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(d) an authorised midwife; or
(e) an authorised nurse practitioner.

pharmaceutical benefit means the following:
(a) if a declaration under subsection 85(2) is in force in relation to a drug or medicinal preparation (the ***drug***) and paragraph (b), (c) and (d) do not apply—the drug;
(b) if a determination under subsection 85(3) is in force in relation to a form of the drug and paragraph (c) and (d) do not apply—the drug in that form;
(c) if a determination under subsection 85(5) is in force in relation to a manner of administration of that form of the drug and paragraph (d) does not apply—the drug in that form with that manner of administration;
(d) if a determination under subsection 85(6) is in force in relation to a brand of a pharmaceutical item that is the drug in that form with that manner of administration—that brand of the drug in that form with that manner of administration.

pharmaceutical benefit has a drug: see subsection 84ABA(3).

pharmaceutical item has the meaning given by section 84AB.

pharmaceutical item has a drug: see subsection 84ABA(1).

prescriber bag provisions means the following:
(a) section 93 (supplies by medical practitioners);
(b) section 93AA (supplies by authorised midwives);
(c) section 93AB (supplies by authorised nurse practitioners).

price agreement means an agreement under section 85AD.

price determination means a determination under subsection 85B(2).

pricing quantity of a listed brand of a pharmaceutical item: see subsection 84AK(1).

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proportional ex-manufacturer price of a listed brand of a pharmaceutical item: see section 85D.

record form means a pharmaceutical benefits prescription record form, or an out-patient medication prescription record form, issued under section 84D.

refund agreement means an agreement or arrangement under which a payment may be made by or at the direction of a person to another person in the event of the other person being charged an amount in respect of the supply of a pharmaceutical benefit.

relevant entitlement period means:

(a) in the application of this Part before 1 January 1992:
  (i) in relation to a pensioner—the period commencing on 1 November 1990 and ending on 31 December 1991; or
  (ii) in relation to any other person—the year commencing on 1 January 1990 or 1 January 1991; or
(b) in the application of this Part on or after 1 January 1992:
  (i) the year commencing on 1 January 1992; or
  (ii) a succeeding year.

relevant price: see subsection 99ACF(5).

repatriation pharmaceutical benefit means a pharmaceutical benefit within the meaning of:

(a) section 91 of the *Veterans' Entitlements Act 1986*; or
(b) subsection 4(1) of the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006*; or
(c) subsection 5(1) of the *Treatment Benefits (Special Access) Act 2019*.

responsible person for a brand of a pharmaceutical item means the person determined by the Minister under section 84AF to be the responsible person for the brand of the pharmaceutical item.

Schedule equivalent has the meaning given by section 84AJ.

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special number, in relation to a particular person who is included within a class of persons identified by the Minister in a determination under subsection 86E(1)—the particular combination of numbers, or letters and numbers, allocated in accordance with a procedure set out in that determination, that is applicable to that person as a person included in that class.

special patient contribution has the meaning given by subsection 85B(5).

State or Territory officer means:

(a) the Governor of a State; or

Note: See also section 16B of the *Acts Interpretation Act 1901*.

(b) the Administrator, an Acting Administrator, or a Deputy Administrator, of the Northern Territory; or

(c) a Minister of a State, a Minister for the Australian Capital Territory or a Minister of the Northern Territory; or

(d) a member of the Parliament of a State, a member of the Legislative Assembly for the Australian Capital Territory or a member of the Legislative Assembly of the Northern Territory; or

(e) a person who is in the employment of a State or Territory; or

(f) a person who holds or performs the duties of any office or position established by or under a law of a State or Territory; or

(g) a member of the police force or police service of a State or Territory.

Territory includes an external Territory to which this Act extends.

therapeutic group means a therapeutic group determined by the Minister under section 84AG.

Tribunal means the Pharmaceutical Benefits Remuneration Tribunal established by section 98A.

value for safety net purposes means:

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(a) for the supply of a pharmaceutical benefit—the amount prescribed by regulations made for the purposes of subsection 84C(1E); and

(b) for the supply of a repatriation benefit—the amount charged for the supply; and

(c) for the supply of out-patient medication—the applicable amount in relation to the supply.

(1A) Where a refund agreement was entered into before 24 April 1964, and, on or after that date:

(a) the agreement was or is renewed on or before the date on which it would, but for that renewal, have expired;

(b) the period of operation of the agreement was or is extended on or before the date on which it would, but for that extension, have expired; or

(c) the rights and obligations under the agreement of the party by or at whose direction payments may be made under the agreement were or are transferred to another person;

the renewal, extension or transfer shall, for the purposes of this Act, be deemed not to have been or to be an entering into a new agreement.

(1B) If:

(a) a prescription directs a repeated supply of a pharmaceutical benefit (the ***specified benefit***); and

(b) another pharmaceutical benefit (the ***supplied benefit***) is supplied, on the repeated supply, in accordance with subsection 103(2A);

then, for the purposes of determining whether a repeated supply of the specified benefit has occurred, the supplied benefit is taken to be the repeated supply, upon the prescription, of the specified benefit.

(2) In this Part, a reference to the supply, obtaining or receipt of a pharmaceutical benefit shall, unless the contrary intention appears, be read as a reference to the supply, obtaining or receipt of that pharmaceutical benefit under this Part.

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(2A) A reference in this Part to a prescription for the supply of a pharmaceutical benefit to a person who is a holder of a concession card or an entitlement card is a reference to a prescription for the supply of a pharmaceutical benefit to a person who is, at the time when the prescription is written or communicated, or becomes, after the prescription is written or communicated and before the benefit is supplied upon the prescription, a holder of a concession card or an entitlement card.

(3) If the Minister so determines, the Minister of State of a State administering the laws of that State relating to public hospitals shall, for the purposes of this Part, be deemed to be the governing body of the public hospitals in that State.

(3A) A reference in this Part to the governing body, in relation to a public hospital in the Territory of Cocos (Keeling) Islands or the Territory of Christmas Island, shall be read as a reference to the Administrator of the relevant Territory.

(3AA) A reference in this Part to the governing body, in relation to a public hospital on Norfolk Island, is a reference to the person or body specified in the regulations.

(3B) A reference in the definition of ***child*** in subsection (1) to a child of a member includes a reference to:

(a) an adoptive child or a stepchild of the person; and

(b) someone who would be the stepchild of the person except that the person is not legally married to the person's de facto partner; and

(c) someone who is a child of the person within the meaning of the *Family Law Act 1975*.

(3C) If a person would have been a concessional beneficiary at a particular time on a day except that the person died on that day then, despite that death, the person is taken still to be a concessional beneficiary at that time (whether that time is before or after the time of death).

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(4) A ***dependant***, in relation to a person to whom paragraph (c) or (d) of the definition of ***concessional beneficiary*** applies, is a person who is an Australian resident within the meaning of the *Health Insurance Act 1973* and:

(a) the spouse of the person; or

(b) a child under the age of 16 years who is in the custody, care and control of the person or the spouse of the person; or

(c) a person who:

(i) has attained the age of 16 years but is under the age of 25 years; and

(ii) is receiving full time education at a school, college or university; and

(iii) is not being paid a disability support pension under the *Social Security Act 1991*; and

(iv) is wholly or substantially dependent on the person or on the spouse of the person.

(7) For the purposes of this Part, if:

(a) paragraph (e) of the definition of ***concessional beneficiary*** applies to a person (the ***seniors health card holder***); and

(b) no other paragraph of the definition of ***concessional beneficiary*** applies to the seniors health card holder;

a person who, apart from this subsection, would be a dependant of the seniors health card holder is taken not to be a dependant of the seniors health card holder.

Note: A person who is the holder of a seniors health card within the meaning of the *Veterans' Entitlements Act 1986* is a person to whom paragraph (e) of the definition of ***concessional beneficiary*** applies.

(7A) If a person (the ***relevant person***) would have been a dependant of a concessional beneficiary at a particular time on a day except that:

(a) the relevant person died on that day; or

(b) the concessional beneficiary died on that day;

then, despite that death, the relevant person is taken still to be a dependant of a concessional beneficiary at that time (whether that time is before or after the time of death).

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(8) A reference in this Part to the provision to a person or body of a medicare number as a number applicable to a particular individual is a reference to:

(a) the production to that person or body of a medicare card having on it a medicare number as a number applicable to that particular individual; or

(b) the provision to that person or body of any other information, whether documentary or oral, that indicates a medicare number as a number applicable to that particular individual.

(9) A reference in this Part to the provision to a person or body of the expiry date in relation to a medicare number provided as a number applicable to a particular individual is a reference to:

(a) the production to the person or body of a medicare card that indicates the expiry date in relation to that medicare number; or

(b) the provision to the person or body of any other information, whether documentary or oral, that indicates the expiry date in relation to that medicare number.

(10) A reference in this Part to a medicare number, or a special number, ultimately supplied to the Chief Executive Medicare in relation to a prescription, is a reference to:

(a) if the number is not inserted in a CTS claim relating to that prescription—the number in the form in which it appears on the prescription (or in the case of a communicated prescription, the written version of the prescription), at the time when the prescription is sent to the Chief Executive Medicare by an approved supplier with a claim for payment; or

(b) if that number is inserted in a CTS claim relating to the prescription—the number so inserted.

84AAA Early supply of a specified pharmaceutical benefit

(1) A supply of a pharmaceutical benefit to a person is an ***early supply of a specified pharmaceutical benefit*** if:

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(a) the pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection (2); and

(b) the supply of the pharmaceutical benefit is made within the period specified in an instrument under subsection (2) following a previous supply to the person of:

(i) the pharmaceutical benefit; or

(ii) another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit; or

(iii) another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit; and

(c) the supply does not result from a prescription originating from a hospital.

Note: For ***hospital*** see subsection 4(1).

(2) The Minister may, by legislative instrument, specify:

(a) pharmaceutical items for the purposes of paragraph (1)(a); and

(b) periods following previous supply for the purposes of paragraph (1)(b).

(3) A pharmaceutical item may be specified in an instrument under subsection (2) by reference to:

(a) the circumstances in which a pharmaceutical benefit that has the pharmaceutical item is supplied; or

(b) any other circumstances in relation to a pharmaceutical benefit that has the pharmaceutical item.

(4) In this section, a reference to a pharmaceutical benefit includes a reference to a repatriation pharmaceutical benefit.

84AA Concessional benefit prescriptions, concession card prescriptions and entitlement card prescriptions

(1) A prescription that is written by a PBS prescriber in accordance with the Act and the regulations shall not be taken, for the purposes of this Part, to be a prescription in respect of a concessional beneficiary or a person who, in relation to a concessional

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beneficiary, is a dependant of the beneficiary within the meaning of subsection 84(4) or (7) unless there is written or marked on the prescription, or there purports to be written or marked on the prescription, in such manner as is prescribed by regulations made for the purposes of this subsection, such information relating to the status of the person to whom the prescription relates as such a concessional beneficiary or dependant as is prescribed by those last-mentioned regulations in relation to persons having that status.

(1A) A prescription that is written by a PBS prescriber in accordance with this Act and the regulations shall not be taken, for the purposes of this Part, to be a prescription for the supply of a pharmaceutical benefit to a person who is a holder of a concession card or an entitlement card unless there is written or marked on the prescription, or there purports to be written or marked on the prescription, in such a manner as is prescribed by regulations made for the purposes of this subsection, such information relating to the status of the person to whom the prescription relates as a holder of a concession card or an entitlement card as is prescribed by those last-mentioned regulations.

(2) A prescription that is communicated to an approved pharmacist in pursuance of paragraph 89(a) in such circumstances as are prescribed for the purposes of that paragraph shall not be taken, for the purposes of this Part, to be a prescription in respect of a concessional beneficiary or a person who, in relation to a concessional beneficiary, is a dependant of the beneficiary within the meaning of subsection 84(4) or (7) unless, before supply of the pharmaceutical benefit upon that prescription, there is communicated, or there is purportedly communicated, to the pharmacist, in such manner as is prescribed by regulations made for the purposes of this subsection, such information relating to the status of the person to whom the prescription relates as such a concessional beneficiary or dependant as is prescribed by those last-mentioned regulations in relation to persons having that status.

(3) A prescription that is communicated to an approved pharmacist in pursuance of paragraph 89(a) in such circumstances as are prescribed for the purposes of that paragraph shall not be taken, for

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the purposes of this Part, to be a prescription for the supply of a pharmaceutical benefit to a person who is a holder of a concession card or an entitlement card unless, before supply of the benefit upon that prescription, there is communicated, or there is purportedly communicated, to the pharmacist, in such manner as is prescribed by regulations made for the purposes of this subsection, such information relating to the status of the person to whom the prescription relates as a holder of a concession card or an entitlement card as is prescribed by those last-mentioned regulations.

(4) Nothing in subsection (1), (1A), (2) or (3) shall be read as derogating from subsection 87(3A).

84A Participating dental practitioners

(1) A dental practitioner may give to the Secretary a notification, in writing, that the dental practitioner wishes to become a participating dental practitioner for the purposes of this Part.

(2) Where the Secretary receives a notification under subsection (1), the Secretary shall, by writing signed by the Secretary, approve the dental practitioner concerned as a participating dental practitioner for the purposes of this Part.

(3) The Secretary shall notify the dental practitioner concerned of the dental practitioner's approval under this section.

84AAB Authorised optometrists

(1) An optometrist may apply to the Secretary, in writing, to be an authorised optometrist for the purposes of this Part.

(2) The Secretary may approve the application if satisfied that the optometrist meets the criteria determined under paragraph (3)(a). The approval is subject to any conditions determined under paragraph (3)(b).

(3) The Minister may, by legislative instrument, determine either or both of the following:

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(a) criteria by which applications are to be considered under this section;

(b) conditions to which approvals under this section are subject.

(4) The Secretary must, as soon as is practicable, approve or reject an application under subsection (1) and notify the applicant in writing of the decision.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

84AAC Secretary may suspend or revoke approval of authorised optometrist

(1) The Secretary may suspend or revoke an approval under section 84AAB if satisfied that the optometrist to whom the approval relates:

(a) does not, at the time of the suspension or revocation, meet the criteria that would apply if the optometrist were to apply under subsection 84AAB(1) to be an authorised optometrist at that time; or

(b) has breached a condition to which the approval is subject under paragraph 84AAB(3)(b); or

(c) has breached a condition to which an approval would be subject under paragraph 84AAB(3)(b) if the person were to apply under subsection 84AAB(1) to be an authorised optometrist at that time.

(2) Before deciding to suspend or revoke the approval, the Secretary must notify the optometrist that suspension or revocation is being considered. The notice must:

(a) be in writing; and

(b) include the Secretary's reasons for considering the suspension or revocation; and

(c) invite the optometrist to make written submission to the Secretary within the period of 28 days (the ***submission period***) after being given the notice.

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(3) In deciding whether to suspend or revoke the approval, the Secretary must consider any written submissions made by the optometrist during the submission period.

(4) The Secretary must give to the optometrist written notice of the decision. If the decision is to suspend an approval, the notice must specify the period for which the approval is suspended.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

(5) If the Secretary does not give the optometrist written notice of the decision within the period of 60 days after the end of the submission period, the Secretary is taken to have decided not to suspend or revoke the approval.

(6) If the Secretary suspends the approval, the Secretary may, by written notice at any time, further suspend or revoke the approval under subsection (1) or remove the suspension.

84AAD Review of decisions relating to authorised optometrists

(1) If the Secretary:

(a) decides not to approve an optometrist under section 84AAB; or

(b) suspends or revokes the approval of an optometrist under section 84AAC;

the optometrist may apply, in writing, to the Secretary for reconsideration by the Secretary of the decision.

(2) On receiving an application under subsection (1) relating to a decision not to approve an optometrist under section 84AAB, the Secretary must reconsider the decision and:

(a) affirm the decision; or

(b) approve the optometrist.

An approval under paragraph (b) is taken, for the purposes of this Act, to be an approval under section 84AAB.

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(3) On receiving an application under subsection (1) relating to a suspension or revocation of the approval of an optometrist under section 84AAC, the Secretary must reconsider the decision and:

(a) affirm the suspension or revocation; or

(b) reinstate the approval of the optometrist.

A reinstatement under paragraph (b) has effect as if the approval had never been revoked.

(4) The Secretary must give to the applicant written notice of the Secretary's decision under subsection (2) or (3).

Note: Sections 105AC of this Act and 266 of the *Administrative Review Tribunal Act 2024* require the person to be notified of the person's review rights.

(5) In this section:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024*.

84AAE Meaning of *eligible midwife*

(1) For the purposes of this Part, a person is an ***eligible midwife*** if the person:

(a) is a midwife; and

(b) meets the requirements set out in a determination made under subsection (3).

(2) However, if there is no determination in force under subsection (3), a person cannot be an ***eligible midwife*** for the purposes of this Part.

(3) The Minister may, by legislative instrument, determine one or more requirements that a specified person must meet in order to be an ***eligible midwife*** for the purposes of this Part.

(4) The requirements that may be determined under subsection (3), include (but are not limited to) one or more of the following:

(a) a requirement to hold particular qualifications in midwifery;

(b) a requirement to have particular experience in midwifery;

(c) a requirement to be credentialled by a particular body.

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84AAF Authorised midwives

(1) An eligible midwife may apply to the Secretary, in writing, to be an authorised midwife for the purposes of this Part.

(2) The Secretary may approve the application if satisfied that the eligible midwife meets the criteria determined under paragraph (3)(a). The approval is subject to any conditions determined under paragraph (3)(b).

(3) The Minister may, by legislative instrument, determine either or both of the following:
  (a) criteria by which applications are to be considered under this section;
  (b) conditions to which approvals under this section are subject.

(4) The Secretary must, as soon as is practicable, approve or reject an application under subsection (1) and notify the applicant in writing of the decision.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

84AAG Secretary may suspend or revoke approval of authorised midwife

(1) The Secretary may suspend or revoke an approval under section 84AAF if satisfied that the person to whom the approval relates:
  (a) is not, at the time of the suspension or revocation, an eligible midwife; or
  (b) does not, at the time of the suspension or revocation, meet the criteria that would apply if the person were to apply under subsection 84AAF(1) to be an authorised midwife at that time; or
  (c) has breached a condition to which the approval is subject under paragraph 84AAF(3)(b); or
  (d) has breached a condition to which an approval would be subject under paragraph 84AAF(3)(b) if the person were to

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apply under subsection 84AAF(1) to be an authorised midwife at that time.

(2) Before deciding to suspend or revoke the approval, the Secretary must notify the person that suspension or revocation is being considered. The notice must:
  (a) be in writing; and
  (b) include the Secretary's reasons for considering the suspension or revocation; and
  (c) invite the person to make written submissions to the Secretary within the period of 28 days (the ***submission period***) after being given the notice.

(3) In deciding whether to suspend or revoke the approval, the Secretary must consider any written submissions made by the person during the submission period.

(4) The Secretary must give to the person written notice of the decision. If the decision is to suspend an approval, the notice must specify the period for which the approval is suspended.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

(5) If the Secretary does not give the person written notice of the decision within the period of 60 days after the end of the submission period, the Secretary is taken to have decided not to suspend or revoke the approval.

(6) If the Secretary suspends the approval, the Secretary may, by written notice at any time, further suspend or revoke the approval under subsection (1) or remove the suspension.

84AAH Review of decisions relating to authorised midwives

(1) If the Secretary:
  (a) decides not to approve an eligible midwife under section 84AAF; or
  (b) suspends or revokes an approval under section 84AAG;

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the person to whom the approval relates may apply, in writing, to the Secretary for reconsideration by the Secretary of the decision.

(2) On receiving an application under subsection (1) relating to a decision not to approve an eligible midwife under section 84AAF, the Secretary must reconsider the decision and:

(a) affirm the decision; or

(b) approve the eligible midwife.

An approval under paragraph (b) is taken, for the purposes of this Act, to be an approval under section 84AAF.

(3) On receiving an application under subsection (1) relating to a suspension or revocation of an approval under section 84AAG, the Secretary must reconsider the decision and:

(a) affirm the suspension or revocation; or

(b) reinstate the approval.

A reinstatement under paragraph (b) has effect as if the approval had never been revoked.

(4) The Secretary must give to the applicant written notice of the Secretary's decision under subsection (2) or (3).

Note: Sections 105AC of this Act and 266 of the *Administrative Review Tribunal Act 2024* require the person to be notified of the person's review rights.

(5) In this section:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024*.

84AAI Meaning of *eligible nurse practitioner*

(1) For the purposes of this Part, a person is an ***eligible nurse practitioner*** if the person:

(a) is a nurse practitioner; and

(b) meets the requirements (if any) set out in a determination made under subsection (2).

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(2) The Minister may, by legislative instrument, determine one or more requirements that a specified person must meet in order to be an ***eligible nurse practitioner*** for the purposes of this Part.

84AAJ Authorised nurse practitioners

(1) An eligible nurse practitioner may apply to the Secretary, in writing, to be an authorised nurse practitioner for the purposes of this Part.

(2) The Secretary may approve the application if satisfied that the eligible nurse practitioner meets the criteria determined under paragraph (3)(a). The approval is subject to any conditions determined under paragraph (3)(b).

(3) The Minister may, by legislative instrument, determine either or both of the following:
   (a) criteria by which applications are to be considered under this section;
   (b) conditions to which approvals under this section are subject.

(4) The Secretary must, as soon as is practicable, approve or reject an application under subsection (1) and notify the applicant in writing of the decision.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

84AAK Secretary may suspend or revoke approval of authorised nurse practitioner

(1) The Secretary may suspend or revoke an approval under section 84AAJ if satisfied that the person to whom the approval relates:
   (a) is not, at the time of the suspension or revocation, an eligible nurse practitioner; or
   (b) does not, at the time of the suspension or revocation, meet the criteria that would apply if the person were to apply

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under subsection 84AAJ(1) to be an authorised nurse practitioner at that time; or

(c) has breached a condition to which the approval is subject under paragraph 84AAJ(3)(b); or

(d) has breached a condition to which an approval would be subject under paragraph 84AAJ(3)(b) if the person were to apply under subsection 84AAJ(1) to be an authorised nurse practitioner at that time.

(2) Before deciding to suspend or revoke the approval, the Secretary must notify the person that suspension or revocation is being considered. The notice must:

(a) be in writing; and

(b) include the Secretary's reasons for considering the suspension or revocation; and

(c) invite the person to make written submissions to the Secretary within the period of 28 days (the ***submission period***) after being given the notice.

(3) In deciding whether to suspend or revoke the approval, the Secretary must consider any written submissions made by the person during the submission period.

(4) The Secretary must give to the person written notice of the decision. If the decision is to suspend an approval, the notice must specify the period for which the approval is suspended.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

(5) If the Secretary does not give the person written notice of the decision within the period of 60 days after the end of the submission period, the Secretary is taken to have decided not to suspend or revoke the approval.

(6) If the Secretary suspends the approval, the Secretary may, by written notice at any time, further suspend or revoke the approval under subsection (1) or remove the suspension.

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84AAL Review of decisions relating to authorised nurse practitioners

(1) If the Secretary:

(a) decides not to approve an eligible nurse practitioner under section 84AAJ; or

(b) suspends or revokes an approval under section 84AAK;

the person to whom the approval relates may apply, in writing, to the Secretary for reconsideration by the Secretary of the decision.

(2) On receiving an application under subsection (1) relating to a decision not to approve an eligible nurse practitioner under section 84AAJ, the Secretary must reconsider the decision and:

(a) affirm the decision; or

(b) approve the eligible nurse practitioner.

An approval under paragraph (b) is taken, for the purposes of this Act, to be an approval under section 84AAJ.

(3) On receiving an application under subsection (1) relating to a suspension or revocation of an approval under section 84AAK, the Secretary must reconsider the decision and:

(a) affirm the suspension or revocation; or

(b) reinstate the approval.

A reinstatement under paragraph (b) has effect as if the approval had never been revoked.

(4) The Secretary must give to the applicant written notice of the Secretary's decision under subsection (2) or (3).

Note: Sections 105AC of this Act and 266 of the *Administrative Review Tribunal Act 2024* require the person to be notified of the person's review rights.

(5) In this section:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024*.

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84AB Pharmaceutical items

If:

(a) a declaration under subsection 85(2) is in force in relation to a drug or medicinal preparation (the ***drug***); and

(b) a determination under subsection 85(3) is in force in relation to a form of the drug; and

(c) a determination under subsection 85(5) is in force in relation to a manner of administration of that form of the drug;

then the drug in that form with that manner of administration is a ***pharmaceutical item***.

84ABA References to pharmaceutical items, combination items or pharmaceutical benefits having a drug

(1) A reference in this Part to a pharmaceutical item having a drug is a reference to the pharmaceutical item having the drug or medicinal preparation referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item.

(2) A reference in this Part to a combination item having a drug is a reference to the combination item having the drug or medicinal preparation referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item that is the combination item.

(3) A reference in this Part to a pharmaceutical benefit having a drug is a reference to the pharmaceutical benefit having the drug or medicinal preparation referred to in paragraph (a) of the definition of ***pharmaceutical benefit*** in subsection 84(1) in relation to the pharmaceutical benefit.

84AC When listed drug is on F1 or F2

F1

(1) A ***drug is on F1*** if there is a determination in force under section 85AB or 99AEJ that the drug is on F1.

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(2) A ***drug is on F1*** if:
  (a) the regulations prescribe that the drug is on F1; and
  (b) there is not a determination under section 85AB in force that the drug is on F2.

F2

(3) A ***drug is on F2*** if there is a determination in force under section 85AB that the drug is on F2.

(4) A ***drug is on F2*** if the regulations prescribe that the drug is on F2.

Regulations

(5) On the day on which this section commences, the regulations may prescribe that a drug or medicinal preparation that is a listed drug on that day is on F1 or F2.

84AE Co-marketed brands

When co-marketed brands are to be treated as one brand

(1) For the purposes of section 85AB, 2 or more brands of a pharmaceutical item that are co-marketed brands of the pharmaceutical item are to be treated as if they were only one brand of the pharmaceutical item.

Meaning of co-marketed brands

(2) 2 or more brands of a pharmaceutical item are ***co-marketed brands*** of the pharmaceutical item if:
  (a) a determination is in force under subsection (3) that the brands are co-marketed brands of the pharmaceutical item; or
  (b) both of the following apply:
    (i) the regulations prescribe under subsection (4) that the brands are co-marketed brands of the pharmaceutical item;

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(ii) there is no determination in force under subsection (3B) that the brands cease to be co-marketed brands of the pharmaceutical item.

Ministerial determination

(3) The Minister may, by legislative instrument, determine that 2 or more brands (the ***co-marketed brands***) of a pharmaceutical item (the ***co-marketed item***) are co-marketed brands of the co-marketed item if the following paragraphs are satisfied:

(a) within 4 months of the first of the co-marketed brands of the co-marketed item being included on the Australian Register of Therapeutic Goods, applications are made to include the other co-marketed brands of the co-marketed item on the Register;

(b) the first determination that is made under subsection 85(6) in relation to a brand of the co-marketed item is made only in relation to the co-marketed brands of the co-marketed item;

(c) each of the co-marketed brands is a listed brand of the co-marketed item;

(d) no other brand is a listed brand of the co-marketed item;

(e) if there is another pharmaceutical item that has the same drug as the co-marketed item:

(i) each of the co-marketed brands is a listed brand of that pharmaceutical item; and

(ii) no other brand is a listed brand of that pharmaceutical item.

(3A) The Minister may, by legislative instrument, vary or revoke a determination under subsection (3) so that all brands (the ***co-marketed brands***) that are co-marketed brands of a pharmaceutical item (the ***co-marketed item***) cease to be co-marketed brands of the co-marketed item if:

(a) any of the co-marketed brands is not a listed brand of the co-marketed item; or

(b) another brand is a listed brand of the co-marketed item; or

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(c) if there is another pharmaceutical item that has the same drug as the co-marketed item:

(i) any of the co-marketed brands is not a listed brand of that pharmaceutical item; or

(ii) another brand is a listed brand of that pharmaceutical item.

(3B) The Minister may, by legislative instrument, determine that all brands (the ***co-marketed brands***) that are prescribed by the regulations as being co-marketed brands of a pharmaceutical item (the ***co-marketed item***) cease to be co-marketed brands of the co-marketed item if:

(a) any of the co-marketed brands is not a listed brand of the co-marketed item; or

(b) another brand is a listed brand of the co-marketed item; or

(c) if there is another pharmaceutical item that has the same drug as the co-marketed item:

(i) any of the co-marketed brands is not a listed brand of that pharmaceutical item; or

(ii) another brand is a listed brand of that pharmaceutical item.

Regulations

(4) For the purposes of paragraph (2)(b), on the day on which this section commences, the regulations may prescribe that 2 or more brands that are listed brands of a pharmaceutical item on that day are co-marketed brands of the pharmaceutical item.

84AF Responsible person for a brand of a pharmaceutical item

(1) The Minister may, by legislative instrument, determine that a person is the responsible person for a brand of a pharmaceutical item if:

(a) the person notified the Minister that the person is or will be the supplier of the brand of the pharmaceutical item to:

(i) wholesalers; or

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(ii) in the case of a supply where wholesalers are not involved—approved pharmacists directly; and

(b) the brand of the pharmaceutical item is a listed brand; and

(c) there is no determination in force under this section that another person is the responsible person for:

(i) the brand of the pharmaceutical item; or

(ii) the brand of any other pharmaceutical item.

(2) The notification referred to in paragraph (1)(a) may be made before or after the commencement of this section.

84AG Therapeutic groups

Determinations

(1) The Minister may, by legislative instrument, determine:

(a) one or more therapeutic groups; and

(b) that 2 or more listed drugs are in the same therapeutic group.

(1A) If the Minister proposes to make a determination under paragraph (1)(a), the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed determination.

(2) A determination for the purposes of paragraph (1)(b) may specify the circumstances in which a listed drug is, or is not, in a therapeutic group.

(3) In making a determination for the purposes of paragraph (1)(b), the Minister may have regard to advice (if any) given (whether before or after the commencement of this section) to the Minister by the Pharmaceutical Benefits Advisory Committee to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.

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(4) If:

(a) either:

(i) section 99ADH has applied to a brand of a pharmaceutical item; or

(ii) the price of the brand of the pharmaceutical item is reduced under 99ADHB; and

(b) the Minister has determined, under paragraph (1)(b), that the drug in the pharmaceutical item is in a therapeutic group;

the Minister must, by legislative instrument, vary the determination to remove the drug from that group with effect on the day that section 99ADH applied to the brand of the pharmaceutical item or the price of the brand of the pharmaceutical item was reduced under section 99ADHB.

(5) Without limiting the powers of the Minister under subsection (1), the Minister may, by legislative instrument, vary a determination to remove a drug from a therapeutic group that contains only 2 drugs. In that case, the group will contain only that remaining drug.

Regulations

(6) On the day on which this section commences, the regulations may prescribe one or more therapeutic groups.

84AH Exempt items

The Minister may, by legislative instrument, determine that a pharmaceutical item (the ***relevant item***) is an ***exempt item*** if:

(a) there is only one listed brand of the relevant item; and

(b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and

(c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and

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(d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:

(i) the listed drug in the relevant item represents suitable therapy for a particular patient population; and

(ii) the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and

(iii) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

84AI Rounding amounts

If an amount worked out under this Part is not a number of whole cents, round the amount to the nearest cent (rounding 0.5 cents upwards).

84AJ When pharmaceutical benefits are Schedule equivalent

A pharmaceutical benefit (the ***first benefit***) is ***Schedule equivalent*** to another pharmaceutical benefit (the ***second benefit***) if the Schedule of Pharmaceutical Benefits referred to in paragraph 103(2A)(b) states that the first benefit and the second benefit are equivalent.

84AK Quantities of pharmaceutical items

Pricing quantity

(1) The ***pricing quantity*** of a listed brand of a pharmaceutical item is the lowest of any pack quantity of any listed brand of the pharmaceutical item.

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Pack quantity

(2) The Minister may, by legislative instrument, determine for a listed brand of a pharmaceutical item that one or more quantities or numbers of units of the pharmaceutical item is a ***pack quantity*** of the brand of the pharmaceutical item.

Determined quantity

(3) The Minister may, by legislative instrument, determine for a listed brand of a pharmaceutical item that one or more quantities or numbers of units of the pharmaceutical item is a ***determined quantity*** of the brand of the pharmaceutical item.

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Division 1A—Safety net concession cards and pharmaceutical benefits entitlement cards

84B Family relationships

(1) For the purposes of this Division, the following are the members of a person's family:
  (a) the person's spouse;
  (b) any dependent child of the person or the person's spouse.

(2) For the purposes of this section, a person who is, at any time during a relevant entitlement period, a dependent child of another person shall be taken to be a dependent child of that other person throughout the remainder of that period.

(3) For the purposes of this section, a person shall not be taken to have the custody of a child unless the person, whether alone or jointly with another person, has the right to have, and to make decisions concerning, the daily care and control of the child.

(4) In this section:

child means a person who:
  (a) is under the age of 16 years; or
  (b) is a student child.

dependent child, in relation to a person, means:
  (a) a child under the age of 16 years who is:
    (i) in the custody, care and control of the person; or
    (ii) where no other person has the custody, care and control of the child—is wholly or substantially in the care and control of the person; or
  (b) a student child who is wholly or substantially dependent on the person.

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spouse, in relation to a person, means:

(a) a person who is legally married to, and is not living, on a permanent basis, separately and apart from, that person; and

(b) a de facto partner of the person within the meaning of paragraph (a) of the definition of ***de facto partner*** in subsection 4(1), who is not living, on a permanent basis, separately and apart from the person;

(c) a de facto partner of the person within the meaning of paragraph (b) of the definition of ***de facto partner*** in subsection 4(1).

student child means a person who:

(a) has attained the age of 16 years but has not attained the age of 25 years; and

(b) is receiving full-time education at a school, college or university.

(5) For the purposes of the definition of ***spouse*** in subsection (4):

(a) a person who is the spouse of another person (the ***person's partner***) under paragraph (a) or (b) of the definition is not taken to be living separately and apart from the person's partner on a permanent basis, if the person is living apart from the person's partner only because of the illness or infirmity of either or both of them; and

(b) a person who is the spouse of another person (the ***person's partner***) under paragraph (c) of the definition is not taken to have ceased to live with the person's partner on a de facto basis, if the person is living apart from the person's partner only because of the illness or infirmity of either or both of them.

84BA Supplies of out-patient medication

(1) The purpose of this section is to make provision so that account may be taken of payments made by a person to a public hospital authority for supplies of out-patient medication when it is being ascertained, for the purposes of this Part, whether the person is eligible to be issued with a concession card or an entitlement card.

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(2) Before the beginning of a relevant entitlement period, the Minister must determine in writing the amounts that, for the purposes of this Part, will be taken to have been paid to a public hospital for supplies of out-patient medication made, against payment, by the hospital during the relevant entitlement period.

(3) In making a determination, the Minister may determine:

(a) different amounts in respect of a supply of out-patient medication, having regard to the State or Territory in which the hospital supplying the medication is situated; and

(b) different amounts in respect of:

(i) supplies made to concessional beneficiaries and persons who, in relation to concessional beneficiaries, are dependants within the meaning of subsection 84(4) or (7); and

(ii) supplies made to holders of a concession card; and

(iii) supplies made to general patients other than holders of a concession card.

(4) In this Part:

applicable amount, in relation to a supply of out-patient medication made by a public hospital to a person during a relevant entitlement period, means the amount that, under the determination applicable for that period, is to be taken to have been paid to the hospital for the supply of medication.

84C Eligibility for concession and entitlement cards

(1AA) A person who has been, at any time during a relevant entitlement period, a general patient is eligible to be issued with a concession card in respect of that period if the total value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made:

(a) to the person during the period; or

(b) to the person and the person's family during the period;

is not less than the amount of the general patient safety net (within the meaning of section 99F).

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Note: Supplies of pharmaceutical benefits may include supplies referred to in subsections 99(2A), (2AB) and (2B).

(1B) A person is eligible to be issued with a concession card at the time of the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication to the person or a member of the person's family, if including the value for safety net purposes of the supply in the total mentioned in subsection (1AA) would fulfil that subsection.

(1C) A person who has been, at any time during a relevant entitlement period, a concessional beneficiary is eligible to be issued with an entitlement card in respect of that period if either of the following paragraphs applies:

(a) the total of:

(i) the value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person during the relevant entitlement period when the person was a concessional beneficiary; and

(ii) where the person has, during the relevant entitlement period, been a general patient—the transferred value of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person during the period when the person was a general patient;

is not less than the amount of the concessional beneficiary safety net (within the meaning of section 99F);

(b) the total of:

(i) the value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person and the person's family during the relevant entitlement period when the person was a concessional beneficiary; and

(ii) where the person has, during the relevant entitlement period, been a general patient—the transferred value of supplies of pharmaceutical benefits, repatriation

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pharmaceutical benefits and out-patient medication made to the person and the person's family during the period when the person was a general patient;

is not less than the amount of the concessional beneficiary safety net (within the meaning of section 99F).

Note: Supplies of pharmaceutical benefits may include supplies referred to in subsections 99(2A), (2AB) and (2B).

(1D) A person is eligible to be issued with an entitlement card at the time of the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication to the person or a member of the person's family if:

(a) where the person is a concessional beneficiary at the time of the supply—including the value for safety net purposes of the supply; or

(b) where the person is a general patient at the time of the supply—including the transferred value of the supply;

in the total mentioned in paragraph (1C)(a) or (b) would fulfil that paragraph.

(1E) The regulations may prescribe the value for safety net purposes of a supply of a pharmaceutical benefit.

(1F) Regulations made for the purposes of subsection (1E) must take into account the amount charged for the supply, but may make adjustments to the value for safety net purposes such as:

(a) excluding certain components of the amount charged; or

(b) setting a maximum limit on the value.

(2) For the purposes of this section, a pharmaceutical benefit supply or a supply of out-patient medication is taken to have been made, during a relevant entitlement period, to a person's family if and only if the supply was made, during that period, to:

(a) a person who was, at the time when the person applied for the issue of a concessional card or an entitlement card in respect of that period, a member of the person's family; or

(b) a person who was, at the time of supply, a member of the person's family.

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(3) Where:

(a) a prescription is for the supply of a pharmaceutical benefit or a repatriation pharmaceutical benefit to a person (in this subsection referred to as the ***patient***); and

(b) upon the prescription, a pharmaceutical benefit or repatriation pharmaceutical benefit (the ***benefit***) is given to another person, as agent for the patient, for supply to the patient;

the benefit shall, for the purposes of this section, be taken to have been supplied to the patient upon the prescription.

(4) The supply or repeated supply of a pharmaceutical benefit to a person shall not be taken into account for the purposes of this section unless:

(a) the pharmaceutical benefit is supplied:

(i) by an approved pharmacist, at or from premises in respect of which the pharmacist is for the time being approved, on presentation of a prescription written by a PBS prescriber in accordance with this Act and the regulations, or, in such circumstances as are prescribed for the purposes of paragraph 89(a), on communication to the pharmacist, in the manner prescribed for the purposes of that paragraph, of a prescription of a PBS prescriber; or

(ii) in accordance with section 92 or 94; and

(b) at the time of supply, the person is not a holder of an entitlement card; and

(c) in a case where the supply is made upon a general benefit prescription and the Commonwealth price for the pharmaceutical benefit exceeds the general patient charge amount—the amount received in respect of the supply is equal to the sum of the following:

(i) if the supply is not eligible for increased discounting—the general patient charge amount (less any allowable discount);

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(ia) if the supply is eligible for increased discounting—the amount charged for the supply under paragraph 87(2)(e);

(ii) if an amount may be charged for the supply under subsection 87(2A)—that amount;

(iii) any charge for supply at a time outside normal trading hours;

(iv) any charge for delivery in accordance with regulations made for the purposes of paragraph 87(4)(b); and

(d) in a case where the supply is made upon a concessional benefit prescription and the Commonwealth price for the pharmaceutical benefit exceeds $4.60—the amount received in respect of the supply is equal to the sum of the following:

(i) $4.60 (less any allowable discount);

(ii) if an amount may be charged for the supply under subsection 87(2A)—that amount;

(iii) any charge for supply at a time outside normal trading hours;

(iv) any charge for delivery in accordance with regulations made for the purposes of paragraph 87(4)(b); and

(e) in a case where the supply is one to which subsection 99(2A), (2AB) or (2B) applies—the amount charged or received in respect of the supply does not exceed the sum of the following:

(i) the price worked out in accordance with a determination in force under subsection (7) for the pharmaceutical benefit;

(ii) any amount charged or received by reason only that the supply was made at a time outside normal trading hours;

(iii) any amount charged or received in accordance with regulations made for the purposes of paragraph 87(4)(b).

(4AA) The supply or repeated supply of a pharmaceutical benefit or repatriation pharmaceutical benefit to a person must not be taken

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into account for the purposes of this section if it is an early supply of a specified pharmaceutical benefit.

(4A) The supply or repeated supply of a repatriation pharmaceutical benefit to a person is not to be taken into account for the purposes of this section unless:

(a) the repatriation pharmaceutical benefit is supplied:

(i) under the scheme established under section 91 of the *Veterans' Entitlements Act 1986*; or

(ii) in accordance with a determination under paragraph 286(1)(c) of the *Military Rehabilitation and Compensation Act 2004*; or

(iii) under a scheme that applies under section 18 of the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006*; or

(iv) under a scheme that applies under section 20 of the *Treatment Benefits (Special Access) Act 2019*; and

(b) at the time of supply the person was not a holder of an entitlement card.

(4B) A supply of out-patient medication to a person is not to be taken into account for the purposes of this section if, at the time of the supply, the person is the holder of an entitlement card.

(7) The Minister may determine, by legislative instrument, the manner in which the price for particular quantities or numbers of units of all or any pharmaceutical benefits is to be ascertained for the purpose of subparagraph (4)(e)(i).

(8) A manner determined under subsection (7) shall:

(a) in the case of a pharmaceutical benefit that is a listed brand of a pharmaceutical item—take as a basis the approved ex-manufacturer price or a proportional ex-manufacturer price of the brand of the pharmaceutical item that was in force on the first day of the month of the year in which the supply occurs; and

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(b) in the case of other pharmaceutical benefits—take as a basis the basic wholesale price of each ingredient that is applicable on the day on which the supply occurs; and

(c) provide for the addition of such fees and other amounts as are determined by the Tribunal for the purposes of paragraph 98B(2)(c); and

(d) provide for the addition of such other fees and other amounts as are determined by the Minister.

(9) The Minister shall not determine an amount for the purpose of paragraph (8)(d) unless the Pharmacy Guild of Australia has agreed in writing to the making of that determination.

(11) In this section, unless the contrary intention appears:

basic wholesale price has the same meaning as in section 98B.

pharmaceutical benefit supply means a supply or a repeated supply of a pharmaceutical benefit or repatriation pharmaceutical benefit.

84CA Transferred value

For the purposes of subsections 84C(1C) and (1D), the transferred value for the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication is:

(a) if the value for safety net purposes of the supply is less than $4.60—that lesser amount; and

(b) in any other case—$4.60.

Note: The figures expressed in this section in dollars are periodically adjusted under section 99G.

84D Pharmaceutical benefits prescription record forms etc.

(1) Upon application, the Secretary shall issue to a person a pharmaceutical benefits prescription record form in accordance with subsections (3) and (4).

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(1A) Upon application, the Secretary must issue to a person an out-patient medication prescription record form in accordance with subsections (3) and (4).

(2) An approved pharmacist, approved medical practitioner or approved hospital authority may issue to a person a pharmaceutical benefits prescription record form in accordance with subsections (3) and (4).

(2A) A public hospital authority may issue to a person an out-patient medication prescription record form in accordance with subsections (3) and (4).

(3) A pharmaceutical benefits prescription record form and an out-patient medication prescription record form must:

(a) be in accordance with the form approved by the Secretary; and

(b) include the prescribed particulars of the person to whom the form is issued.

(4) A pharmaceutical benefits prescription record form or an out-patient medication prescription record form issued to a person may include the prescribed particulars of any person who is a member of the person's family and:

(c) is not a holder of an entitlement card.

(5) Where a pharmaceutical benefits prescription record form or an out-patient medication prescription record form is issued to a person, the person and each member of the person's family whose particulars are included in the form in accordance with subsection (4) shall be taken, for the purposes of this section, to be a holder of the form.

(6) Where:

(a) an approved pharmacist, approved medical practitioner or approved hospital authority supplies a pharmaceutical benefit or repatriation pharmaceutical benefit to a holder of a pharmaceutical benefits prescription record form;

(b) the form is presented at the time of supply; and

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(c) the supply is:

(i) a supply of a pharmaceutical benefit to be taken into account under subsection 84C(4) for the purposes of section 84C; or

(ii) a supply of a repatriation pharmaceutical benefit to be taken into account, under subsection 84C(4A), for the purposes of section 84C;

the pharmacist, medical practitioner or authority shall record the supply of that pharmaceutical benefit on the form.

(7) A record made for the purposes of subsection (6) shall include:

(a) the prescribed particulars of the prescription upon which the pharmaceutical benefit or repatriation pharmaceutical benefit is supplied;

(b) the date on which the pharmaceutical benefit or repatriation pharmaceutical benefit is supplied; and

(c) such other particulars in relation to the supply of the pharmaceutical benefit or repatriation pharmaceutical benefit as are prescribed;

and shall be signed by:

(d) in a case where the record is made by an approved pharmacist—the pharmacist;

(e) in a case where the record is made by an approved medical practitioner—the medical practitioner; or

(f) in a case where the record is made by an approved hospital authority—the medical practitioner or pharmacist by or under whose supervision the pharmaceutical benefit or repatriation pharmaceutical benefit is dispensed.

(8) An approved pharmacist may authorise a person to record, on behalf of the pharmacist, the supply of pharmaceutical benefits and repatriation pharmaceutical benefits for the purposes of subsection (6).

(9) A reference in subsection (7) to an approved pharmacist includes a reference to a person authorised by a pharmacist under

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subsection (8) to record, on behalf of the pharmacist, the supply of pharmaceutical benefits and repatriation pharmaceutical benefits.

(10) Where:

(a) an out-patient medication is supplied to the holder of an out-patient medication prescription record form; and

(b) the form is presented at the time of supply; and

(c) the supply is not excluded under subsection 84C(4B) from being taken into account for the purposes of section 84C;

the medical practitioner or pharmacist by whom, or under whose supervision, the medication is dispensed, or any person authorised under subsection (12) to do so, must record the supply of the medication on the form.

(11) A record made for the purposes of subsection (10) must include:

(a) the prescribed particulars of the prescription upon which the medication is supplied; and

(b) the date on which the medication is supplied; and

(c) any other particulars of the supply that are prescribed;

and must be signed by the person making the record.

(12) The public hospital authority of a public hospital may authorise in writing a person employed at the hospital to record, for the purposes of subsection (10), the supply of an out-patient medication dispensed by, or under the supervision of, a medical practitioner or pharmacist.

84DA Issue of safety net concession card

(1) Where:

(a) a person applies, either personally or through the person's agent, to the Secretary for a safety net concession card in respect of a relevant entitlement period; and

(b) the Secretary is satisfied that the person is eligible to be issued with such a card in respect of that period;

the Secretary must issue a safety net concession card to the person in respect of that period.

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(2) Where:

(a) a person applies, either personally or through the person's agent, to an approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority for a safety net concession card in respect of a relevant entitlement period; and

(b) the pharmacist, medical practitioner or authority is satisfied that the person is eligible to be issued with such a card in respect of that period;

the pharmacist, medical practitioner or authority may issue a safety net concession card to the person in respect of that period.

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

(a) be in the form approved by the Secretary; and

(b) contain such particulars, and be accompanied by such documents, as are prescribed; and

(c) be signed by the person making the application or by the person's agent.

(4) Where an application is made to a person for the issue of a safety net concession card, the person to whom the application is made must, in determining whether to issue a card, have regard to:

(a) the matters contained in the application;

(b) any record form or other document that accompanies the application; and

(c) such other matters as the person considers relevant.

(5) Where:

(a) a person applies, either personally or through the person's agent, to an approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority for a safety net concession card in respect of a relevant entitlement period; and

(b) the pharmacist, medical practitioner or authority issues such a card to the person in respect of that period;

the pharmacist, medical practitioner or authority must submit the application, and all documents that accompanied the application, to

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the Secretary by lodging them at a prescribed office within one month (or such longer period as is prescribed) after the day on which the card is issued.

84E Issue of pharmaceutical benefits entitlement card

(1) Where:

(a) a person applies, either personally or through the person's agent, to the Secretary for a pharmaceutical benefits entitlement card in respect of a relevant entitlement period; and

(b) the Secretary is satisfied that the person is eligible to be issued with a pharmaceutical benefits entitlement card in respect of that period;

the Secretary shall issue a pharmaceutical benefits entitlement card to the person in respect of that period.

(2) Where:

(a) a person applies, either personally or through the person's agent, to an approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority for a pharmaceutical benefits entitlement card in respect of a relevant entitlement period; and

(b) the pharmacist, medical practitioner or authority is satisfied that the person is eligible to be issued with a pharmaceutical benefits entitlement card in respect of that period;

the pharmacist, medical practitioner or authority may issue a pharmaceutical benefits entitlement card to the person in respect of that period.

(3) An application under subsection (1) or (2) shall:

(a) be in accordance with the form approved by the Secretary;

(b) contain such particulars, and be accompanied by such documents, as are prescribed; and

(c) be signed by the person making the application or by the person's agent.

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(4) Where an application is made to a person for the issue of an entitlement card, the person to whom the application is made shall, in determining whether to issue an entitlement card, have regard to:
  (a) the matters contained in the application;
  (b) any record form or other document that accompanies the application; and
  (c) such other matters as the person considers relevant.

(5) Where:
  (a) a person applies, either personally or through the person's agent, to an approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority for a pharmaceutical benefits entitlement card in respect of a relevant entitlement period; and
  (b) the pharmacist, medical practitioner or authority issues a pharmaceutical benefits entitlement card to the person in respect of that period;

the pharmacist, medical practitioner or authority shall submit the application, and all relevant documents that accompanied or supported the application, to the Secretary by lodging them at a prescribed office within one month (or such longer period as is prescribed) after the day on which the entitlement card is issued.

(7) In subsection (5), ***relevant document*** means a document accompanying an application under subsection (1) or (2).

84F Form of cards

(1) A concession card must be in the form approved by the Secretary for that card.

(1A) An entitlement card must be in the form approved by the Secretary for that card.

(2) Without limiting the generality of subsections (1) and (1A), a concession card and an entitlement card shall include particulars of:

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(a) the relevant entitlement period in respect of which the card is issued; and

(b) the person to whom the card is issued and each person who is, at the time when the card is issued, a member of the person's family.

(3) The omission from a concession card or an entitlement card of particulars of a person who is, at the time when the card is issued, a member of the family of the person to whom the card is issued does not affect the validity of the card.

84G Persons covered by card

Subject to subsection 84H(3), where a concession card or an entitlement card is issued to a person, the person and each person who is, at the time when the card is issued, a member of the person's family shall be taken, for the purposes of this Act, to be a holder of the card.

84H Additional and replacement cards

(1) Where a concession card or an entitlement card has been issued, an additional concession card or an additional entitlement card (as the case may be) may, in accordance with the regulations, be issued to a person who is a holder of the card.

(2) Without limiting the generality of subsection (1), regulations made for the purposes of that subsection may provide for the issue of an additional card to a person:

(a) who is or was a holder of a concession card or an entitlement card that has been lost, stolen, damaged or destroyed; or

(b) who is a holder of a concession card or an entitlement card but whose particulars are not included on the card.

(3) Where:

(a) a person (in this subsection called the ***original card holder***) has been issued with a concession card, or an entitlement card, in respect of a relevant entitlement period; and

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(b) a person (in this subsection referred to as the ***new family member***) becomes, after the issue of the card and during that period, a member of the original card holder's family;

a replacement concession card or a replacement entitlement card (as the case may be) may, in accordance with the regulations, be issued to the original card holder, being a card that includes particulars of the holders of the original card and of the new family member and, where such a replacement card is issued, each holder of the original card and the new family member shall be taken, from the time when the replacement card is issued, to be a holder of the replacement card.

(4) Regulations made for the purposes of subsection (1) or (3) may provide for application to be made to the Administrative Review Tribunal for review of a decision of a person refusing to issue an additional card or a replacement card.

84HA Fee to approved pharmacist etc. for issuing card

(1) An approved pharmacist, approved medical practitioner or approved hospital authority who issues a safety net concession card, a pharmaceutical benefits entitlement card or an additional or replacement card in relation to any of those cards is entitled to be paid by the Commonwealth, in respect of the issue of the card, the fee determined by the Minister, for the purposes of this section, for the issue of cards generally or for the issue of cards of that kind, as the case requires.

(2) The Minister shall not determine a fee for the purposes of this section unless the Pharmacy Guild of Australia has agreed in writing to the making of that determination.

(3) A determination under subsection (1) shall:
(a) be made by notice in writing published in the *Gazette*; and
(b) come into operation on such day as is specified in the determination.

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84J Period of effect of card

A concession card or an entitlement card issued in respect of a relevant entitlement period commences to have effect on the day on which it is issued and ceases to have effect at the end of that period.

84K Return of card

Where a concession card or an entitlement card is issued to a person who is not eligible to be issued with the card, the Secretary may, by notice in writing to a holder of the card, require the holder to deliver the card, within such period (not being a period of less than 7 days) as is specified in the notice, to:

(a) the Secretary; or

(b) such other person as is specified in the notice;

for cancellation and the holder shall comply with the notice.

84L Offences

(1) An approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority shall not issue a concession card or an entitlement card to a person who is not eligible to be issued with such a card.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(2) An approved pharmacist, approved medical practitioner, approved hospital authority or public hospital authority shall not include in a concession card or an entitlement card, as the name of a member of a person's family, the name of a person who is not a member of the person's family.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(3) A person shall not fail to comply with a notice given to the person under section 84K.

Penalty: Imprisonment for 12 months or 20 penalty units, or both.

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(4) A person shall not fail to comply with subsection 84DA(5) or 84E(5).

Penalty: Imprisonment for 12 months or 20 penalty units, or both.

(5) Subsections (3) and (4) do not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (5). See subsection 13.3(3) of the *Criminal Code*.

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Division 2—Supply of pharmaceutical benefits

85 Pharmaceutical benefits

Pharmaceutical benefits

(1) Benefits shall be provided by the Commonwealth, in accordance with this Part, in respect of pharmaceutical benefits.

Note 1: While most pharmaceutical benefits are generally available for supply under this Part, some pharmaceutical benefits (see sections 85AAA and 85AA) can only be supplied under this Part under the prescriber bag provisions or in accordance with special arrangements under section 100.

Note 2: Special arrangements under section 100 can modify the effect of this Part in relation to the supply of pharmaceutical benefits that are covered by the arrangements (see subsection 100(3)).

Drugs etc.

(2) The drugs and medicinal preparations in relation to which this Part applies are:

(a) drugs and medicinal preparations that are:

(i) declared by the Minister, by legislative instrument, to be drugs and medicinal preparations to which this Part applies; or

(ii) included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this Part applies; and

(b) medicinal preparations composed of:

(i) one or more of the drugs and medicinal preparations referred to in paragraph (a), being a drug or medicinal preparation that is, or drugs and medicinal preparations that are, included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this paragraph applies; and

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(ii) one or more of such additives as are declared by the Minister, by legislative instrument, to be additives to which this paragraph applies.

Note 1: The Minister cannot make a declaration under this subsection in relation to a drug or medicinal preparation unless the Pharmaceutical Benefits Advisory Committee has recommended that the drug or medicinal preparation be declared (see subsections 101(4) and (4A)).

Note 2: If the Minister makes a declaration in relation to a drug or medicinal preparation under this subsection, the Minister cannot vary or revoke that declaration so as to delist the drug or medicinal preparation without first obtaining the Pharmaceutical Benefits Advisory Committee's advice (see subsection 101(4AAB)).

Drugs etc. that can only be supplied under the prescriber bag provisions

(2AA) If:

(a) the Minister makes a declaration under subsection (2) in relation to a drug or medicinal preparation (the ***drug***); and

(b) the Pharmaceutical Benefits Advisory Committee has recommended under subsection 101(4AACA) that the drug be supplied only under one or more of the prescriber bag provisions;

then the Minister must, by legislative instrument, declare that the drug can only be supplied under that provision or those provisions.

Note: If the Minister makes a declaration in relation to a drug or medicinal preparation under this subsection, the Minister cannot vary or revoke that declaration without first satisfying the conditions set out in subsection 101(4AACC).

Drugs etc. that can only be supplied under special arrangements

(2A) If:

(a) the Minister makes a declaration under subsection (2) in relation to a drug or medicinal preparation (the ***drug***); and

(b) the Pharmaceutical Benefits Advisory Committee has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100;

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then the Minister must, by legislative instrument, declare that the drug can only be supplied under such special arrangements.

Note: If the Minister makes a declaration in relation to a drug or medicinal preparation under this subsection, the Minister cannot vary or revoke that declaration without first satisfying the conditions set out in subsection 101(4AAF).

Forms

(3) The Minister may, by legislative instrument, determine, by reference to strength, type of unit, size of unit or otherwise, the form or forms of a listed drug.

(4) A form of a listed drug as determined by the Minister under subsection (3) may be such as to require the addition of a substance or substances to the drug so that it will be suitable for administration in a particular manner or at a particular strength.

Manners of administration

(5) The Minister may, by legislative instrument, determine the manner of administration of a form of a listed drug, being a form of the drug in relation to which a determination under subsection (3) is in force.

Brands

(6) The Minister may, by legislative instrument, determine a brand of a pharmaceutical item.

Schedule equivalents

(6A) If the Minister determines a brand of a pharmaceutical item under subsection (6), the Minister may, by legislative instrument, determine that, for the purposes of paragraph 103(2A)(b), the brand is to be treated as equivalent to one or more other brands of pharmaceutical items.

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(6B) In deciding whether the brand of pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items, the Minister must have regard to any advice given by the Pharmaceutical Benefits Advisory Committee.

(6C) If, on 1 November 2015, the Schedule of Pharmaceutical Benefits specifies that a brand of a pharmaceutical item is equivalent to one or more other brands of pharmaceutical items, the specification is taken to have been made following a determination to that effect under subsection (6A).

Prescriptions of pharmaceutical benefits in certain circumstances

(7) The Minister may, by legislative instrument, determine:
  (a) that a particular pharmaceutical benefit is to be a relevant pharmaceutical benefit for the purposes of section 88A; and
  (b) the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written.

Pharmaceutical benefits that can only be supplied under the prescriber bag provisions

(7A) The Minister may, by legislative instrument, determine that a particular pharmaceutical benefit can only be supplied under one or more of the prescriber bag provisions.

Pharmaceutical benefits that can only be supplied under special arrangements

(8) The Minister may, by legislative instrument, determine that:
  (a) a particular pharmaceutical benefit (other than a pharmaceutical benefit that has a drug covered by subsection (2A)) can only be supplied under special arrangements under section 100; or
  (b) one or more of the circumstances in which a prescription for the supply of a pharmaceutical benefit may be written under paragraph (7)(b) are circumstances in which the benefit can only be supplied under special arrangements under section 100.

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Brand or pharmaceutical item that is biosimilar or bioequivalent to listed item is taken to have the same drug

(9) If:

(a) a listed brand of a pharmaceutical item (the ***listed brand***) has a drug; and

(b) another brand of the pharmaceutical item, or a brand of another pharmaceutical item, is biosimilar or bioequivalent to the listed brand;

then, for the purposes of this Part, the other brand or pharmaceutical item is taken to have the same drug as the listed brand.

(10) Subsection (9) does not affect the separate declarations of the following drugs made under subsection (2) before the commencement of this subsection:

(a) epoetin lambda;

(b) epoetin alfa.

Alternative names or terminology

(11) The Minister may, by notifiable instrument, determine that, for the purposes of this Part:

(a) more than one name is recognised for the same listed drug; or

(b) more than one description is recognised for the same form of a listed drug; or

(c) more than one description is recognised for the same manner of administration of a form of a listed drug.

(12) Without limiting subsection (11), the Minister may determine a name or description as being used during a period of time, such as before or after a specified date.

85AAA Pharmaceutical benefits that can only be supplied under the prescriber bag provisions

(1) If the Minister makes a declaration under subsection 85(2AA) in relation to a drug or medicinal preparation (the ***drug***) declaring that

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the drug can only be supplied under one or more of the prescriber bag provisions, then every pharmaceutical benefit that has that drug can only be supplied under this Part under that provision or those provisions.

(2) If the Minister makes a determination under subsection 85(7A) that a particular pharmaceutical benefit can only be supplied under one or more of the prescriber bag provisions, then that pharmaceutical benefit can only be supplied under this Part under that provision or those provisions.

(3) Despite subsections (1) and (2), if:

(a) the Minister makes a declaration under subsection 85(2AA) declaring that a drug or medicinal preparation (the ***drug***) can only be supplied under one or more (but not all) of the prescriber bag provisions (the ***drug prescriber bag provision***); and

(b) the Minister makes a determination under subsection 85(7A) determining that a pharmaceutical benefit that has the drug can only be supplied under a different prescriber bag provision or different prescriber bag provisions (the ***pharmaceutical benefit prescriber bag provision***);

then the pharmaceutical benefit can only be supplied under this Part under the drug prescriber bag provision and the pharmaceutical benefit prescriber bag provision.

85AA Pharmaceutical benefits that can only be supplied under special arrangements

(1) If the Minister makes a declaration under subsection 85(2A) in relation to a drug or medicinal preparation (the ***drug***), then every pharmaceutical benefit that has that drug can only be supplied under this Part in accordance with special arrangements under section 100.

(2) If the Minister makes a determination under paragraph 85(8)(a) in relation to a pharmaceutical benefit, then that pharmaceutical

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benefit can only be supplied under this Part in accordance with special arrangements under section 100.

(3) If the Minister makes a determination under paragraph 85(8)(b) about the circumstances in which a pharmaceutical benefit can only be supplied under special arrangements under section 100, then, in those circumstances, the pharmaceutical benefit can only be supplied under this Part in accordance with those arrangements.

85A Determinations of forms of pharmaceutical benefits or pharmaceutical items with respect to classes of persons

(1) The Minister may determine, by reference to strength, type of unit, size of unit or otherwise, the form or forms of a pharmaceutical benefit or pharmaceutical item that is or are allowable for the purposes of this Part for prescription by persons included in a class of persons specified in the determination.

(2) The Minister may, with respect to the writing of prescriptions by persons included in a specified class of persons for the supply of a pharmaceutical benefit:

(a) determine the maximum quantity or number of units of:

(i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(ii) in any other case—the pharmaceutical benefit;

that may, in one prescription, be directed to be supplied on any one occasion, either for all purposes or for particular purposes; and

(b) determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated, either for all purposes or for particular purposes; and

(c) determine the manner of administration that may, in a prescription, be directed to be used in relation to the pharmaceutical benefit.

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(2A) The Minister may determine that particular conditions must be satisfied when writing a prescription to which a determination under paragraph (2)(a) or (b) applies.

(3) The regulations may make provision authorizing the variation of the application, in relation to persons included in a class of persons, of a determination under paragraph (2)(a) or (b) and, where such a variation is made, the determination shall be deemed to have effect as varied.

(3A) The Minister may determine rules that must be applied when deciding whether to authorise a variation under regulations made for the purposes of subsection (3).

(4) A determination made under subsection (1), (2), (2A) or (3A) is a legislative instrument.

85AB Minister may determine that a listed drug is on F1 or F2

(1) Subject to subsection (5), the Minister may, by legislative instrument, determine that a listed drug is on F1 or F2.

(2) The Minister may only determine that the drug is on F1 if the drug satisfies all the criteria for F1.

Note: For other circumstances in which the Minister may determine that a listed drug is on F1, see section 99AEJ.

(3) The Minister may only determine that the drug is on F2 if the drug does not satisfy one or more of the criteria for F1.

(4) The ***criteria for F1*** are as follows:

(a) there are no brands of pharmaceutical items that:

(i) have the drug; and

(ii) are bioequivalent or biosimilar; and

(iii) are listed brands of the pharmaceutical items on any day in the relevant period;

(b) there are no brands of pharmaceutical items that:

(i) have another listed drug that is in the same therapeutic group as the drug; and

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(ii) are bioequivalent or biosimilar; and

(iii) are listed brands of the pharmaceutical items on any day in the relevant period;

(c) the drug was not on F2 on the day before the determination under subsection (1) comes into force.

(4A) For the purposes of working out whether paragraph (4)(a) or (b) is satisfied, a brand of a pharmaceutical item that has the drug is to be disregarded if:

(a) both:

(i) subsection 99ACB(3A) or (3B) applies to the brand of the pharmaceutical item that has the drug; and

(ii) there is not another brand of the pharmaceutical item that has the drug that is a listed brand; or

(b) both:

(i) subsection 99ACB(3A) or (3B) applies to the brand of the pharmaceutical item that has the drug; and

(ii) the drug is not on F2; or

(c) both:

(i) subsection 99ACB(3B) applies to the brand of the pharmaceutical item that has the drug; and

(ii) the tenth anniversary of the drug in the pharmaceutical item being on F1 has not occurred.

(5) This section does not apply to the drug if:

(a) the drug is in a combination item; and

(b) there are no brands of combination items that:

(i) have the drug; and

(ii) are bioequivalent or biosimilar; and

(iii) are listed brands of the combination items on any day in the relevant period.

(6) In this section:

relevant period means the period that consists of:

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(a) the day before the day the determination under subsection (1) comes into force; and
(b) the day the determination under subsection (1) comes into force.

85AD Price agreements

(1) The Minister and the responsible person for a listed brand of a pharmaceutical item may, from time to time, agree, by reference to the pricing quantity of the brand of the pharmaceutical item, an amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item.

Note: Section 85C and Division 3A limit the Minister's power to agree to amounts for the purposes of subsection (1).

(2) It does not matter that at the time the agreement is made:
(a) the person is not yet the responsible person; or
(b) the item is not yet a pharmaceutical item; or
(c) the quantity or number of units of the item is not yet a pricing quantity; or
(d) the brand is not yet a listed brand.

However, those matters must be satisfied at the time the amount referred to in subsection (1) comes into force.

(3) The agreement must be in writing.

85B Price determinations and special patient contributions

Application

(1) This section applies to a listed brand of a pharmaceutical item.

Price determination

(2) If the Minister and the responsible person have been unable to make a price agreement for the brand of the pharmaceutical item, then the Minister may, by legislative instrument, determine, by

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reference to the pricing quantity of the listed brand of a pharmaceutical item, an amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item.

Note: Section 85C and Division 3A limit the Minister's power to determine amounts under subsection (2).

Claimed price determination

(3) The Minister may, by legislative instrument, determine, by reference to a pack quantity of the listed brand of the pharmaceutical item, an amount that is, for the purposes of this Part, taken to be the price of the brand of the pharmaceutical item claimed by the responsible person for that quantity.

Special patient contribution

(4) If the Minister makes a determination under subsection (3), then the Minister may, by legislative instrument, determine the circumstances in which the Commonwealth is to pay the special patient contribution for the brand of the pharmaceutical item.

(5) The ***special patient contribution*** for a quantity or number of units of a listed brand of a pharmaceutical item is the amount that is the difference between:

(a) the price that would have been the Commonwealth price for that quantity or number of units of the brand of the pharmaceutical item if that Commonwealth price had been based on the claimed price for that quantity or number of units; and

(b) the Commonwealth price for that quantity or number of units of the brand of the pharmaceutical item.

85BA Effect of deemed reductions of, or increases to, approved ex-manufacturer price

(1) If, under a provision of this Part, the approved ex-manufacturer price of a brand of a pharmaceutical item is, or is taken to be,

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reduced by an amount (the ***reduction amount***) or a percentage (the ***reduction percentage***):

(a) in a case where a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be reduced by the reduction amount or the reduction percentage, as the case requires; or

(b) in a case where a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be reduced by the reduction amount or the reduction percentage, as the case requires.

(2) If, under a provision of this Part, the approved ex-manufacturer price of a brand of a pharmaceutical item is, or is taken to be, increased by an amount (the ***increase amount***) or a percentage (the ***increase percentage***):

(a) in a case where a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be increased by the increase amount or the increase percentage, as the case requires; or

(b) in a case where a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be increased by the increase amount or the increase percentage, as the case requires.

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85C Each brand of a pharmaceutical item is to have the same approved ex-manufacturer price

If there are 2 or more listed brands of a pharmaceutical item, then the Minister must ensure, when agreeing an amount under subsection 85AD(1) or determining an amount under subsection 85B(2), that the approved ex-manufacturer price of each listed brand of the pharmaceutical item is the same.

85D Proportional ex-manufacturer price

The ***proportional ex-manufacturer price*** for a pack quantity (other than the pricing quantity) of a listed brand of a pharmaceutical item on a day is the amount worked out as follows:

$$\frac{\text{AEMP}}{\text{PQ}} \times \text{PkQ}$$

where:

AEMP means the approved ex-manufacturer price of the brand of the pharmaceutical item in force on that day.

PkQ means the pack quantity of the brand of the pharmaceutical item on that day.

PQ means the pricing quantity of the brand of the pharmaceutical item on that day.

85E Minister may enter into deeds with responsible persons

Making deeds

(1) The Minister may, on behalf of the Commonwealth, enter into a deed with a person who is, or seeks to be, determined by the Minister under section 84AF to be the responsible person for a brand of a pharmaceutical item.

(2) The deed must relate to one or more of the following:

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(a) one or more pharmaceutical items;
(b) pharmaceutical benefits within the meaning of:
(i) this Act; or
(ii) the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006*; or
(iii) the *Military Rehabilitation and Compensation Act 2004*; or
(iiia) the *Treatment Benefits (Special Access) Act 2019*; or
(iv) Part VA of the *Veterans' Entitlements Act 1986*.

(3) Without limiting subsection (2), the deed may make provision for one or more of the following:
(a) reimbursing the Commonwealth in relation to the provision of pharmaceutical benefits in circumstances set out in the deed;
(b) providing the Commonwealth with information in relation to pharmaceutical benefits.

Existing deeds to be covered by this section

(4) A deed of a kind covered by subsections (1) to (3) entered into by the Minister or another person on behalf of the Commonwealth before the commencement of this section has effect as if, when it was made, it was made by the Minister under this section.

86 Entitlement to receive pharmaceutical benefits

(1) Subject to this Part, a person who:
(a) is, or is to be treated as, an eligible person within the meaning of the *Health Insurance Act 1973*; and
(b) is receiving:
(i) medical treatment by a medical practitioner; or
(ii) dental treatment by a participating dental practitioner; or
(iii) optometrical treatment by an authorised optometrist; or
(iv) midwifery treatment by an authorised midwife; or

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(v) nurse practitioner treatment by an authorised nurse practitioner;

is entitled to receive pharmaceutical benefits under this Part without the payment or provision of money or other consideration other than a charge made in accordance with section 87.

Residency

(2) For the purposes of paragraph (1)(a), while a person is working outside Australia as a Commonwealth officer, he or she is taken to reside in Australia.

(3) For the purposes of paragraph (1)(a), while a person is working outside Australia as a State or Territory officer, he or she is taken to reside in Australia.

(4) For the purposes of paragraph (1)(a), while the spouse, or a dependent child, of a person covered by subsection (2) or (3) is outside Australia accompanying that person, the spouse or child is taken to reside in Australia.

Note: Paragraph (1)(a) refers to a person being an eligible person within the meaning of the *Health Insurance Act 1973*. Under that Act an Australian resident is an eligible person. A person must reside in Australia to be an Australian resident.

Definitions

(5) In this section:

dependent child has the same meaning as in section 84B.

spouse has the same meaning as in section 84B.

86A Pharmaceutical benefits not to be supplied in respect of persons reasonably believed not to be in Australia

(1) An approved supplier must not supply a pharmaceutical benefit in respect of a person if the approved supplier has reason to believe that the person is not in Australia at the time of the supply.

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Commonwealth, State or Territory officers working outside Australia

(2) However, subsection (1) does not apply to the supply of a pharmaceutical benefit in respect of:

(a) a person working outside Australia as a Commonwealth officer; or

(b) a person working outside Australia as a State or Territory officer; or

(c) the spouse, or a dependent child, of a person covered by paragraph (a) or (b) if the spouse or child is outside Australia accompanying that person.

Definitions

(3) In this section:

dependent child has the same meaning as in section 84B.

spouse has the same meaning as in section 84B.

86B Approved supplier may request provision of medicare number

Approved supplier may request provision of medicare number

(1) If:

(a) an approved supplier is presented with a prescription for the supply of a pharmaceutical benefit to a person; and

(b) the person presenting the prescription claims to be, or to be the agent of, the person to whom the prescription relates; and

(c) the person presenting the prescription does not request that the drug or medicinal preparation to which the prescription relates not be supplied as a pharmaceutical benefit;

the approved supplier may request the person presenting the prescription to provide to the approved supplier a medicare number applicable to the person to whom the prescription relates and the expiry date in relation to the number.

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Inclusion of medicare number in a prescription does not prevent later request

(2) The approved supplier may make the request under subsection (1) whether or not:

(a) the prescription already contains a medicare number as a number applicable to the person to whom the prescription relates; or

(b) the approved supplier's records already contain such a number (whether with or without the expiry date in relation to that number) recorded and retained in accordance with section 86D.

Approved supplier's powers if medicare number is provided

(3) If a medicare number is provided to the approved supplier as a number applicable to the person following a request under subsection (1), or is included as such a number in the approved supplier's records in accordance with section 86D, the approved supplier may:

(a) if the prescription has already been endorsed with a medicare number as such a number, check the number so provided or included against the endorsed number and:

(i) confirm that they are the same; or

(ii) if they are not the same and the approved supplier considers the number so provided or included more reliable than the endorsed number—alter the endorsed number to the number so provided or included or insert the number so provided or included in the CTS claim relating to the prescription, noting the discrepancy; or

(iii) if they are not the same and the approved supplier considers the endorsed number more reliable than the number so provided or included—disregard the number so provided or included and, if making a CTS claim, insert the endorsed number in the CTS claim relating to that prescription; and

(b) if the prescription has not already been endorsed with a medicare number as such a number:

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(i) endorse the prescription with the medicare number so provided or included as a number applicable to the person; or

(ii) insert the number so provided or included in the CTS claim relating to that prescription; and

(c) if the approved supplier has also been provided with, or has, in the approved supplier's records, the expiry date in relation to the medicare number ultimately supplied to the Chief Executive Medicare—confirm that the supply of a pharmaceutical benefit authorised by the prescription is not being sought after the expiry date.

Approved supplier's powers in respect of prescription (other than communicated prescription) covering person included in class determined under subsection 86E(1)

(4) If:

(a) the prescription for the supply of a pharmaceutical benefit that is presented to the approved supplier does not contain a medicare number as a number applicable to the person to whom the prescription relates; and

(b) despite a request under subsection (1), a medicare number is not provided to the approved supplier as such a number; and

(c) a medicare number is not retained in the approved supplier's records in accordance with section 86D as such a number; and

(d) the approved supplier is satisfied that the person to whom the prescription relates is included within a class of persons identified by the Minister under subsection 86E(1);

the approved supplier may:

(e) endorse on the prescription the special number applicable to the person as a member of that class; or

(f) insert that number in the CTS claim relating to that prescription.

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Approved supplier's powers in respect of written version of communicated prescription not containing medicare number

(5) If:

(a) a prescription for the supply of a pharmaceutical benefit is not presented to an approved supplier as described in subsection (1) but is communicated to the approved supplier in circumstances set out in regulations made for the purposes of paragraph 89(a); and

(b) the approved supplier later receives a written version of the prescription that does not contain a medicare number as a number applicable to the person to whom the prescription relates;

the approved supplier may, after the written version of the prescription is received, endorse on the written version, or insert in the CTS claim relating to the prescription:

(c) if a medicare number is already retained in the approved supplier's records in accordance with section 86D as a number applicable to the person to whom the prescription relates—that medicare number; or

(d) if a medicare number is not so retained as a number applicable to the person to whom the prescription relates—the special number applicable to the person under subsection 86E(1) as a person in respect of whom a prescription has been so communicated.

86C On and after 1 January 2001 approved supplier must request provision of medicare number in certain circumstances

Approved supplier must request provision of medicare numbers in certain circumstances

(1) If:

(a) an approved supplier is presented, on or after 1 January 2001, with a prescription for the supply of a pharmaceutical benefit to a person; and

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(b) the pharmaceutical benefit is one in respect of the supply of which the approved supplier would, but for the operation of subsection 99AAAB(2), be entitled to receive a payment under subsection 99(2) or (4) or 99AAAA(2); and

(c) the person presenting the prescription claims to be, or to be the agent of, the person to whom the prescription relates; and

(d) the person presenting the prescription does not request that the drug or medicinal preparation to which the prescription relates not be supplied as a pharmaceutical benefit;

the approved supplier must, if:

(e) the prescription does not contain a medicare number as a number applicable to the person to whom the prescription relates; and

(f) the approved supplier's records do not already contain a medicare number as such a number (whether with or without the expiry date in relation to that number) recorded and retained in accordance with section 86D;

request the person presenting the prescription to provide to the approved supplier a medicare number applicable to the person to whom the prescription relates and the expiry date in relation to that number.

Inclusion of medicare number in a prescription does not prevent later request

(2) Even if:

(a) the prescription presented to the approved supplier already contains a medicare number as a number applicable to the person to whom the prescription relates; or

(b) the approved supplier's records already contain a medicare number as such a number (whether with or without the expiry date in relation to that number) recorded and retained in accordance with section 86D;

the approved supplier may request the person presenting the prescription to provide to the approved supplier a medicare number applicable to the person to whom the prescription relates and the expiry date in relation to that number.

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Approved supplier's obligations in relation to medicare number provided

(3) If:

(a) a medicare number is provided to the approved supplier as a number applicable to the person to whom the prescription relates following a request under subsection (1) or is included as such a number in the approved supplier's records in accordance with section 86D; and

(b) the prescription has not already been endorsed with a medicare number as a number applicable to the person to whom the prescription relates;

the approved supplier must:

(c) endorse the prescription with the medicare number so provided or included; or

(d) insert the number so provided or included in the CTS claim relating to the prescription.

If medicare number is provided, approved supplier may check prescription endorsed by practitioner

(4) If:

(a) a medicare number applicable to the person to whom the prescription relates is provided to the approved supplier following a request under subsection (2) or is included in the approved supplier's records in accordance with section 86D; and

(b) the prescription has already been endorsed with a medicare number as a number applicable to the person to whom the prescription relates;

the approved supplier may check the number so provided or included against the endorsed number and:

(c) confirm that they are the same; or

(d) if they are not the same and the approved supplier considers the number so provided or included more reliable than the endorsed number:

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(i) alter the endorsed number to the number so provided or included; or

(ii) insert the number so provided or included in the CTS claim relating to the prescription, noting the discrepancy; or

(e) if they are not the same and the approved supplier considers the endorsed number more reliable than the number so provided or included—disregard the number so provided or included and, if making a CTS claim, insert the endorsed number in the CTS claim relating to that prescription.

Approved supplier may check to ensure that supply not being sought after relevant expiry date

(5) If the approved supplier has also been provided with, or has in the approved supplier's records, the expiry date in relation to the medicare number ultimately supplied to the Chief Executive Medicare, the approved supplier may confirm that the supply of the pharmaceutical benefit authorised by the prescription is not being sought after the expiry date.

Requirement in respect of prescription (other than communicated prescription) covering person included in class determined under subsection 86E(1)

(6) If:

(a) the prescription for the supply of a pharmaceutical benefit that is presented to the approved supplier does not contain a medicare number as a number applicable to the person to whom the prescription relates; and

(b) despite a request under subsection (1), a medicare number is not provided to the approved supplier as such a number; and

(c) a medicare number is not retained in the approved supplier's records in accordance with section 86D as such a number; and

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(d) the approved supplier is satisfied that the person to whom the prescription relates is included within a class of persons identified by the Minister in a determination under subsection 86E(1);

the approved supplier must:

(e) endorse on the prescription the special number applicable to the person as a member of that class; or

(f) insert that special number in the CTS claim relating to the prescription.

Requirement in respect of written version of communicated prescription not containing medicare number

(7) If:

(a) a prescription for the supply of a pharmaceutical benefit is not presented to an approved supplier as described in subsection (1) but is communicated to the approved supplier in circumstances set out in regulations made for the purposes of paragraph 89(a); and

(b) the pharmaceutical benefit is one in respect of the supply of which the approved supplier would, but for the operation of subsection 99AAAB(2), be entitled to receive a payment under subsection 99(2) or (4) or 99AAAA(2); and

(c) the approved supplier later receives a written version of the prescription that does not contain a medicare number as a number applicable to the person to whom the prescription relates;

the approved supplier must, after the written version of the prescription is received, endorse on the written version, or insert in the CTS claim relating to the prescription:

(d) if a medicare number is already retained in the approved supplier's records in accordance with section 86D as a number applicable to the person to whom the prescription relates—that medicare number; or

(e) if a medicare number is not so retained as a number applicable to the person to whom the prescription relates—the special number applicable to the person under

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subsection 86E(1) as a person in respect of whom a prescription has been so communicated.

Note 1: Subsection 99AAAB(2) sets out the consequences of a failure ultimately to supply a medicare number or special number to the Chief Executive Medicare or, in the case of a medicare number that is so supplied, of a discrepancy with a medicare number held in the records of the Chief Executive Medicare.

Note 2: If, because a medicare number is not provided and a special number is not applicable, a person pays the full amount to an approved supplier for the supply of a pharmaceutical benefit, the person may be entitled to an appropriate refund from the Commonwealth (see subsection 87A(2)).

86D Power of approved suppliers to record and retain medicare numbers and expiry dates

Approved supplier may record and retain medicare numbers and expiry dates supplied by or on behalf of patients

(1) If:

(a) an approved supplier is provided with a medicare number as a number applicable to a person (whether with or without the expiry date in relation to that number) either:

(i) as a result of a request under section 86B or 86C; or

(ii) to facilitate the supply of pharmaceutical benefits at a later time or times; and

(b) the approved supplier is satisfied that the person providing the number, or number and date, is:

(i) the person in respect of whom the number was provided; or

(ii) the legal guardian of that person; or

(iii) another person who, in accordance with a determination made by the Minister under subsection (5), is capable of giving an authorisation under this subsection;

the approved supplier may, with the authorisation of the person providing the number, or number and date, undertake the permitted recording and retention activities in relation to that number, or number and date.

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Supplier may record and retain medicare numbers and expiry dates supplied by PBS prescribers in respect of communicated prescriptions

(2) If:

(a) a prescription for the supply of a pharmaceutical benefit is communicated to an approved supplier in circumstances set out in regulations made for the purposes of paragraph 89(a); and

(b) at the time the prescription is communicated, the PBS prescriber communicating the prescription informs the approved supplier of a medicare number as a number applicable to the person to whom the prescription relates (whether with or without the expiry date in relation to that number);

the approved supplier may undertake the permitted recording and retention activities in relation to that number, or number and date.

Note: An approved supplier can only be informed of a medicare number under this section with the authority of the person whose number it is, or of another person on that person's behalf (see subsection 88(3B)).

Persons not obliged to authorise recording and retention of particulars

(3) Nothing in this section implies that a person is under any obligation to authorise an approved supplier to undertake the permitted recording and retention activities in respect of a medicare number, or of a medicare number and the expiry date in relation to such a number, provided as a result of a request under section 86B or 86C.

Approved supplier responsible for storage and security

(4) An approved supplier who, under this section, records and retains medicare numbers, or medicare numbers and expiry dates in relation to those numbers, in the approved supplier's records must ensure:

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(a) that the record of those numbers, or numbers and dates, is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse; and

(b) if it is necessary for access to the record of those numbers, or numbers and dates, to be given to a person in connection with the provision of services to the approved supplier—that everything reasonably within the power of the approved supplier is done to prevent unauthorised use or disclosure of information contained in that record.

Determinations are legislative instruments

(5) For the purposes of subsection (1), the Minister may, by legislative instrument, determine a person to be capable of giving an authorisation.

Permitted recording and retention activities

(6) In this section:

permitted recording and retention activities, in relation to a medicare number provided to an approved supplier under subsection (1) or (2) as a number applicable to a person (whether with or without an expiry date in relation to that number), are:

(a) to record and retain that number, or that number and date, in the approved supplier's records in relation to that person; or

(b) if the approved supplier has already recorded and retained either or both of those particulars in relation to that person by virtue of a previous operation of this section—to check the accuracy and completeness of the recorded particulars in respect of that person and, if the recorded particulars are inaccurate or incomplete, to modify those particulars appropriately.

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86E Minister may determine certain persons to be special evidentiary categories

Determination of classes of persons whose entitlement to pharmaceutical benefits can be evidenced otherwise than by provision of medicare numbers

(1) The Minister may, by legislative instrument, determine that certain classes of persons are classes of persons in respect of whom an entitlement to pharmaceutical benefits can be evidenced otherwise than by provision of a medicare number.

Classes that may be the subject of a determination

(2) Without limiting the classes that may be so determined, those classes may include the following:
  (a) persons who are not legally competent;
  (b) persons requiring drugs or medicinal preparations in an emergency, including an emergency to which a national emergency declaration (within the meaning of the *National Emergency Declaration Act 2020*) relates;
  (c) foreign persons:
    (i) who are entitled to be treated as eligible persons within the meaning of the *Health Insurance Act 1973* under section 7 of that Act; and
    (ii) who are able to produce evidence, of a kind specified in the determination, to prove that entitlement;
  (d) persons in respect of whom a prescription is communicated in circumstances set out in regulations made for the purposes of paragraph 89(a).

Determinations may set out particulars of which suppliers must be satisfied

(3) In a determination under subsection (1), the Minister may set out:
  (a) the particular matters in respect of which an approved supplier must be satisfied before being satisfied that a person

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is included within a particular class determined under that subsection; and

(b) the procedure to be followed by the approved supplier in establishing such matters.

Determinations under subsection (1) must establish procedure for allocation of special numbers

(4) The Minister must include, in each determination under subsection (1) that identifies a class of persons, a procedure for allocating a particular combination of numbers, or letters and numbers, that is to be the special number applicable to a person included within that class as a member of that class.

87 Limited charges for pharmaceutical benefits

(1) Subject to this section, an approved pharmacist, an approved medical practitioner or an approved hospital authority shall not demand or receive a payment (other than a payment from the Commonwealth) or other valuable consideration in respect of the supply of a pharmaceutical benefit.

(2) Subject to subsection (2A), an approved pharmacist or an approved medical practitioner acting in accordance with his or her approval may, in respect of each supply (including each repeated supply) by the approved pharmacist or approved medical practitioner, as the case may be, of a pharmaceutical benefit:

(a) upon:

(i) a concessional benefit prescription; or

(ii) an entitlement card prescription where the supply is an early supply of a specified pharmaceutical benefit; or

(iii) a concession card prescription (other than where the supply is an early supply of a specified pharmaceutical benefit);

charge the person to whom the pharmaceutical benefit is supplied $4.60 (less any allowable discount); or

(b) upon a general benefit prescription if, during the relevant entitlement period in which the supply is made, the person

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supplied is eligible to be issued with a concession card—charge the person $4.60 (less any allowable discount); or

(e) upon a general benefit prescription (other than one relating to a supply to which paragraph (b) applies), or a concession card prescription (where the supply is an early supply of a specified pharmaceutical benefit)—charge the person to whom the pharmaceutical benefit is supplied either:

(i) in any case—the general patient charge amount; or

(ii) if the supply is eligible for increased discounting—an amount that is less than the general patient charge amount, but greater than nil.

Note 1: The figures expressed in this subsection in dollars, and the general patient charge amount, are periodically adjusted under section 99G.

Note 2: For when a person is eligible to be issued with a concession card, see subsection 84C(1AA).

(2AAAA) For a supply other than an early supply, the ***allowable discount*** is an amount of not more than $1.

Note: The allowable discount is periodically reduced under Subdivision C of Division 4A.

(2AAA) Paragraph (2)(b) does not apply to an early supply of a specified pharmaceutical benefit.

(2A) In addition to any amount that may be charged in accordance with subsection (2), an approved pharmacist or an approved medical practitioner acting in accordance with his or her approval may, in respect of each supply (including each repeated supply) of a pharmaceutical benefit that is a listed brand of a pharmaceutical item and in relation to which a determination under subsection 85B(3) is in force, charge the person to whom it is supplied an amount equal to the special patient contribution for the brand of the pharmaceutical item, unless the approved pharmacist or approved medical practitioner is entitled to be paid by the Commonwealth that special patient contribution under subsection 99(2AA).

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(3) Where an approved pharmacist or an approved medical practitioner supplies a pharmaceutical benefit in accordance with a direction included in a prescription in pursuance of subsection 88(6) or (6A), the amount chargeable in accordance with subsection (2), of this section is, in lieu of whichever of the amounts referred to in subsection (2), of this section is applicable, an amount equal to the product of that applicable amount and the minimum number of occasions of supply that would have had to be directed if the medical practitioner, authorised midwife or authorised nurse practitioner had prescribed the same total quantity or number of units of the pharmaceutical benefit by way of repeated supplies.

(3A) An approved pharmacist, approved medical practitioner or approved hospital authority shall not supply a pharmaceutical benefit to a person on terms that are appropriate for the supply of the benefit to:

(ba) a holder of a concession card; or

(c) a holder of an entitlement card; or

(d) a concessional beneficiary; or

(e) a person who is a dependant of a concessional beneficiary within the meaning of subsection 84(4) or (7); or

(f) a general patient;

unless the pharmacist, medical practitioner or authority is satisfied that the person is entitled to receive the benefit on those terms.

(3B) Without limiting the generality of subsection (3A), an approved pharmacist, approved medical practitioner or approved hospital authority may refuse to supply a pharmaceutical benefit to a person on terms that are appropriate for the supply of the benefit to:

(ba) a holder of a concession card; or

(c) a holder of an entitlement card; or

(d) a concessional beneficiary; or

(e) a person who is a dependant of a concessional beneficiary within the meaning of subsection 84(4) or (7); or

(f) a general patient;

unless the person produces evidence (whether by way of the production of a card or evidence of identity or otherwise) to the

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pharmacist, medical practitioner or authority that the person is entitled to receive the benefit on those terms.

(4) The regulations may provide for the making of a charge, not exceeding an amount ascertained in accordance with the regulations:

(b) by an approved pharmacist or an approved medical practitioner in respect of the supply of a pharmaceutical benefit by delivery at or to a place other than premises in respect of which the approved pharmacist is approved, or premises at which the approved medical practitioner carries on practice, as the case may be.

(5) Subsection (1) does not prevent an approved hospital authority from charging, in respect of the supply of pharmaceutical benefits to a patient receiving treatment in or at a hospital, amounts not exceeding the sum of the charges that the patient could have been required to pay in accordance with subsections (2) and (2A), if the patient had obtained the pharmaceutical benefits from an approved pharmacist upon a prescription or prescriptions directing the supply of the maximum quantity or number of units applicable under a determination of the Minister under subsection 85A(2).

(5A) Subsection (5) does not apply to a supply if:

(a) the patient is the holder of an entitlement card; and

(b) the supply is not an early supply of a specified pharmaceutical benefit.

(6) The reference in subsection (1) to a payment or other valuable consideration in respect of the supply of a pharmaceutical benefit does not include a reference to a charge demanded or received by reason only that the supply is made at a time outside normal trading hours.

87AA Meaning of *eligible for increased discounting*

A supply of a pharmaceutical benefit by an approved pharmacist or an approved medical practitioner is ***eligible for increased discounting*** if:

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(a) the supply is upon a general benefit prescription (other than one relating to a supply to which paragraph 87(2)(b) applies); and

(b) the supply is not an early supply of a specified pharmaceutical benefit; and

(c) at the time of the supply, the Commonwealth price in relation to the pharmaceutical benefit is:

(i) greater than the general patient charge amount; and

(ii) less than or equal to $42.50.

Note: The general patient charge amount and the figure in subparagraph (c)(ii) are adjusted annually under section 99G.

87A Entitlement to refund in certain circumstances

(1) If:

(a) an approved supplier did not supply a pharmaceutical benefit to a person on terms that are appropriate for the supply of a benefit to:

(i) the holder of a concession card or entitlement card; or

(ii) a concessional beneficiary; or

(iii) a person who is a dependant of a concessional beneficiary within the meaning of subsection 84(4) or (7);

because the supplier was not satisfied that the person was entitled to receive the benefit on those terms; and

(b) the Secretary is satisfied that the person was entitled at the time to receive the benefit on those terms;

the person is entitled to be paid by the Commonwealth an amount equal to the difference between:

(c) the amount payable for the supply of the benefit on those terms; and

(d) an amount equal to:

(i) if the supply of the benefit is one to which subsection 99(2A), (2AB) or (2B) applies—the Commonwealth price for the supply of the benefit; or

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(ii) in any other case—the amount that the person was charged under section 87.

(2) A person is entitled to be paid by the Commonwealth an amount equal to the difference between the amount payable for the supply of a pharmaceutical benefit on terms that are appropriate for the supply of the benefit to a general patient and an amount equal to the Commonwealth price for the supply of the benefit if:

(a) an approved supplier did not supply the benefit to the person on those terms because the supplier was not satisfied that the person was entitled to receive the benefit on those terms; and

(b) the Secretary is satisfied that the person was entitled at the time to receive the benefit on those terms.

(3) Subsection (4) applies if:

(a) under this Act an approved supplier charged a person an amount in respect of a supply of a pharmaceutical benefit; and

(b) at the time of the supply, the person was eligible to be issued with a concession card or an entitlement card but was not the holder of such a card.

Note: For when a person is eligible to be issued with a concession or entitlement card, see section 84C.

(4) If the Secretary is satisfied:

(a) that the failure to issue a concession card or entitlement card was not caused by some wilful action of the person; and

(b) that in the circumstances the person should be treated as if:

(i) the person had been at the time when the pharmaceutical benefit was supplied the holder of a concession card or entitlement card; and

(ii) the prescription upon which the pharmaceutical benefit had been supplied were a concession card prescription or entitlement card prescription (as the case may be);

the person is entitled to be paid by the Commonwealth an amount equal to any amount paid by the person that would not have been payable if the pharmaceutical benefit had been supplied on a

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concession card prescription or an entitlement card prescription (as the case may be).

88 Prescribing of pharmaceutical benefits

(1) Subject to this Part, a medical practitioner is authorised to write a prescription for the supply of any pharmaceutical benefit determined from to time to time by the Minister, for the purposes of this subsection, by legislative instrument.

(1A) Subject to this Part, a participating dental practitioner is authorised to write a prescription for the supply of any pharmaceutical benefit determined from time to time by the Minister, for the purposes of this subsection, by legislative instrument.

(1C) Subject to this Part, an authorised optometrist is authorised to write a prescription on or after 1 January 2008 for the supply of any pharmaceutical benefit determined from time to time by the Minister for the purposes of this subsection, by legislative instrument.

(1D) Subject to this Part, an authorised midwife is authorised to write a prescription on or after 1 November 2010 for the supply of any pharmaceutical benefit determined from time to time by the Minister for the purposes of this subsection, by legislative instrument.

(1E) Subject to this Part, an authorised nurse practitioner is authorised to write a prescription on or after 1 November 2010 for the supply of any pharmaceutical benefit determined from time to time by the Minister for the purposes of this subsection, by legislative instrument.

(1EA) In deciding whether a prescription for the supply of a pharmaceutical benefit should be authorised for the purposes of subsection (1), (1A), (1C), (1D) or (1E), the Minister must have regard to any advice given by the Pharmaceutical Benefits Advisory Committee.

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(1EB) The Minister is not required to determine, in relation to a pharmaceutical benefit, that at least one kind of PBS prescriber is authorised to write a prescription for the supply of the benefit.

Note: Paragraph 89(b) lists provisions that may permit supply of a pharmaceutical benefit other than on presentation of a prescription.

(1F) When writing a prescription under subsection (1), (1A), (1C), (1D) or (1E) for the supply of a pharmaceutical benefit that has a pharmaceutical item, the PBS prescriber, in identifying the pharmaceutical benefit that he or she is directing to be supplied, need not specify:

(a) a listed brand of the pharmaceutical item in the pharmaceutical benefit; or

(b) the manner of administration of the pharmaceutical item in the pharmaceutical benefit.

(2) A PBS prescriber shall not, by writing a prescription or otherwise, authorize the supply of a pharmaceutical benefit, being a narcotic drug, for the purpose of the administration of that benefit to himself or herself.

(3) A prescription for the supply of a pharmaceutical benefit must not be written:

(a) by a medical practitioner otherwise than in relation to the medical treatment of a person requiring that pharmaceutical benefit; or

(b) by a participating dental practitioner otherwise than in relation to the dental treatment of a person requiring that pharmaceutical benefit; or

(c) by an authorised optometrist otherwise than in relation to the optometrical treatment of a person requiring that pharmaceutical benefit; or

(d) by an authorised midwife otherwise than in relation to the midwifery treatment of a person requiring that pharmaceutical benefit; or

(e) by an authorised nurse practitioner otherwise than in relation to the nurse practitioner treatment by the authorised nurse practitioner of a person requiring that pharmaceutical benefit.

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(3A) A PBS prescriber, when writing or communicating a prescription for the supply of a pharmaceutical benefit to a person, may:

(a) request the provision of a medicare number applicable to the person and of the expiry date in relation to that number; and

(b) if a medicare number (whether with or without the expiry date in relation to that number):

(i) is so provided as a number applicable to the person; or

(ii) is retained as such a number in the PBS prescriber's records in accordance with section 88AA;

endorse the medicare number on a prescription written for that person (including, in the case of a communicated prescription, a subsequent written version of that communicated prescription).

(3B) A PBS prescriber must not inform an approved supplier of a medicare number, or a medicare number and an expiry date in relation to that number, in the circumstances described in subsection 86D(2), unless:

(a) the person in respect of whom the number was provided; or

(b) the legal guardian of that person; or

(c) another person identified in a determination made by the Minister under section 86D or 88AA as capable of authorising the recording and retention of such number or number and date;

authorises the PBS prescriber to inform the approved supplier of that number, or number and date.

(3C) Nothing in this section implies that a person is under any obligation:

(a) to provide a medicare number, or a medicare number and the expiry date in relation to that number, to a PBS prescriber; or

(b) to authorise such a PBS prescriber to inform an approved supplier of such a number, or number and date, in the circumstances described in subsection 86D(2).

(4) Where a determination of the Minister under subsection 85A(1) is applicable to a PBS prescriber, the PBS prescriber shall not write a

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prescription for the supply of a pharmaceutical benefit except in accordance with that determination or any other determination that is applicable to him or her.

(5) Subject to subsection (6), a PBS prescriber is not authorized, in a prescription for the supply of a pharmaceutical benefit, to direct that:

(a) there be supplied on one occasion a quantity or number of units of:

(i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(ii) in any other case—the pharmaceutical benefit;

in excess of the maximum quantity or number of units (if any) applicable under a determination of the Minister under subsection 85A(2); or

(b) the pharmaceutical benefit is to be administered in a manner other than the manner (if any) applicable under a determination of the Minister under subsection 85A(2).

(6) Where a medical practitioner may, in accordance with this Part, direct a repeated supply of a pharmaceutical benefit, the medical practitioner may, in such circumstances and subject to such conditions as are prescribed, instead of directing a repeated supply, direct in the prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit not exceeding the total quantity or number of units of:

(a) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(b) in any other case—the pharmaceutical benefit;

not exceeding the total quantity or number of units that could be prescribed if the medical practitioner directed a repeated supply.

(6A) If a person who is an authorised midwife or authorised nurse practitioner may, in accordance with this Part, direct a repeated supply of a pharmaceutical benefit, the person may, instead of directing a repeated supply, direct in the prescription the supply on one occasion of a quantity or number of units of the

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pharmaceutical benefit not exceeding the total quantity or number of units of:

(a) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(b) in any other case—the pharmaceutical benefit;

not exceeding the total quantity or number of units that could be prescribed if the person directed a repeated supply.

(6B) However, the person may only make a direction under subsection (6A) if:

(a) the regulations prescribe either or both of the following:

(i) circumstances in which the person may make such a direction;

(ii) conditions on the making of such a direction; and

(b) the direction is made in those circumstances and in accordance with those conditions.

(7) Except in accordance with a determination of the Minister under subsection 85A(2), a PBS prescriber is not authorized, in a prescription for the supply of a pharmaceutical benefit, to direct that the supply of the pharmaceutical benefit be repeated on one or more occasions.

(8) If, in one prescription:

(a) the supply of a pharmaceutical benefit (the ***first benefit***) and another pharmaceutical benefit (the ***second benefit***) is directed; and

(b) the second benefit is:

(i) Schedule equivalent to the first benefit; or

(ii) if the first benefit is a listed brand of a pharmaceutical item—another listed brand of the pharmaceutical item;

then the prescription is taken to direct the repeated supply of the first benefit.

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88AA Power of PBS prescribers to record and retain medicare numbers and expiry dates

(1) If:

(a) a PBS prescriber is provided with a medicare number as a number applicable to a person (whether with or without the expiry date in relation to that number) either:

(i) as a result of a request under subsection 88(3A); or

(ii) to facilitate the writing of a prescription for the supply of pharmaceutical benefits at a later time or times; and

(b) the PBS prescriber is satisfied that the person providing the number, or number and date, is:

(i) the person in respect of whom the number was provided; or

(ii) the legal guardian of that person; or

(iii) another person who, in accordance with a determination made by the Minister under subsection (4), is capable of giving an authorisation under this subsection;

the PBS prescriber may, with the authorisation of the person providing the number, or number and date:

(c) record and retain that number, or number and date, in the PBS prescriber's records; or

(d) if the PBS prescriber has already recorded and retained either or both of those particulars by virtue of a previous operation of this section—check the accuracy and completeness of the recorded particulars and, if the recorded particulars are inaccurate or incomplete, appropriately modify those particulars.

(2) Nothing in subsection (1) implies that a person is under any obligation to authorise the recording and retention, in a PBS prescriber's records, of a medicare number, or of the expiry date in relation to such a number, provided as a result of a request under subsection 88(3A).

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PBS prescriber responsible for storage and security

(3) A PBS prescriber who, under this section, records and retains medicare numbers, or medicare numbers and expiry dates in relation to those numbers, in the PBS prescriber's records must ensure:

(a) that the record of those numbers, or numbers and dates, is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse; and

(b) that if it is necessary for access to the record of those numbers, or numbers and dates, to be given to a person in connection with the provision of services to the PBS prescriber, everything reasonably within the power of the PBS prescriber is done to prevent unauthorised use or disclosure of information contained in that record.

(4) For the purposes of subsection (1), the Minister may, by legislative instrument, determine a person to be capable of giving an authorisation.

88A Prescription of certain pharmaceutical benefits authorised only in certain circumstances

Where a pharmaceutical benefit is determined, under subsection 85(7), to be a relevant pharmaceutical benefit for the purposes of this section, the writing of a prescription for the supply of the benefit is authorised under this Part only in circumstances specified in the determination under subsection 85(7).

89 Pharmaceutical benefits to be supplied only on prescription etc.

A person is not entitled to receive a pharmaceutical benefit unless it is supplied:

(a) by an approved pharmacist, at or from premises in respect of which the pharmacist is for the time being approved, on presentation of a prescription written by a PBS prescriber in

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accordance with this Act and the regulations, or, in such circumstances as are prescribed, on communication to that pharmacist, in the prescribed manner, of a prescription of a PBS prescriber; or

(b) in accordance with the provisions of section 89A, section 92, section 93, section 93AA, section 93AB, section 93A or section 94.

89A When pharmaceutical benefits may be supplied by approved pharmacists without prescription

(1) An approved pharmacist may, at or from premises in respect of which the pharmacist is for the time being approved, supply a pharmaceutical benefit without a prescription for that supply if:

(a) the pharmaceutical benefit is covered by an instrument made under subsection (3); and

(b) the supply is made in accordance with conditions that are specified in an instrument made under subsection (3).

(2) If an approved pharmacist makes a supply in accordance with subsection (1), then this Act (other than paragraph 89(a)) applies in relation to the supply as if:

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

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

(ii) did not contain a medicare number; and

(b) a reference in this Part to a prescription for the supply of a pharmaceutical benefit to a person who is a holder of a concession card or an entitlement card included a reference to a supply made in accordance with subsection (1) to a person who is a holder of a concession card or an entitlement card on the day of the supply; and

(c) the following provisions were omitted:

(i) subsection 84(2A) and paragraph 84(10)(a);

(ii) section 84AA;

(iii) subparagraph 86B(3)(b)(i) and paragraph 86B(4)(e);

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(iv) paragraphs 86C(3)(c) and (6)(e);
(v) paragraph 92A(1)(ca); and

(d) the words ", in accordance with section 84AA," in the definitions of ***concessional benefit prescription***, ***concession card prescription*** and ***entitlement card prescription*** in subsection 84(1) were omitted.

(3) The Minister may, by legislative instrument, determine:
(a) the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription; and
(b) the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

(4) The Minister must publish statistics annually for each pharmaceutical item supplied under subsection (1).

(5) The Minister must:
(a) cause a written report to be prepared of a review of this section no more than two years from the commencement of the section; and
(b) cause a copy of the report to be laid before each House of the Parliament within six months of the commencement of the review.

90 Approved pharmacists

(1) Subject to this section, the Secretary may, upon application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, approve that pharmacist for the purpose of supplying pharmaceutical benefits at those premises.

Note: There is an application fee for the application: see subsection (9).

(2) Where a pharmacist desires to supply pharmaceutical benefits at more than 1 premises, a separate application under subsection (1) shall be made in respect of each of the premises and, where approval is granted in respect of 2 or more premises, a separate approval shall be granted in respect of each of the premises.

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(3) Subject to this section, where an approved pharmacist desires to supply pharmaceutical benefits at premises other than premises in respect of which approval has been granted, the Secretary may on application by the approved pharmacist, grant approval in respect of those other premises.

Note: There is an application fee for the application: see subsection (9).

(3A) Subject to subsections (3AA), (3AE) and (13), an application under this section must be referred to the Authority.

(3AA) Subsection (3A) does not apply to an application for an approval arising out of a change in the ownership of a pharmacy situated at particular premises if the change results or resulted from:

(a) the sale of the pharmacy; or

(b) the acquisition, following the death of a person who was the owner or one of the owners of the pharmacy, of that person's interest in the business of the pharmacy; or

(c) a change in the constitution of a partnership that owned the pharmacy;

if the pharmacy is to continue to operate at the same premises.

(3AB) In subsections (3AA) and (3AE):

pharmacy means a business in the course of the carrying on of which pharmaceutical benefits are supplied.

(3AC) For the purposes of paragraph (3AA)(b), if a person who is the owner or one of the owners of the business of a pharmacy dies, another person will be taken to have acquired the interest of the deceased person only after:

(a) a grant of probate of the will, or letters of administration of the estate, of the owner who has died, by a court of a State or Territory having jurisdiction in relation to the owner; and

(b) the transfer to that other person of that interest.

(3AD) Despite the grant of that probate or those letters of administration being taken to have had effect from the date of death of the owner, any permission to supply pharmaceutical benefits at particular premises that is granted under section 91 in respect of:

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(a) a period preceding that grant of probate or those letters of administration; or

(b) a period following that grant of probate or those letters of administration and preceding the subsequent transfer of the business;

is unaffected.

(3AE) Subsection (3A) does not apply to an application for an approval if:

(a) the application arises out of an expansion or contraction of particular premises (the ***original premises***) at which a pharmacy is situated; and

(b) the expanded or contracted premises occupy any of the space occupied by the original premises.

(3AF) However, the Secretary may, at his or her discretion, refer to the Authority an application referred to in subsection (3AE).

(3B) An approval may be granted under this section in respect of an application that has been referred to the Authority under subsection (3A) or (3AF) only if the Authority has recommended the grant of the approval, but the Secretary may refuse to grant an approval even if the grant has been recommended by the Authority.

(3D) The Secretary must not grant approval under this section to a pharmacist in respect of particular premises if the Secretary is satisfied that on or after the day the approval would otherwise be granted:

(a) the pharmacist would be unable to supply pharmaceutical benefits at the premises; or

(b) the premises would not be accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable.

(4) Nothing in this section authorizes the Secretary to grant approval to a pharmacist in respect of premises at which that pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.

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(5) Where the Secretary makes a decision granting or rejecting an application made by a pharmacist under this section, the Secretary shall cause to be served on the pharmacist, notice in writing of that decision.

Note: In certain circumstances, the Minister may substitute for a decision of the Secretary rejecting an application for approval, a decision granting the approval (see section 90A).

(5AA) If, under this section, a pharmacist is granted approval to supply pharmaceutical benefits at particular premises, the pharmacist may also supply pharmaceutical benefits from those premises.

(5A) A pharmacist who:

(a) before 18 December 1990, was granted an approval to supply pharmaceutical benefits at or from particular premises; and

(b) supplied pharmaceutical benefits on or before 18 December 1990 from other premises without the Secretary having granted approval under subsection (3) in respect of those other premises;

is to be taken to have been granted in respect of those other premises, or whichever of those premises was the premises from which the pharmacist last supplied pharmaceutical benefits before 18 December 1990, an approval under subsection (3).

(5B) The reference in paragraph (5A)(b) to supplying pharmaceutical benefits includes a reference to supplying drugs and medicinal preparations for which payment was made as if they were pharmaceutical benefits.

(5C) Subsection (5A) does not apply if:

(a) the approval referred to in paragraph (5A)(a) was not in force immediately before the commencement of section 20 of the *Health and Community Services Legislation Amendment Bill (No. 2) 1993*; or

(b) the pharmacist is not permitted, under the law of the State or Territory in which the premises referred to in paragraph (5A)(b) are situated, to carry on business at those premises.

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(6) For the purposes of this section, a reference to a pharmacist is taken to include a reference to a person who owns, or is about to own, a business for the supply of pharmaceutical benefits at particular premises.

(7) Subsection (6) does not permit an application to be made under subsection (1) by a beneficiary of a deceased approved pharmacist who is not himself or herself a pharmacist before the interest in the business of the deceased pharmacist is transferred to the beneficiary in the course of the administration of the estate of the deceased pharmacist.

(8) Nothing in this section prevents the approval of more than one pharmacist for the purpose of supplying pharmaceutical benefits at particular premises.

Application fee

(9) An application under subsection (1) or (3) must be accompanied by the application fee determined in an instrument under subsection (10).

(10) The Minister may, by legislative instrument, determine application fees for applications under subsection (1) or (3).

(11) The Minister may determine different fees for different kinds of applications.

(12) A fee must not be such as to amount to taxation.

Consequences of application fee not being paid

(13) An application under subsection (1) or (3) is not required to be referred under subsection (3A) to the Authority if the applicant has not paid the application fee for the application.

(14) The Secretary may refuse to make a decision on an application under subsection (1) or (3) if the applicant has not paid the application fee for the application.

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90A Minister may substitute decision approving pharmacist

(1) This section applies in relation to a decision of the Secretary under section 90 rejecting an application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, if:

(a) the application was made on or after 1 July 2006; and

(b) the decision was made on the basis that the application did not comply with the requirements of the relevant rules determined by the Minister under section 99L.

(2) The Minister may substitute for the Secretary's decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:

(a) the Secretary's decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and

(b) it is in the public interest to approve the pharmacist.

(3) For the purposes of subsection (2):

community means a group of people that, in the opinion of the Minister, constitutes a community.

reasonable access, in relation to pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister, is reasonable.

(4) The power under subsection (2) may only be exercised:

(a) on request by the pharmacist made under section 90B; and

(b) by the Minister personally.

(6) The power under subsection (2) does not authorise the Minister to approve a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises at which the pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.

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(7) A decision by the Minister not to exercise the power under subsection (2) in respect of the Secretary's decision does not prevent the pharmacist from making an application to the Administrative Review Tribunal under subsection 105AB(7) for review of the Secretary's decision.

(8) For the purposes of this section (other than subsection (7)):
  (a) a reference to a decision of the Secretary includes a reference to a decision of the Secretary that has been affirmed by a decision of the Administrative Review Tribunal or an order of a federal court; and
  (b) a reference to a decision of the Administrative Review Tribunal includes a reference to a decision of the Administrative Review Tribunal that has been affirmed by an order of a federal court.

90B Request to Minister to approve pharmacist

(1) If section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist, the pharmacist may, in writing, request the Minister to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.

(2) The Minister may determine the form in which a request under subsection (1) must be made and, if the Minister does so, such a request must be made in that form.

(3) A request under subsection (1) must be made:
  (a) within 30 days after the pharmacist is notified of the Secretary's decision; or
  (b) if the pharmacist has applied to the Administrative Review Tribunal for review of the Secretary's decision—within 30 days after:
    (i) the pharmacist is given a copy of the Administrative Review Tribunal's decision affirming the Secretary's decision; or

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(ii) the application has been discontinued, withdrawn or dismissed; or

(c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the Administrative Review Tribunal affirming the Secretary's decision—within 30 days after:

(i) the court has made an order affirming the Secretary's decision or the Administrative Review Tribunal's decision, as the case requires; or

(ii) the court proceeding has been discontinued, withdrawn or dismissed.

(3A) Despite subsection (3), if:

(a) the pharmacist makes an application under section 123 of the *Administrative Review Tribunal Act 2024* for the President of the Administrative Review Tribunal to refer a decision on review of the Secretary's decision to the guidance and appeals panel for review; and

(b) the President refuses the application;

the pharmacist may make a request under subsection (1) within 30 days of the day on which the pharmacist is notified of the refusal under section 129 of the *Administrative Review Tribunal Act 2024*.

(5) The Minister must, within 4 months after the day a request is received under subsection (1), personally decide whether to exercise the power under subsection 90A(2) in respect of the Secretary's decision. If the Minister has not made a decision within this period, the Minister is taken to have decided not to exercise the power under subsection 90A(2) in respect of the Secretary's decision.

(6) The Secretary must, by notice in writing, advise the pharmacist of the decision made, or taken to have been made, by the Minister under subsection (5).

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90C Circumstances in which request may not be made

Proceedings before the Administrative Review Tribunal or a federal court

(1) A request must not be made under subsection 90B(1) in relation to a decision of the Secretary to which section 90A applies if:

(a) the Secretary's decision is the subject of a proceeding before the Administrative Review Tribunal or a federal court; and

(b) the proceeding has not been discontinued, withdrawn or dismissed, or otherwise finally determined.

(2) A request under subsection 90B(1) is taken to have been withdrawn if, before the Minister has made a decision in relation to the request under subsection 90B(5), the Secretary's decision becomes the subject of a proceeding before the Administrative Review Tribunal or a federal court.

Previous requests in relation to premises

(3) If a pharmacist makes a request (the ***previous request***) under subsection 90B(1) in relation to a decision of the Secretary under section 90 rejecting the pharmacist's application to supply pharmaceutical benefits at particular premises, the pharmacist must not make a further request under subsection 90B(1), in relation to the premises, unless at least 12 months have passed since the day the previous request was made.

90D Provision of further information

(1) For the purpose of deciding whether to exercise the power under subsection 90A(2) in relation to a request made by a pharmacist under subsection 90B(1):

(a) the Minister may, by notice in writing given to the pharmacist, require the pharmacist to provide such further information, or produce such further documents, to the Minister as the Minister specifies, within the period specified in the notice; and

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(b) the Minister may give a notice in writing to any other person:
(i) advising the person of the request; and
(ii) inviting the person to provide comments on, or information or documents relevant to, the request within the period specified in the notice.

(2) If:
(a) the Minister gives a notice to a pharmacist under paragraph (1)(a); and
(b) the pharmacist does not provide the information specified in the notice or produce the documents specified in the notice within the period specified in the notice;
the Minister may treat the request as having been withdrawn.

(3) If the Minister gives a notice to a person under paragraph (1)(b), the Minister:
(a) is only required to consider comments, information or documents provided by the person during the period specified in the notice; and
(b) if the person does not provide any comments, information or documents within that period—is not required to take any further action to obtain such comments, information or documents.

90E Effect of decision by Minister to approve pharmacist

If the Minister decides to substitute for a decision of the Secretary to which section 90A applies a decision approving a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises:
(a) the pharmacist is to be treated for all purposes of this Act as if the pharmacist is approved under section 90 in respect of those premises; and
(b) references in this Act to an approval granted under section 90 include references to an approval treated as having been granted under section 90 by paragraph (a) of this section; and

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(c) the conditions to which an approval granted under section 90 is subject (including any condition that is imposed by means of a determination for the purposes of paragraph 92A(1)(f)) apply also to an approval that is treated as having been granted under section 90 by paragraph (a) of this section; and

(d) the rights conferred and obligations imposed on an approved pharmacist apply to the pharmacist in his or her activities as an approved pharmacist.

91 Application to supply pharmaceutical benefits following the death of approved pharmacist

(1) If:

(a) a person is an approved pharmacist in respect of a pharmacy at particular premises; and

(b) the approved pharmacist dies at any time on or after the commencement of this section; and

(c) another person claims to be:

(i) the executor, or one of the executors, of the will of the deceased pharmacist in respect of which probate has been granted; or

(ii) the executor, or one of the executors, of the will of the deceased pharmacist although probate has not yet been granted; or

(iii) a person, or one of the persons, to whom the administration of the estate of the deceased pharmacist has been granted; or

(iv) a person, or one of the persons, intending to apply for administration of the estate of the deceased pharmacist; and

(d) that other person applies to the Secretary for permission to supply pharmaceutical benefits at those premises;

the Secretary may, if the Secretary reasonably believes that the applicant is, or on the grant of probate of the will or letters of administration of the estate is likely to be, such an executor or

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administrator, grant the applicant permission to supply such pharmaceutical benefits at those premises.

(2) An application under subsection (1) in relation to the supply of pharmaceutical benefits at particular premises:

(a) must be made in writing in a form approved by the Secretary; and

(b) must be made as soon as reasonably practicable after the death of the pharmacist who previously supplied such pharmaceutical benefits at those premises; and

(c) must be accompanied by documentary evidence relating to:

(i) the identity of the applicant; and

(ii) the nature of the applicant's claim to be a person referred to in a subparagraph of paragraph 91(1)(c);

of a kind determined by the Secretary under subsection (3).

(3) For the purposes of paragraph (2)(c), the Secretary may, by legislative instrument, determine kinds of documentary evidence.

(4) For the purpose of considering an application under this section, the Secretary may, by notice in writing given to the applicant, require the applicant to provide such further information, or produce such further documents, to the Secretary as the Secretary specifies, within such period as the Secretary specifies.

(5) If the Secretary requires the provision of information or the production of documents within a specified period and the information or documents are not provided or produced within that period, the Secretary may treat the application as having been withdrawn.

(6) When the Secretary makes a decision to grant or refuse an application under this section, the Secretary must cause notice in writing of that decision to be given to the applicant. If the Secretary decides to refuse an application, the notice must include reasons for the refusal.

(7) If the Secretary grants an applicant permission to supply pharmaceutical benefits at premises the subject of the application:

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(a) the person granted that permission is to be treated for all purposes of this Act as if the person is, and, since the referral day in relation to the permission, had been, approved under section 90 as an approved pharmacist in relation to the pharmacy at those premises; and

(b) any supply of pharmaceutical benefits at or from those premises by a pharmacist who is not an approved pharmacist after the referral day in relation to the permission and before the grant of that permission is to be treated as if it had been a supply of those pharmaceutical benefits by the person to whom the permission is granted; and

(c) references in this Act to an approval granted under section 90 include references to an approval treated as having been granted under section 90 by paragraph (a); and

(d) the conditions to which an approval granted under section 90 is subject (including any condition that is imposed by means of the Minister's determination for the purposes of paragraph 92A(1)(f)) apply also to an approval that is treated as having been granted under section 90 by paragraph (a); and

(e) the rights conferred and obligations imposed on an approved pharmacist apply to that person in his or her activities as such an approved pharmacist.

(8) For the purposes of subsection (7), the ***referral day***, in relation to a permission granted under this section, is:

(a) unless paragraph (b) applies—the day following the date of death of the deceased pharmacist to whom the application for permission related; or

(b) if there has been a prior permission granted under this section in relation to the premises to which the permission relates—the day following the date the prior permission was revoked.

(9) A permission granted to a person under subsection (1) in relation to particular premises continues, unless it is sooner revoked, until that person or another person is approved by the Secretary under section 90 in respect of those premises.

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(10) Nothing in this section authorises the Secretary to grant a permission under subsection (1) to a person to supply pharmaceutical benefits at particular premises at which the person is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.

(11) If:

(a) probate of the will, or administration of the estate, of a deceased approved pharmacist is granted; and

(b) the person granted a permission under subsection (1) in relation to the supply of pharmaceutical benefits at premises where that pharmacist carried on business is not, or is not included among persons who are, granted that probate or administration;

he or she must, as soon as he or she becomes aware of that fact, notify the Secretary in writing of that fact.

(12) If the Secretary becomes aware, either as a result of a notification under subsection (11) or otherwise, that:

(a) probate of the will, or administration of the estate, of a deceased approved pharmacist is granted; and

(b) the person granted a permission under subsection (1) is not, or is not included among persons who are, granted that probate or administration;

the Secretary must, by notice in writing given to the person granted that permission, revoke the permission.

(13) If a partnership agreement provides for the disposal of the pharmacy business of a deceased approved pharmacist to any surviving partner or partners, nothing in this section is to be taken to override the operation of the terms of that agreement.

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91A Application to supply pharmaceutical benefits at alternative premises because of disaster or exceptional circumstances

(1) The Secretary may, on application by a pharmacist who is approved under section 90 in respect of particular premises (the ***affected premises***), grant the approved pharmacist permission to supply pharmaceutical benefits at other premises (the ***alternative premises***) if the Secretary is satisfied that:

(a) because of a disaster or exceptional circumstances relating to the affected premises:

(i) the approved pharmacist is unable to supply pharmaceutical benefits at the affected premises; or

(ii) the affected premises are not accessible by members of the public for the purpose of receiving pharmaceutical benefits; and

(b) the alternative premises are in substantially the same locality as the affected premises.

Note: The Minister may determine matters for the purposes of the Secretary making decisions under this subsection: see subsection (11).

(2) The Secretary must refuse to grant the permission if the Secretary is satisfied that:

(a) the approved pharmacist is unable to supply pharmaceutical benefits at the alternative premises; or

(b) the alternative premises are not accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable.

Application requirements

(3) The application must:

(a) be in writing and in a form approved by the Secretary (if any); and

(b) unless the Secretary otherwise allows, be made:

(i) as soon as reasonably practicable after the condition in paragraph (1)(a) is first met in relation to the affected premises; and

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(ii) before the end of the period of 14 days beginning on the day the approved pharmacist starts supplying pharmaceutical benefits at or from the alternative premises; and

(c) be accompanied by documentary evidence, of a kind determined under paragraph (11)(e) (if any), demonstrating that:

(i) paragraphs (1)(a) and (b) are satisfied for the application; and

(ii) paragraphs (2)(a) and (b) are not satisfied for the application.

Secretary may require further information or documents

(4) For the purposes of considering the application, the Secretary may, by written notice given to the approved pharmacist, require the approved pharmacist to give the Secretary specified information, or produce to the Secretary specified documents, within a specified period.

(5) If the approved pharmacist does not give the information or produce the documents within the specified period, the Secretary may treat the application as having been withdrawn.

Notifying approved pharmacist of decision on application

(6) The Secretary must give the approved pharmacist written notice of the Secretary's decision on the application.

Effect of permission

(7) If the Secretary grants the approved pharmacist permission to supply pharmaceutical benefits at the alternative premises:

(a) the approved pharmacist is to be treated for all purposes of this Act (except section 92 and subsection 98(4)) as if the approved pharmacist were, during the temporary supply period, approved under section 90 as an approved pharmacist in relation to the alternative premises; and

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(b) references in this Act to an approval granted under section 90 include references to an approval treated as having been granted under section 90 by paragraph (a) of this subsection; and

(c) the conditions to which an approval granted under section 90 is subject (including any condition that is imposed by means of the Minister's determination for the purposes of paragraph 92A(1)(f)) also apply to an approval that is treated as having been granted under section 90 by paragraph (a) of this subsection; and

(d) in addition to supplying pharmaceutical benefits at the alternative premises during the temporary supply period, the approved pharmacist may also supply pharmaceutical benefits from the alternative premises during that period.

Note: For paragraph (a), section 92 and subsection 98(4) deal with the approval of medical practitioners to supply pharmaceutical benefits if there is no convenient and efficient pharmaceutical service being supplied by an approved pharmacist in an area.

*Meaning of **temporary supply period***

(8) For the purposes of subsection (7), the ***temporary supply period*** begins immediately before the approved pharmacist first starts to supply pharmaceutical benefits at or from the alternative premises and ends at the earliest of the following times:

(a) the end of the following period beginning on the day after the condition in paragraph (1)(a) is first met in relation to the affected premises:

(i) 6 months (unless subparagraph (ii) or (iii) applies);

(ii) a shorter period specified in the notice of the Secretary's decision granting the permission;

(iii) if the Secretary, by written notice given to the approved pharmacist before the end of the period that would otherwise apply under subparagraph (i) or (ii) or this subparagraph, extends that period by a further specified period—that period as so extended;

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(b) when the approved pharmacist supplies pharmaceutical benefits, after the beginning of the temporary supply period, at or from:
  (i) the affected premises; or
  (ii) premises (other than the alternative premises or premises for which the pharmacist is approved under section 90) that the Secretary is satisfied are in substantially the same locality as the affected premises;
(c) when an approval is granted to the approved pharmacist under section 90 in respect of the alternative premises;
(d) when the approved pharmacist's approval for the affected premises is cancelled under section 98;
(e) when the permission is revoked under subsection (9) of this section.

Revoking permission

(9) The Secretary may, by written notice given to the approved pharmacist, revoke the permission if the Secretary is satisfied that:
(a) both:
  (i) the approved pharmacist is able to supply pharmaceutical benefits at the affected premises; and
  (ii) the affected premises are accessible by members of the public for the purpose of receiving pharmaceutical benefits; or
(b) the approved pharmacist is unable to supply pharmaceutical benefits at the alternative premises; or
(c) the alternative premises are not accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable; or
(d) it is in the public interest to do so.

Effect of certain State and Territory laws

(10) Nothing in this section authorises the Secretary to grant a permission under subsection (1) to an approved pharmacist to supply pharmaceutical benefits at premises at which the approved

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pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.

Minister may determine certain matters for purposes of this section

(11) The Minister may, by legislative instrument, determine any or all of the following:

(a) matters to which the Secretary may, must or must not have regard for the purposes of making a decision for the purposes of this section;

(b) events that are taken to be, or not to be, disasters for the purposes of paragraph (1)(a);

(c) circumstances that are taken to be, or not to be, exceptional circumstances for the purposes of paragraph (1)(a);

(d) circumstances in which premises are taken to be, or not to be, in substantially the same locality as other premises for the purposes of paragraph (1)(b) or subparagraph (8)(b)(ii);

(e) kinds of documentary evidence for the purposes of paragraph (3)(c).

91B Application to supply pharmaceutical benefits if approved pharmacist is bankrupt or external administrator in relation to pharmacy

Approved pharmacist is an individual and individual is bankrupt

(1) If:

(a) an approval under section 90 in respect of particular premises covers one individual and the individual is bankrupt; and

(b) the trustee (the ***applicant***) of the estate of the bankrupt individual makes an application to the Secretary for permission to supply pharmaceutical benefits at those premises;

the Secretary must grant, or refuse to grant, the applicant permission to supply pharmaceutical benefits at those premises.

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Approved pharmacist is a partnership and partners are bankrupt

(2) If:

(a) an approval under section 90 in respect of particular premises covers a partnership that consists only of individuals and each of the partners is bankrupt; and

(b) either:

(i) if the same person is the trustee of the estate of each of the bankrupt partners—the trustee (the ***applicant***) makes an application to the Secretary for permission to supply pharmaceutical benefits at those premises; or

(ii) otherwise—the trustees (the ***applicant***) of the estates of the bankrupt partners make a joint application to the Secretary for permission to supply pharmaceutical benefits at those premises;

the Secretary must grant, or refuse to grant, the applicant permission to supply pharmaceutical benefits at those premises.

External administrator in relation to pharmacy

(3) If:

(a) an approval under section 90 is in force in respect of particular premises; and

(b) there is an external administrator in relation to the pharmacy situated at those premises; and

(c) the external administrator (the ***applicant***) makes an application to the Secretary for permission to supply pharmaceutical benefits at those premises;

the Secretary must grant, or refuse to grant, the applicant permission to supply pharmaceutical benefits at those premises.

Note: For ***external administrator***, see subsection (16). For ***pharmacy***, see subsection (17).

Application requirements

(4) An application under subsection (1), (2) or (3) in relation to particular premises must:

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(a) be in writing and in a form approved by the Secretary; and

(b) unless the Secretary otherwise allows, be made before the end of the period of 10 business days beginning on:

(i) for an application under subsection (1)—the day the trustee became the trustee of the estate of the bankrupt individual; or

(ii) for an application under subsection (2)—the first day on which there was a trustee of the estate of each bankrupt partner; or

(iii) for an application under subsection (3)—the day the applicant became the external administrator; and

(c) be accompanied by documentary evidence that:

(i) for an application under subsection (1) or (2)—there is a trustee of the estate of the bankrupt individual or of the estate of each bankrupt partner; or

(ii) for an application under subsection (3)—there is an external administrator in relation to the pharmacy; and

(d) be accompanied by a statement setting out:

(i) whether, at the time of the application, the pharmacy situated at the premises is operating at the premises; and

(ii) if the pharmacy is not operating at the premises—the day the pharmacy ceased operating and the day of the proposed resumption of operation; and

(iii) the grounds on which the applicant considers the pharmacy can continue or resume operating at the premises.

Secretary may require further information or documents

(5) For the purposes of considering the application, the Secretary may, by written notice given to the applicant, require the applicant to give the Secretary further specified information, or produce to the Secretary further specified documents, within a specified period.

(6) If the applicant does not give the information, or produce the documents, within the specified period, the Secretary may treat the application as having been withdrawn.

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Rules about grant of permission

(7) The Secretary must, under subsection (1), (2) or (3), grant the applicant permission to supply pharmaceutical benefits at the premises if the Secretary is satisfied that:

(a) at the time of the application, the pharmacy situated at the premises is operating at the premises; and

(b) the pharmacy can continue operating after the grant of the permission; and

(c) the premises are accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable.

Note: If, at the time of the application, the pharmacy situated at the premises is not operating at the premises, the Secretary is still able to grant the permission under subsection (1), (2) or (3).

(8) However, while a permission granted under this section is in force in relation to particular premises, the Secretary must not grant any further permission under this section in relation to those premises.

Notifying decision on application

(9) The Secretary must:

(a) give the applicant written notice of the Secretary's decision on the application; and

(b) if the Secretary refuses to grant the permission—state in the notice the reasons for the refusal.

Effect of permission

(10) If the Secretary grants a permission under subsection (1), (2) or (3) to supply pharmaceutical benefits at particular premises:

(a) the holder of the permission is to be treated for all purposes of this Act as if the holder were, on and after the day the application for the permission was made, approved under section 90 as an approved pharmacist in relation to those premises; and

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(b) any supply of pharmaceutical benefits at or from those premises by a pharmacist, who is not an approved pharmacist, on or after the day the application for the permission was made and before the grant of that permission is to be treated as if it had been a supply of those pharmaceutical benefits by the holder of the permission; and

(c) references in this Act to an approval granted under section 90 include references to an approval treated as having been granted under section 90 by paragraph (a) of this subsection; and

(d) the conditions to which an approval granted under section 90 is subject (including any condition that is imposed by means of the Minister's determination for the purposes of paragraph 92A(1)(f)) also apply to an approval treated as having been granted under section 90 by paragraph (a) of this subsection; and

(e) the rights conferred and obligations imposed on an approved pharmacist apply to the holder of the permission in the holder's activities as such an approved pharmacist.

Note 1: One of the effects of paragraph (a) is that, if the holder of the permission supplies a pharmaceutical benefit, the holder may be entitled to a payment under section 99 or 99AAAA for the supply of the benefit.

Note 2: For ***pharmacist*** see subsection 4(1).

Duration of permission

(11) A permission granted under subsection (1), (2) or (3) in relation to particular premises continues, unless it is sooner revoked, until the Secretary grants another approval under section 90 in respect of those premises.

Note: Subsections (12) and (13) deal with revocation of the permission and subsection (14) deals with variation of the permission.

Revoking permission

(12) The Secretary may, by written notice given to the holder of the permission, revoke the permission if the Secretary is satisfied that:

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(a) there has been a contravention of a condition covered by paragraph (10)(d); or
(b) the holder of the permission is not carrying on the business of a pharmacist at the premises in respect of which the permission is granted; or
(c) the premises are not accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable; or
(d) it is otherwise appropriate in the circumstances to revoke the permission.

(13) The Secretary must, by written notice given to the holder of the permission, revoke the permission if the holder makes a request in writing (including reasons for the request) to the Secretary for revocation of the permission.

Varying permission

(14) The Secretary may, by notice in writing, vary a permission granted under subsection (1), (2) or (3) to reflect changes in the trustee or trustees of the estate or estates concerned or in the external administrator in relation to the pharmacy concerned. A variation takes effect on the day specified in the notice (which may be earlier than the day the variation is made).

Note: A variation will result in a different holder of the permission.

Effect of certain State and Territory laws

(15) Nothing in this section authorises the Secretary to grant a permission under subsection (1), (2) or (3) to a person to supply pharmaceutical benefits at premises at which the person is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.

Definitions

(16) For the purposes of this section, an ***external administrator***, in relation to a pharmacy, is:

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(a) an administrator of the pharmacy; or

(b) a managing controller (within the meaning of the *Corporations Act 2001*) in relation to property of any company operating the pharmacy; or

(c) an external administrator (within the meaning of section 5-20 of Schedule 2 to the *Corporations Act 2001*) of any company operating the pharmacy.

(17) For the purposes of this section, a ***pharmacy*** is a business in the course of the carrying on of which pharmaceutical benefits are supplied.

(18) A reference in this section to the trustee of the estate of a bankrupt is to be read:

(a) in relation to an estate in respect of which there are 2 or more joint trustees—as a reference to all the trustees; or

(b) in relation to an estate in respect of which there are 2 or more joint and several trustees—as a reference to all of the trustees or any one or more of the trustees.

(19) A reference in this section to the external administrator in relation to a pharmacy is to be read:

(a) in relation to a pharmacy in respect of which there are 2 or more joint external administrators—as a reference to all of the external administrators; and

(b) in relation to a pharmacy in respect of which there are 2 or more joint and several external administrators—as a reference to all of the external administrators or any one or more of the external administrators.

92 Approved medical practitioners

(1) Where there is no pharmacist approved in respect of premises from which, in the opinion of the Secretary, a convenient and efficient pharmaceutical service may be supplied in a particular area and a medical practitioner is practising in that area, the Secretary may approve the medical practitioner for the purpose of supplying pharmaceutical benefits to persons in that area.

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(1A) Where the Secretary makes a decision under subsection (1) approving or refusing to approve a medical practitioner, the Secretary shall cause to be served on the medical practitioner, notice in writing of that decision.

(2) Pharmaceutical benefits supplied by a medical practitioner so approved shall be supplied in accordance with such conditions as are prescribed.

92A Approvals to be subject to conditions

(1) The approval of a person as an approved pharmacist, or the approval of a medical practitioner, for the purposes of this Part (including an approval granted before the commencement of this section and an approval of a person or body referred to in section 83Z) is, by force of this section, subject to the following conditions:

(a) a condition that the approved pharmacist or approved medical practitioner will not, by advertisement, notice or otherwise, state or indicate that he or she is willing to supply all or any pharmaceutical benefits to all or any persons without charge or for a charge other than the charge that he or she may make without contravening section 87;

(b) a condition that, where the approved pharmacist or approved medical practitioner makes, by advertisement, notice or otherwise, a statement with respect to the charge for which he or she is willing to supply, or with respect to his or her willingness to supply without charge, drugs or medicinal preparations generally or a class of drugs or medicinal preparations, he or she will indicate in the statement whether or not the statement relates to the supply of pharmaceutical benefits;

(c) a condition that the approved pharmacist or approved medical practitioner will not follow a practice of supplying all or any pharmaceutical benefits to all or any persons without charge or for a charge other than the charge that he or she may make without contravening section 87;

(ca) a condition that where:

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(i) the approved pharmacist supplies a pharmaceutical benefit upon a prescription that, in accordance with subsection 84AA(2) or (3), is a concessional benefit prescription, a concession card prescription or an entitlement card prescription; and

(ii) that prescription is subsequently reduced to a document in writing (in this paragraph referred to as the ***relevant document***) and given to the approved pharmacist in pursuance of regulations in force for the purposes of this Part;

the approved pharmacist shall write or mark on the relevant document the information communicated, or purportedly communicated, to him or her under subsection 84AA(2) or (3) in such manner as would, if the relevant document were a written prescription, cause that prescription to be, in accordance with subsection 84AA(1) or (1A), a concessional benefit prescription, a concession card prescription or an entitlement card prescription, as the case requires;

(d) a condition that the approved pharmacist or approved medical practitioner will not enter into a refund agreement or become an agent of a party to a refund agreement for the purposes of the refund agreement;

(e) a condition that the approved pharmacist, being a friendly society or a friendly society body, will keep a record, in a form approved by the Secretary, of the names and addresses, being addresses last known to the pharmacist, of all members:

(i) where the pharmacist is a friendly society—of the friendly society; or

(ii) where the pharmacist is a friendly society body—of the friendly society, or of any of the friendly societies, for the benefit of the members of which the pharmacist is carrying on business;

who were, immediately before 24 April 1964, and have continued to be, parties to agreements or arrangements under which contributions were and are payable by those members or on their behalf to friendly societies, or to friendly society

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bodies, for the purpose of obtaining benefits in respect of medicines;

(f) any other condition (including, but not limited to, a condition relating to premises) determined by the Minister under subsection (1A).

(1A) For the purposes of paragraph (1)(f), the Minister may, by legislative instrument, determine conditions.

(2) The conditions specified in paragraphs 92A(1)(a), (b) and (c) do not apply in relation to:

(a) the supply, or a statement relating to the supply, of pharmaceutical benefits upon entitlement card prescriptions;

(b) the supply, or a statement relating to the supply, of pharmaceutical benefits by a friendly society or by a friendly society body to members:

(i) in the case of a friendly society—of the friendly society; or

(ii) in the case of a friendly society body—of the friendly society, or of any of the friendly societies, for the benefit of the members of which the friendly society body is carrying on business;

who were, immediately before 24 April 1964, and have continued to be, parties to agreements or arrangements under which contributions were and are payable by those members or on their behalf to friendly societies, or to friendly society bodies, for the purpose of obtaining benefits in respect of medicines; or

(c) the supply, or a statement relating to the supply, of pharmaceutical benefits by a friendly society or by a friendly society body to the spouses, or to the children, of members referred to in paragraph (b).

(3) For the purposes of section 95, any conduct of an approved pharmacist that is a contravention of the conditions specified in this section shall be deemed to be conduct that is an abuse of his or her approval.

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(4) For all purposes in connection with the writing or marking on a document by an approved pharmacist of information of the kind referred to in paragraph (1)(ca), the communication, or purported communication, of the information referred to in subsection 84AA(2) or (3), as the case requires, shall be taken to afford full and sufficient grounds for the writing or marking of that information by the pharmacist on that document.

92B Persons not to enter into certain refund agreements

(1) Except as provided in subsection (2), a person who is an insurer must not enter into a contract of insurance that comprises or contains a refund agreement.

Penalty: 20 penalty units

(2) This section does not prevent a private health insurer from entering into a complying health insurance policy under which the insurer covers the cost of pharmaceutical benefits dispensed to a person as part of an episode of hospital treatment or hospital-substitute treatment covered by the policy.

93 Prescriber bag supplies—medical practitioners

(1) Except as prescribed, a medical practitioner is authorized to supply such pharmaceutical benefits as the Minister, by legislative instrument, determines to persons who are entitled under this Part to receive those pharmaceutical benefits.

(2) For the purpose of this section, the Minister may, by legislative instrument, determine the maximum quantity or number of units of a pharmaceutical benefit which may be obtained by a medical practitioner during a specified period and a medical practitioner shall obtain the pharmaceutical benefit as prescribed.

(3) Payment by the Commonwealth in respect of the supply of pharmaceutical benefits under this section shall be made as prescribed.

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93AA Prescriber bag supplies—authorised midwives

(1) Except as prescribed by the regulations, an authorised midwife is authorised to supply such pharmaceutical benefits as the Minister, by legislative instrument, determines to persons who are entitled under this Part to receive those pharmaceutical benefits.

(2) For the purposes of this section, the Minister may, by legislative instrument, determine the maximum quantity or number of units of a pharmaceutical benefit which may be obtained by an authorised midwife during a specified period.

(3) The regulations may make provision for or in relation to the obtaining of pharmaceutical benefits by an authorised midwife for the purposes of this section.

(4) The regulations may make provision for or in relation to payments by the Commonwealth in respect of the supply of pharmaceutical benefits under this section.

93AB Prescriber bag supplies—authorised nurse practitioners

(1) Except as prescribed by the regulations, an authorised nurse practitioner is authorised to supply such pharmaceutical benefits as the Minister, by legislative instrument, determines to persons who are entitled under this Part to receive those pharmaceutical benefits.

(2) For the purposes of this section, the Minister may, by legislative instrument, determine the maximum quantity or number of units of a pharmaceutical benefit which may be obtained by an authorised nurse practitioner during a specified period.

(3) The regulations may make provision for or in relation to the obtaining of pharmaceutical benefits by an authorised nurse practitioner for the purposes of this section.

(4) The regulations may make provision for or in relation to payments by the Commonwealth in respect of the supply of pharmaceutical benefits under this section.

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93A Supply of certain pharmaceutical benefits to patients in private hospitals or aged care facilities

(1) In this section:

prescribed institution means:

(a) a private hospital; or

(b) an approved residential care home within the meaning of the *Aged Care Act 2024*.

(2) For the purposes of this section, the Minister may determine:

(a) the pharmaceutical benefits or classes of pharmaceutical benefits that may be supplied under this section to patients receiving treatment in prescribed institutions; and

(b) the conditions under which such pharmaceutical benefits may be supplied to, and held by, prescribed institutions.

Note: Subsection 33(3A) of the *Acts Interpretation Act 1901* applies to a determination under subsection (2). This means that, for example, a determination could determine conditions for private hospitals that are different from conditions that are determined for residential care services.

(3) A copy of each determination made by the Minister under subsection (2) is to be published in the *Gazette*.

(4) An approved supplier may supply to a prescribed institution, in accordance with determinations made under paragraph (2)(b), pharmaceutical benefits that are covered by a determination made under paragraph (2)(a).

(5) A PBS prescriber may authorise a prescribed institution to supply a pharmaceutical benefit to patients receiving treatment in the institution if:

(a) the pharmaceutical benefit is covered by a determination made under paragraph (2)(a); and

(b) the PBS prescriber is authorised under section 88 to write a prescription for the supply of the pharmaceutical benefit.

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(6) Payment by the Commonwealth in respect of the supply of pharmaceutical benefits under this section is to be made as prescribed.

94 Approved hospital authorities

(1) Upon application by a hospital authority, the Minister may, in the Minister's discretion but subject to subsection (5), approve a hospital authority for the purpose of its supplying pharmaceutical benefits to patients receiving treatment in or at the hospital of which it is the governing body or proprietor.

(2) The approval of a hospital authority under subsection (1) may be expressed to be subject to such terms and conditions as the Minister determines.

(3) Where a hospital authority desires to supply pharmaceutical benefits to patients receiving treatment in or at several hospitals:

(a) a separate application shall, unless the Minister otherwise allows, be made in respect of each hospital; and

(b) separate approval may be granted in respect of each hospital.

(4) Where an approved hospital authority desires to supply pharmaceutical benefits to patients receiving treatment in or at a hospital other than a hospital in respect of which approval has been granted, the Minister may, on application by the approved hospital authority, grant approval in respect of that other hospital.

(4A) Where the Minister makes a decision granting or rejecting an application made by a hospital authority under this section, the Minister shall cause to be served on the hospital authority, notice in writing of that decision.

(5) A hospital authority shall not be approved under this section in respect of a hospital unless the dispensing of drugs and medicinal preparations at that hospital is performed by or under the direct supervision of a medical practitioner or pharmacist.

(5A) The Minister may, in the Minister's discretion, at any time, by notice in writing, vary, or suspend or revoke, an approval in force

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under this section (including an approval granted before the commencement of this subsection).

(5B) A suspension under subsection (5A) has effect for such period as the Minister determines and specifies in the notice of suspension.

94A Suspension of approval of pharmacist—State or Territory suspension

(1) The Secretary may suspend the approval of an approved pharmacist under section 90 if the pharmacist's registration as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists has been suspended (however described).

(2) Before deciding to suspend the approval, the Secretary must notify the pharmacist that suspension under this section is being considered. The notice must:

(a) be in writing; and

(b) invite the pharmacist to make written submissions to the Secretary within the period of 28 days (the ***submission period***) after being given the notice.

(3) In deciding whether to suspend the approval, the Secretary must consider any written submissions made by the person during the submission period.

(4) The Secretary must give to the pharmacist written notice of the decision. The notice must specify the period for which the approval is suspended.

Note: Section 266 of the *Administrative Review Tribunal Act 2024* requires the person to be notified of the person's review rights.

(5) If the Secretary does not give the pharmacist written notice of the decision within the period of 60 days after the end of the submission period, the Secretary is taken to have decided not to suspend the approval.

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(6) If the Secretary suspends the approval, the Secretary may, by written notice at any time, further suspend the approval under subsection (1) or remove the suspension.

(7) For the purposes of this section, a reference to a pharmacist is taken to include a person to whom subsection 90(6) applies.

94B Review of suspension decisions

(1) If the Secretary suspends the approval of an approved pharmacist under section 94A, the pharmacist may apply, in writing, to the Secretary for reconsideration by the Secretary of the decision.

(2) On receiving an application under subsection (1), the Secretary must reconsider the decision and:
   (a) affirm the suspension; or
   (b) remove the suspension.

(3) The Secretary must give to the applicant written notice of the Secretary's decision under subsection (2).

Note: Section 105AC of this Act and section 266 of the *Administrative Review Tribunal Act 2024* require the person to be notified of the person's review rights.

(4) In this section:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024.*

95 Suspension or revocation of approval—investigation by Committee of Inquiry

(1) The Minister may, after investigation and report by the appropriate Committee of Inquiry, by notice in writing:
   (a) reprimand an approved pharmacist; or
   (b) suspend or revoke the approval of the pharmacist under section 90;

and may, at any time, by notice in writing, remove that suspension or restore that approval.

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(3) A suspension under subsection (1) has effect for such period as the Minister determines and specifies in the notice of suspension.

(4) If the Secretary considers that it is necessary in the public interest so to do pending investigation and report by the appropriate Committee of Inquiry, the Secretary may suspend an approval referred to in subsection (1) and the Secretary may at any time remove the suspension.

(5) Where the approval of a pharmacist is suspended under subsection (4), the Secretary shall forthwith refer the matter to the appropriate Committee of Inquiry for investigation and report to the Minister.

(6) A suspension by the Secretary under subsection (4) has effect only until the Minister has dealt with the matter in accordance with subsection (7).

(7) On receipt of a report from a Committee of Inquiry on a matter referred to it in accordance with subsection (5), the Minister may, by notice in writing, further suspend the approval for such period as the Minister specifies in the notice, revoke the approval or remove the suspension.

(8) The Minister shall not suspend, further suspend or revoke an approval under the preceding provisions of this section unless, having regard to the evidence before the Committee of Inquiry and the report of the Committee, the Minister is satisfied that the pharmacist has, in relation to or arising out of the approval, been guilty of conduct which is an abuse of that approval or is an abuse or contravention of this Act or the regulations or shows the pharmacist, as the case may be to be unfit to continue to enjoy the approval.

(9) The suspension or revocation of the approval of a pharmacist under this section may be in respect of all of the premises in respect of which the approval was granted or may be in respect of particular premises.

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(10) For the purposes of this section, a reference to a pharmacist is taken to include a person to whom subsection 90(6) applies.

98 Cancellation by Secretary of approval of pharmacists etc.

(1) Whenever:

(a) an approved pharmacist requests that his or her approval under section 90 in respect of all or any of the premises in respect of which he or she is approved be cancelled;

(aa) a participating dental practitioner requests that his or her approval as a participating dental practitioner under section 84A be cancelled; or

(b) an approved medical practitioner requests that his or her approval in respect of an area under section 92 be cancelled; or

(c) an authorised optometrist requests that his or her approval as an authorised optometrist under section 84AAB be cancelled; or

(d) an authorised midwife requests that his or her approval as an authorised midwife under section 84AAF be cancelled; or

(e) an authorised nurse practitioner requests that his or her approval as an authorised nurse practitioner under section 84AAJ be cancelled;

the Secretary shall cancel that approval.

(2) Where:

(a) an approved pharmacist gives the Secretary notice in writing that the pharmacist has ceased to carry on business as a pharmacist at premises in respect of which the pharmacist is approved; or

(b) an approved medical practitioner gives the Secretary notice in writing that the medical practitioner has ceased to practise in the area in respect of which the medical practitioner is approved;

the Secretary may (at his or her discretion) cancel the approval.

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(2A) Despite subsections (1) and (2), the Secretary may refuse to cancel an approval of an approved pharmacist in respect of particular premises if:

(a) the approved pharmacist is bankrupt; or

(b) there is an external administrator (within the meaning of section 91B) in relation to the pharmacy (within the meaning of that section) situated at those premises; or

(c) a matter referred to a Committee of Inquiry concerns the conduct of the approved pharmacist and the Committee has not concluded its inquiry into the matter.

(3) If the Secretary is satisfied that:

(a) an approved pharmacist is not carrying on business as a pharmacist at premises in respect of which the pharmacist is approved; or

(b) the premises are not accessible by members of the public for the purpose of receiving pharmaceutical benefits at times that, in the opinion of the Secretary, are reasonable; or

(c) an approved pharmacist's registration as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists has been suspended (however described); or

(d) an approved pharmacist has been deregistered (however described) as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists; or

(e) if an approved pharmacist is a body corporate:

(i) a person who is a director of the body corporate has been suspended or deregistered (however described) as a pharmacist or pharmaceutical chemist under a law of a State or Territory providing for the registration of pharmacists or pharmaceutical chemists; and

(ii) there is no other director of the body corporate who is registered (however described) as a pharmacist or pharmaceutical chemist under a law of a State or

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Territory providing for the registration of pharmacists or pharmaceutical chemists; or

(f) if an approved pharmacist is granted approval to supply pharmaceutical benefits at a particular premises in a State or territory—the approved pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business; or

(g) an approved pharmacist has breached the conditions to which the pharmacist's approval is subject;

then the Secretary may (at his or her discretion), by notice in writing to the pharmacist, cancel the approval of the pharmacist under section 90.

(3AA) If:

(a) a permission under section 91B is in force in relation to particular premises; and

(b) the holder of the permission requests that the approval of the pharmacist under section 90 in respect of those premises be cancelled;

the Secretary must cancel the approval. The Secretary must give written notice of the cancellation to the pharmacist and the holder of the permission.

(3AB) If a permission under section 91B in relation to particular premises is revoked under subsection 91B(12) or (13), the Secretary may cancel the approval of the pharmacist under section 90 in respect of those premises. The Secretary must give written notice of the cancellation to the pharmacist.

(3A) Where the Secretary is satisfied that an approved medical practitioner is not practising in the area in respect of which the medical practitioner is approved, the Secretary may (at his or her discretion), by notice in writing to the medical practitioner, cancel the approval of the medical practitioner under section 92.

(4) If a person becomes an approved pharmacist in respect of premises in an area in respect of which a medical practitioner is approved under section 92, the Secretary shall cancel the approval of the

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medical practitioner in respect of that area or of that part of the area in relation to which that section no longer applies.

(4A) If a pharmacist:

(a) before 18 December 1990, was granted an approval to supply pharmaceutical benefits at or from particular premises; and

(b) because of the operation of subsection 90(5A), is taken to have been granted such an approval in respect of other premises;

the Secretary is taken, immediately after the commencement of section 20 of the *Health and Community Services Legislation Amendment Act (No. 2) 1993*, to have cancelled the approval in respect of the premises referred to in paragraph (a).

(5) A reference in this section to an approved pharmacist carrying on business as a pharmacist at premises is a reference, in the case of an approved pharmacist to whom subsection 90(6) applies, to an approved pharmacist carrying on a business for the supply of pharmaceutical benefits at the premises.

(6) For the purposes of this section, an approved pharmacist is taken not to be carrying on business as a pharmacist if the approved pharmacist is not supplying pharmaceutical benefits in the course of carrying on the business.

98AA Cancellation by Minister of approval of hospital

(1) Whenever an approved hospital authority requests that its approval under section 94 in respect of all or any of the hospitals in respect of which it is approved be cancelled, the Minister shall cancel that approval.

(2) Where an approved hospital authority gives the Minister notice in writing that the authority has ceased to conduct a hospital in respect of which it is approved, the Minister may (at his or her discretion) cancel the approval.

(3) Where the Minister is satisfied that an approved hospital authority is not conducting a hospital in respect of which it is approved, the

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Minister may (at his or her discretion), by notice in writing to the authority, cancel the approval of the authority under section 94.

98AB Notification by Department of alterations to pharmaceutical benefits scheme

The Secretary must cause to be made publicly available on the Department's website information on the outcomes of the changes to the pharmaceutical benefits scheme resulting from the introduction of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*.

98AC Information about supplies

Information to be given about supplies

(1) An approved supplier that supplies a pharmaceutical benefit (including a supply to which subsection 99(2A), (2AB) or (2B) applies):

(a) must give to the Secretary, in relation to the supply of that benefit, the information specified in rules made by the Minister under paragraph (4)(a); and

(b) must give the information in accordance with the rules made by the Minister under paragraph (4)(b).

(2) Subsection (1) does not apply if the approved supplier makes, or proposes to make, a claim for payment in relation to the supply of the pharmaceutical benefit under section 99AAA.

Procedures for giving information

(3) Subject to the rules made by the Minister under paragraph (4)(b), subsections 99AAA(4) and (5) and section 99AAB (about the procedures for giving information) apply in relation to the giving of information under this section in the same way as they apply in relation to the giving of information under section 99AAA.

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Rules relating to information given to the Secretary

(4) The Minister must, by legislative instrument, make:
  (a) rules specifying the information to be given to the Secretary by approved suppliers in relation to the supply by them of pharmaceutical benefits; and
  (b) rules defining the procedures to be followed by approved suppliers in giving information to the Secretary in relation to the supply by them of pharmaceutical benefits.

(5) In making rules for the purposes of paragraph (4)(b), the Minister may define different procedures:
  (a) for the giving of information by electronic means; and
  (b) for the giving of information otherwise than by electronic means.

(6) Rules made under this section may be set out in the same document as rules made under subsection 99AAA(8).

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Division 3—Payment for supply of pharmaceutical benefits

Subdivision A—Preliminary

98AD What this Division is about

This Division is about payments made by the Commonwealth with respect to the provision of pharmaceutical benefits by approved suppliers.

An approved supplier who supplies a pharmaceutical benefit may be entitled to be paid by the Commonwealth in respect of the supply under:

(a) section 99 (payment for the supply of benefits); and

(b) for an approved pharmacist—section 99AAAA (additional payment for ACSS eligible supplies).

This Division also establishes the Pharmaceutical Benefits Remuneration Tribunal. The functions of the Tribunal are:

(a) to determine the manner in which the Commonwealth price of a pharmaceutical benefit supplied by an approved pharmacist is to be worked out; and

(b) to determine the kinds of supplies of pharmaceutical benefits that are eligible for an ACSS payment, and the amount of the payment or the manner in which that amount is to be worked out; and

(c) any other functions provided for under an agreement entered into between the Minister and the Pharmacy Guild of Australia, or another pharmacists' organisation that represents a majority of approved pharmacists, about the Commonwealth price of a pharmaceutical benefit supplied by an approved pharmacist or about an ACSS payment.

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Subdivision B—Determination of Commonwealth price and Commonwealth payments

98A Establishment of Pharmaceutical Benefits Remuneration Tribunal

(1) For the purposes of this Part, there is hereby established a Tribunal to be known as the Pharmaceutical Benefits Remuneration Tribunal.

(2) The Tribunal shall consist of:
  (a) a Chairperson appointed by the Governor-General; and
  (b) 4 additional members appointed by the Minister.

(2A) The Minister:
  (a) must appoint as an additional member at least one person who has been, but is no longer, engaged either directly or indirectly in community pharmacy; and
  (b) is to make that appointment only after he or she has consulted with the Pharmacy Guild of Australia.

(3) An appointment under subsection (2) shall be on a part-time basis.

(4) A person is not eligible to be appointed as Chairperson unless the person is a Deputy President of the Fair Work Commission.

98B Functions of Tribunal

(1) The functions of the Tribunal are:
  (a) to determine the manner in which the Commonwealth price for particular quantities or numbers of units of all or any pharmaceutical benefits is to be worked out for the purpose of payments to approved pharmacists in respect to the supply by them of pharmaceutical benefits; and
  (b) to determine, by legislative instrument:
    (i) the kinds of supplies by approved pharmacists of pharmaceutical benefits (if any) that are ACSS eligible supplies; and

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(ii) the amount (which may be nil) of the ACSS payment for any or all ACSS eligible supplies, or the manner in which that amount is to be worked out; and

(c) if an agreement referred to in section 98BAA provides for the Tribunal to perform functions under the agreement—those functions.

Commonwealth price determinations

(2) A manner determined under paragraph (1)(a) shall:

(a) in the case of a pharmaceutical benefit that is a listed brand of a pharmaceutical item—take as a basis the approved ex-manufacturer price or a proportional ex-manufacturer price of the brand of the pharmaceutical item that was in force on the first day of the month of the year in which the supply occurs; and

(b) in the case of other pharmaceutical benefits—take as a basis the basic wholesale price of each ingredient that is applicable on the day on which the supply occurs; and

(c) provide for the addition of such fees and other amounts as are determined by the Tribunal.

(3) In subsection (2):

basic wholesale price in relation to an ingredient in a pharmaceutical benefit, means the amount that The Pharmacy Guild of Australia and the Minister agree from time to time is to be taken to be, for the purposes of this Part, the appropriate price for sales of that ingredient to approved pharmacists.

(4) The Tribunal may approve criteria that it considers to be appropriate for use in determining the nature or magnitude of fees or other amounts referred to in paragraph (2)(c), and may, at any time, vary or revoke such criteria.

(5) In determining fees or other amounts referred to in paragraph (2)(c), and in approving criteria under subsection (4), the Tribunal must have regard to national minimum wage orders of the Fair Work Commission, and, in particular, any statements by the

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Commission about the effect of wage increases on productivity, inflation and levels of employment.

ACSS payment determinations

(6) In determining a kind of supply by approved pharmacists of pharmaceutical benefits under subparagraph (1)(b)(i), the Tribunal must be satisfied that it is necessary, to ensure that kind of supply, for approved pharmacists to be paid the ACSS payment for that kind of supply.

(7) In determining an amount or manner under subparagraph (1)(b)(ii) in relation to an ACSS eligible supply, the Tribunal must be satisfied that it is necessary, to ensure that supply, for the ACSS payment for that supply:
  (a) to be that amount; or
  (b) to be worked out in that manner.

(8) The Tribunal must determine under subparagraph (1)(b)(ii) that the amount of the ACSS payment for all ACSS eligible supplies is nil if:
  (a) an agreement referred to in subsection 98BAA(1) (agreements relating to Commonwealth price) is in force; and
  (b) no agreement referred to in subsection 98BAA(1A) (agreements relating to ACSS payment) is in force.

98BA Inquiries by Tribunal

(1) The Tribunal must, at such intervals as are determined by the Chairperson, hold an inquiry to ascertain either or both of the following:
  (a) whether the Commonwealth price of any or all pharmaceutical benefits should be varied;
  (b) both:
    (i) the kinds of supplies by approved pharmacists of pharmaceutical benefits (if any) that should be ACSS eligible supplies; and

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(ii) the amount (which may be nil) of the ACSS payment for any or all ACSS eligible supplies, or the manner in which that amount is to be worked out.

(2) The holding of an inquiry under subsection (1) shall be by means of proceedings before the Tribunal.

(3) A person interested in the subject matter of an inquiry under subsection (1) may seek the leave of the Tribunal to appear, or be represented, in the proceedings before the Tribunal for the purpose of making a submission, or presenting evidence or other material, to the Tribunal.

(4) The Tribunal shall ensure that its findings resulting from its second or any subsequent inquiry, and the reasons for them, are issued not later than 12 months after the date on which the Tribunal issued its findings resulting from its first inquiry or from the last inquiry held by it, as the case may be.

98BAA Tribunal must give effect to certain agreements

Agreements relating to Commonwealth price

(1) Despite anything else contained in this Part, where the Minister (acting on the Commonwealth's behalf) and the Pharmacy Guild of Australia or another pharmacists' organisation that represents a majority of approved pharmacists have entered into an agreement in relation to the manner in which the Commonwealth price of all or any pharmaceutical benefits is to be ascertained for the purpose of payments to approved pharmacists in respect of the supply by them of pharmaceutical benefits, the Tribunal, in making a determination under paragraph 98B(1)(a) while the agreement is in force, must give effect to the terms of that agreement.

Agreements relating to ACSS payment

(1A) Despite anything else contained in this Part, where the Minister (acting on the Commonwealth's behalf) and the Pharmacy Guild of Australia, or another pharmacists' organisation that represents a

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majority of approved pharmacists, have entered into an agreement in relation to:

(a) the kinds of supplies by approved pharmacists of pharmaceutical benefits (if any) that are ACSS eligible supplies; and

(b) the amount (which may be nil) of the ACSS payment for any or all ACSS eligible supplies, or the manner in which that amount is to be worked out;

the Tribunal, in making a determination under paragraph 98B(1)(b) while the agreement is in force, must give effect to the terms of that agreement.

No inquiries while Commonwealth price agreement in force

(2) Where:

(a) at the time an agreement referred to in subsection (1) is entered into, an inquiry under section 98BA is being held or such an inquiry has been completed but the Tribunal has not issued a statement under subsection 98BD(1); or

(b) such an agreement was in force immediately before the commencement of this section and at that time such an inquiry was being held or such an inquiry had been completed but the Tribunal had not issued a statement under subsection 98BD(1);

the Tribunal must terminate the inquiry or, in a case where the inquiry has been completed but a statement has not been so issued, take no further action for the purposes of that inquiry.

(3) Section 98BA does not apply while there is in force an agreement referred to in subsection (1) except so far as otherwise provided in that agreement.

98BB Constitution of Tribunal

(1) For all purposes, including the purposes of any proceeding before the Tribunal, the Tribunal is to be constituted by the Chairperson and at least 2 additional members.

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(1A) The Chairperson may give directions as to the constitution of the Tribunal for the purposes of any inquiry.

(2) In this section:

additional member includes an acting additional member; and

Chairperson includes an acting Chairperson.

98BC Procedure of Tribunal

(1) Subject to this Part, in any proceeding before the Tribunal:
  (a) the procedure of the Tribunal is within the discretion of the Tribunal;
  (b) the Tribunal is not bound to act in a formal manner and is not bound by any rules of evidence but may inform itself of any matter in such manner as it thinks just; and
  (c) the Tribunal shall act according to equity, good conscience and the substantial merits of the case, without regard to technicalities and legal forms.

(2) Subject to subsection (3), a proceeding before the Tribunal shall be conducted in public.

(3) If the Tribunal is satisfied, upon the application of a party to a proceeding before the Tribunal, that, by reason of the confidential nature of a submission, or other evidence or material, submitted to the Tribunal in the proceeding, or for any other reason, it is undesirable to conduct the proceeding or a part of the proceeding in public, the Tribunal may direct that the proceeding or the part of the proceeding, as the case may be, be conducted in private.

(4) A direction by the Tribunal under subsection (3) may:
  (a) specify persons for the purpose of permitting them, but no other persons, to be present when the proceeding, or the part of the proceeding, concerned is conducted in private; or
  (b) specify persons for the purpose of prohibiting them from being present when the proceeding, or the part of the proceeding, concerned is conducted in private.

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(5) The Chairperson is to preside in any proceeding before the Tribunal and all questions to be decided by the Tribunal are to be decided by a majority of votes of the members and, for that purpose, the Chairperson has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

98BD Findings etc. of Tribunal to be made public

(1) After the completion of an inquiry under section 98BA, the Tribunal shall issue, in a proceeding conducted in public, a statement, in writing, of its findings and the reasons for them.

(2) Where the Tribunal:

(a) determines fees or other amounts referred to in paragraph 98B(2)(c); or

(b) makes a decision approving criteria under subsection 98B(4) or varying or revoking such criteria;

the Tribunal shall issue, in a proceeding conducted in public, a statement, in writing, setting out the terms of that determination or decision and the reasons for making it.

(3) Where the Tribunal issues a statement under subsection (1) or (2), the Tribunal shall:

(a) submit to the Minister a report setting out the terms of the statement so issued; and

(b) cause to be published in the *Gazette* a notice setting out the terms of the statement so issued.

98BE Date of operation of determination of the Tribunal

A determination of the Tribunal under subsection 98B(1) shall come into operation on a date specified in the determination, not being a date earlier than the date on which a statement setting out the terms of the determination is issued by the Tribunal in accordance with section 98BD.

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98C Determinations by Minister

(1) The Minister may, by legislative instrument, determine:

(a) the manner in which the Commonwealth price for particular quantities or numbers of units of all or any pharmaceutical benefits is to be ascertained for the purpose of payments to approved medical practitioners in respect of the supply of pharmaceutical benefits, including any fees or other amounts that are to be taken into account in determining that price; and

(b) the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

(2) The Minister may, before making a determination with respect to the conditions referred to in paragraph (1)(b), request the Tribunal to make a report with respect to the matters in respect of which the determination is to be made and, where such a request is made, the Tribunal shall comply with the request.

98E Secrecy

(1) The Chairperson may, if he or she thinks it desirable to do so, give a direction in writing that any document, or evidence or other material, presented to the Tribunal in a proceeding before the Tribunal shall be treated as confidential.

(2) Where a direction is given under subsection (1) in relation to any document or evidence or other material:

(a) a person who, by virtue of the person's office or employment under or for the purposes of this Act, has acquired any information obtained from that document or evidence or other material shall not, either directly or indirectly, except in the performance of a duty or the exercise of a function under or in connection with this Act, use, or disclose to any person, that information; and

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(b) a person who, by virtue of the person's office or employment under or for the purposes of this Act, has access to that document or a record of that evidence or other material shall not be required to produce in a court, or to permit a court to have access to, that document or record, except when it is necessary to do so for the purposes of, or of a prosecution under or arising out of, this Act.

Subdivision C—Payments for the supply of pharmaceutical benefits

99 Payment for supply of benefits—general

Supply by approved pharmacist or approved medical practitioner

(2) An approved pharmacist or approved medical practitioner who has supplied a pharmaceutical benefit is, subject to section 99AAA and to the conditions determined under section 98C and applicable at the time of the supply, entitled to be paid by the Commonwealth:

(a) where the prescription for the supply of the pharmaceutical benefit was an entitlement card prescription, and the supply was not an early supply of a specified pharmaceutical benefit—an amount equal to the Commonwealth price of the pharmaceutical benefit as at the time of the supply; and

(b) in any other case—the amount (if any) by which the Commonwealth price of the pharmaceutical benefit, as at the time of the supply, exceeded the amount (without any allowable discount) that the pharmacist or approved medical practitioner was entitled to charge under subsection 87(2) or (3).

(2AA) If:

(a) an approved pharmacist or approved medical practitioner is entitled to be paid an amount by the Commonwealth under subsection (2) in relation to the supply of a pharmaceutical benefit; and

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(b) a determination under subsection 85B(4) is in force in relation to a listed brand of a pharmaceutical item that is the pharmaceutical benefit; and

(c) the brand of the pharmaceutical item was supplied in the circumstances specified in that determination;

then, subject to section 99AAA and the conditions determined under section 98C and applicable at the time of the supply, the approved pharmacist or approved medical practitioner is entitled to be paid by the Commonwealth an amount that is equal to the amount of the special patient contribution for the brand of the pharmaceutical item.

Under co-payment supply

(2A) Where a pharmaceutical benefit is supplied upon a general benefit prescription (other than in a case to which subsection (2AB) applies), or a supply of a pharmaceutical benefit is an early supply of a specified pharmaceutical benefit upon a concession card prescription, and:

(a) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner otherwise than as referred to in paragraph (b) and the Commonwealth price of the pharmaceutical benefit does not, at the time of the supply, exceed the general patient charge amount; or

(aa) the pharmaceutical benefit is supplied by an approved hospital authority and the amount that would have been the Commonwealth price of the pharmaceutical benefit if it had been supplied by an approved pharmacist does not, at the time of the supply, exceed the general patient charge amount; or

(b) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner in accordance with a direction included in a prescription in pursuance of subsection 88(6) or (6A) and the Commonwealth price of the maximum quantity or number of units of the pharmaceutical benefit that could, but for that subsection, have been directed to be supplied on any one occasion does not, at the time of the supply, exceed the general patient charge amount;

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the supply and receipt of that pharmaceutical benefit shall, for all purposes of this Part (other than for the purposes of Division 1A), be deemed to be a supply and receipt otherwise than under this Part.

(2AB) Where a pharmaceutical benefit is supplied upon a general benefit prescription to a person referred to in paragraph 87(2)(b) and:

(a) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner otherwise than as referred to in paragraph (c) and the Commonwealth price of the pharmaceutical benefit does not, at the time of the supply, exceed $4.60; or

(b) the pharmaceutical benefit is supplied by an approved hospital authority and the amount that would have been the Commonwealth price of the pharmaceutical benefit if it had been supplied by an approved pharmacist does not, at the time of the supply, exceed $4.60; or

(c) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner in accordance with a direction included in a prescription under subsection 88(6) or (6A) and the Commonwealth price of the maximum quantity or number of units of:

(i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(ii) in any other case—the pharmaceutical benefit;

that could, apart from that subsection, have been directed to be supplied on any one occasion does not, at the time of the supply, exceed $4.60;

the supply and receipt of that pharmaceutical benefit is, for all purposes of this Part (other than the purposes of Division 1A), taken to be a supply and receipt otherwise than under this Part.

Note: The figures expressed in this subsection in dollars are periodically adjusted under section 99G.

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(2B) Where a pharmaceutical benefit is supplied upon a concessional benefit prescription and:

(a) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner otherwise than as referred to in paragraph (c) and the Commonwealth price of the pharmaceutical benefit does not, at the time of the supply, exceed $4.60; or

(b) the pharmaceutical benefit is supplied by an approved hospital authority and the amount that would have been the Commonwealth price of the pharmaceutical benefit if it had been supplied by an approved pharmacist does not, at the time of the supply, exceed $4.60; or

(c) the pharmaceutical benefit is supplied by an approved pharmacist or an approved medical practitioner in accordance with a direction included in a prescription in pursuance of subsection 88(6) or (6A) and the Commonwealth price of the maximum quantity or number of units of:

(i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or

(ii) in any other case—the pharmaceutical benefit;

that could, apart from that subsection, have been directed to be supplied on any one occasion does not, at the time of the supply, exceed $4.60;

the supply and receipt of that pharmaceutical benefit shall, for all purposes of this Part (other than for the purposes of Division 1A), be deemed to be a supply and receipt otherwise than under this Part.

Note: The figures expressed in this subsection in dollars are periodically adjusted under section 99G.

Supply eligible for increased discounting

(2C) If a supply is eligible for increased discounting, then:

(a) subject to paragraph (b) of this subsection, paragraph (2)(b) applies in relation to the supply as if the reference in paragraph (2)(b) to the amount (without any allowable discount) that the pharmacist or medical practitioner was

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entitled to charge under subsection 87(2) were a reference to the general patient charge amount; and

(b) if an amount is charged for the supply under subparagraph 87(2)(e)(ii)—subsection (2) of this section does not apply in relation to the supply.

Note: Subparagraph 87(2)(e)(i) allows an approved pharmacist or approved medical practitioner to charge the general patient charge amount for certain supplies. Subparagraph 87(2)(e)(ii) allows the approved pharmacist or approved medical practitioner to charge a lower amount if the supply is eligible for increased discounting.

Supply by approved hospital authority

(4) An approved hospital authority is, subject to this Part, entitled to payment from the Commonwealth, at such rates and subject to such conditions as the Minister determines, in respect of the supply of particular quantities or numbers of units of pharmaceutical benefits to patients receiving treatment in or at a hospital in respect of which the approved hospital authority is approved.

(5) A payment to which an approved hospital authority in a State is entitled under this section may be paid to that State, or to an authority of that State, on behalf of the approved hospital authority.

99AAAA Additional payment for ACSS eligible supplies

(1) This section applies in relation to an ACSS eligible supply that is made on or after 1 April 2024.

(2) An approved pharmacist who has made an ACSS eligible supply is entitled to be paid by the Commonwealth the ACSS payment for the supply.

(3) Subsection (2) is subject to:

(a) section 99AAA (claim for payment relating to supply of benefits); and

(b) the conditions determined under section 98C (determinations by Minister) and applicable at the time of the supply.

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Note: This section is also subject to the conditions set out in section 99AAAB.

99AAAB Conditions on payments

(1) Nothing in section 99 or 99AAAA authorises payment in respect of the supply of a drug or medicinal preparation:

(a) to a person who is not entitled under this Part to receive that drug or medicinal preparation as a pharmaceutical benefit; or

(b) by an approved pharmacist at or from premises in respect of which the pharmacist is not approved or otherwise than in accordance with the terms of the pharmacist's approval; or

(c) by an approved medical practitioner outside the area in respect of which the medical practitioner is approved or otherwise than in accordance with the terms of the medical practitioner's approval.

Medicare or special number required for Commonwealth payment for supply of pharmaceutical benefit

(2) Subject to subsection (3), an approved supplier is not entitled, despite subsection 99(2) or (4) or 99AAAA(2), to be paid by the Commonwealth for the supply of a pharmaceutical benefit to a person upon a prescription unless:

(a) there is ultimately supplied to the Chief Executive Medicare a medicare number, or a special number, as a number applicable to the person to whom the prescription relates; and

(b) if the number so supplied is such a medicare number—that medicare number corresponds with a medicare number that is held in the records of the Chief Executive Medicare as a number applicable to that person.

Determination about payments for supplies where medicare number does not correspond with records

(3) The Minister may, by legislative instrument, determine circumstances in which subsection (2) does not prevent an approved supplier being paid by the Commonwealth for the supply

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of a pharmaceutical benefit in respect of a person to whom a prescription relates although a medicare number ultimately supplied to the Chief Executive Medicare in relation to the prescription does not correspond with a medicare number that is held in the records of the Chief Executive Medicare as a number applicable to that person.

99AAA Claim for payment relating to supply of benefits

(1) In this section:

Claims Transmission System means the procedures defined in the rules made by the Minister under paragraph (8)(c).

manual system means the procedures defined in the rules made by the Minister under paragraph (8)(d).

(2) An approved supplier who wants to receive payment from the Commonwealth in relation to the supply of a pharmaceutical benefit must make a claim for payment to the Secretary in accordance with the rules made by the Minister under paragraph (8)(a).

(3) An approved supplier who makes, or proposes to make, a claim for payment in relation to the supply of a pharmaceutical benefit must give to the Secretary, in relation to the supply of that benefit, the information specified in the rules made by the Minister under paragraph (8)(b).

(4) Except as provided by section 99AAB, an approved supplier must use the Claims Transmission System to give information to the Secretary in relation to the supply of pharmaceutical benefits.

(5) If an approved supplier does not use the Claims Transmission System to provide information to the Secretary in relation to the supply of pharmaceutical benefits, the approved supplier must use the manual system to provide that information to the Secretary.

(6) The Secretary must process and determine claims made under subsection (2), and make any payments relating to those claims, in

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accordance with the rules made by the Minister under paragraph (8)(e).

(7) Where the Secretary decides not to approve a claim made by an approved supplier under subsection (2), the Secretary must, in writing, inform the approved supplier of the decision and give reasons for the decision.

(8) The Minister must, by legislative instrument, make:

(a) rules defining the procedures to be followed by approved suppliers in making claims for payment in relation to the supply of pharmaceutical benefits; and

(b) rules specifying the information to be given to the Secretary by approved suppliers in relation to the supply by them of pharmaceutical benefits; and

(c) rules defining the procedures to be followed by approved suppliers in providing information by electronic means to the Secretary in relation to the supply by them of pharmaceutical benefits; and

(d) rules defining the procedures to be followed by approved suppliers in providing information otherwise than by electronic means to the Secretary in relation to the supply by them of pharmaceutical benefits; and

(e) rules defining the procedures to be followed by the Secretary in:

(i) processing and determining claims by approved suppliers for payment relating to the supply of pharmaceutical benefits; and

(ii) making the payments.

(10) In making rules for the purposes of paragraph (8)(a), the Minister may define different procedures:

(a) for the making of claims for payment supported by information provided by electronic means; and

(b) for the making of claims for payment supported by information provided otherwise than by electronic means.

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99AAB Certain suppliers exempted from requirement to use the Claims Transmission System

(1) An approved supplier specified in subsection (2) is not required to comply with subsection 99AAA(4) but the approved supplier may do so if the approved supplier so wishes.

(2) For the purposes of subsection (1), the following approved suppliers are specified:

(a) an approved medical practitioner;

(e) an approved supplier in respect of whom a declaration under section 99AAC is in force.

99AAC Declaration by Secretary exempting approved supplier from using Claims Transmission System

(1) The Secretary may, subject to the guidelines determined by the Minister under subsection (2), declare in writing that an approved supplier is exempted from the operation of subsection 99AAA(4).

(2) The Minister must, by legislative instrument, determine guidelines in accordance with which the Secretary is to exercise his or her functions under subsection (1).

(4) Where the Secretary decides:

(a) not to make a declaration under subsection (1) in respect of an approved supplier; or

(b) to revoke such a declaration;

the Secretary must, in writing, inform the approved supplier of the decision and give reasons for the decision.

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Division 3AA—Recovery of payments for the supply of pharmaceutical benefits

99AA Unauthorised payments etc.

(1) Where:

(a) a pharmaceutical benefit has been supplied to a person (in this subsection referred to as the ***patient***) by an approved pharmacist, approved medical practitioner or approved hospital authority;

(b) the pharmacist, medical practitioner or authority is paid an amount (in this subsection referred to as the ***relevant amount***) by the Commonwealth in respect of the supply of the benefit to the patient; and

(c) the patient obtained the benefit on terms that were appropriate for the supply of the benefit to:

(i) a holder of a concession card; or

(iii) a holder of an entitlement card; or

(iv) a concessional beneficiary; or

(v) a person who was a dependant of a concessional beneficiary within the meaning of subsection 84(4) or (7);

knowing, or in circumstances such that he or she ought reasonably to have known, that he or she was not entitled to receive the benefit on those terms;

the Secretary may, by notice in writing to the patient, require the patient to pay to the Commonwealth an amount equal to the relevant amount.

(2) Where:

(a) a pharmaceutical benefit is supplied, or purportedly supplied, to a person by an approved pharmacist, approved medical practitioner or approved hospital authority;

(b) the pharmacist, medical practitioner or authority is paid an amount (in this subsection referred to as the ***relevant***

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amount) by the Commonwealth in respect of the supply or purported supply of the benefit to that person; and

(c) the pharmacist, medical practitioner or authority obtained the relevant amount knowing, or in circumstances such that he or she ought reasonably to have known, that it was not payable;

the Secretary may, by notice in writing to the pharmacist, medical practitioner or authority, require the pharmacist, medical practitioner or authority to pay to the Commonwealth an amount equal to the relevant amount.

(3) Where:

(a) the conditions referred to in paragraphs (1)(a), (b) and (c) or (2)(a), (b) and (c) are satisfied in relation to an amount paid by the Commonwealth; and

(b) the Secretary gives a person notice under subsection (1) or (2) as the case may be, requiring the person to pay to the Commonwealth an amount equal to the amount referred to in paragraph (a) of this subsection;

the Commonwealth may recover the amount referred to in the notice as a debt due to the Commonwealth by action in a court of competent jurisdiction.

(4) Where a person is liable to pay an amount to the Commonwealth under this section, an amount not exceeding that amount may be deducted from any other amount that is payable to the person under this Part and, where an amount is so deducted, the other amount shall, notwithstanding the deduction, be deemed to have been paid in full to the person.

99AB Advances

Amounts that may become payable under section 99

(1) An advance, on account of an amount that may become payable to a person under section 99 in relation to the supply of a pharmaceutical benefit, may be made to the person on such terms and conditions (if any) as are approved by the Secretary in writing.

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Amounts that may become payable under section 99AAAA

(1A) An advance, on account of an amount that may become payable to a person under section 99AAAA in relation to the supply of a pharmaceutical benefit, may be made to the person:

(a) if the amount may become payable on or after a day specified in an instrument under subsection (1B) of this section; and

(b) on such terms and conditions (if any) as are approved by the Secretary in writing.

(1B) The Secretary may, by notifiable instrument, specify a day for the purposes of paragraph (1A)(a) (which must not be before the day the instrument commences).

Repayment of amounts

(2) If a person receives, by way of advances on account of an amount that may become payable to the person under section 99 or 99AAAA in relation to the supply of a pharmaceutical benefit, an amount that exceeds the amount that becomes payable to the person under section 99 or 99AAAA in relation to the supply of the pharmaceutical benefit, the person is liable to repay to the Commonwealth the amount of the excess.

(3) If:

(a) a person receives an amount by way of advances on account of an amount that may become payable to the person under section 99 or 99AAAA in relation to the supply of a pharmaceutical benefit; and

(b) no amount becomes payable to the person under section 99 or 99AAAA in relation to the supply of the pharmaceutical benefit;

the person is liable to repay to the Commonwealth the amount so received.

(4) Where a person is liable to repay an amount to the Commonwealth under this section, the Commonwealth may recover the amount as a debt due to the Commonwealth by action in a court of competent jurisdiction.

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(5) Where a person is liable to repay an amount to the Commonwealth under this section, an amount not exceeding that amount may be deducted from any other amount that is payable to the person under this Part and, where an amount is so deducted, the other amount shall, notwithstanding the deduction, be deemed to have been paid in full to the person.

99ABA Recovery of amounts for false or misleading information

(1) This section applies if, as a result of the giving of false or misleading information, an amount paid, purportedly by way of benefit or payment under this Act, exceeds the amount (if any) that should have been paid.

(2) The amount of the excess is recoverable as a debt due to the Commonwealth from:
  (a) the person by or on behalf of whom the information was given; or
  (b) the estate of that person.

(3) Subsection (2) applies whether or not:
  (a) the amount was paid to the person; and
  (b) any person has been convicted of an offence in relation to the giving of the information.

(4) For the purposes of this section, it is immaterial whether the false or misleading information is given:
  (a) in a document; or
  (b) in a statement; or
  (c) in any other form.

99ABB Notice to produce documents

(1) This section applies if:
  (a) an amount is paid to a person under this Act by the Commonwealth in respect of the supply, or purported supply, of a pharmaceutical benefit; and

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(b) the person was an approved pharmacist, approved medical practitioner or approved hospital authority when the amount was paid; and

(c) the person is required, under a provision of this Act, the regulations or another legislative instrument under this Act, to keep a document relating to the supply of the pharmaceutical benefit.

(2) The Secretary may, by written notice given to the person, require the person to produce the document, or a copy of the document, to the Secretary.

(3) The person must produce the document or copy to the Secretary within the period specified in the notice, which must not be less than 21 days after the day the notice is given.

(4) If the person fails to comply with the notice, the amount paid to the person in respect of the supply, or purported supply, of the pharmaceutical benefit is recoverable as a debt due to the Commonwealth from the person or the estate of the person.

(5) Subsection (4) does not apply if the person satisfies the Secretary that the person's non-compliance is due to circumstances beyond the person's control.

99ABC Notice of decision to claim amounts as debts

(1) If an amount is recoverable under subsection 99ABA(2) or 99ABB(4) as a debt due to the Commonwealth from a person or the estate of the person, the Secretary must give written notice to the person or estate of:

(a) the decision to claim the amount as a debt; and

(b) the reasons for the decision; and

(c) any right of the person or estate to seek review of the decision under section 99ABD.

(2) The Secretary's written notice to the person or estate of a decision may include written notice of other decisions referred to in this section that are also required to be given to the person or estate.

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(3) A failure to comply with the requirements of subsection (1) does not affect the validity of the decision.

(4) The Secretary must not serve a notice on a person or an estate claiming an amount as a debt before the end of the period of 28 days after written notice of the decision referred to in subsection (1) is given to the person or estate.

(5) Subsection (4) does not apply in relation to claiming an amount as a debt if the person or estate has notified the Secretary as mentioned in subsection 99ABD(2) in relation to the debt.

99ABD Review of decisions to claim amounts as debts

(1) If the Secretary makes a decision referred to in subsection 99ABC(1) about a person or an estate, the person or estate may apply in writing to the Secretary, in the form approved in writing by the Secretary, for a review of the decision.

(2) Subsection (1) does not apply if the person or estate has notified the Secretary, in the form approved in writing by the Secretary, that the person waives the person's right to review of the decision to claim the amount as a debt.

(3) In making an application under subsection (1), the person or estate may provide the Secretary with additional information to substantiate (wholly or partly) that the amount paid under this Act in respect of the pharmaceutical benefit should have been paid.

(4) An application for review of a decision must be made within 28 days after the person or estate is notified of the decision.

(5) On receiving an application for review of a decision, the Secretary must:
  (a) review the decision; and
  (b) confirm, vary or revoke the decision.

(6) The Secretary must give to the applicant written notice of the decision (the ***reconsidered decision***) on the review within 28 days after receiving the application for review.

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(7) A failure to comply with the requirements of subsection (6) does not affect the validity of the review or of the reconsidered decision.

(8) Applications may be made to the Administrative Review Tribunal for review of reconsidered decisions.

(9) An application under subsection (8) may be made only if:
  (a) the applicant has been given notice of the reconsidered decision under subsection (6); and
  (b) one or more garnishee notices have been given under subsection 99ABJ(2) in relation to the debt to which the reconsidered decision relates.

(10) Despite subsection 18(1) of the *Administrative Review Tribunal Act 2024*, an application under subsection (8) of this section must be made within the period of 28 days after the day the first garnishee notice is given.

(11) To avoid doubt:
  (a) a decision mentioned in subsection (1) may be reviewed by the Secretary under subsection (5) once only; and
  (b) a reconsidered decision takes effect:
    (i) on the day specified in the reconsidered decision; or
    (ii) if a day is not specified—on the day on which the reconsidered decision is made.

99ABE Liability for administrative penalty

A person is liable for an administrative penalty in respect of the supply or purported supply of a pharmaceutical benefit if:
  (a) the Secretary has served a notice (as mentioned in subsection 99ABC(4)) on the person claiming an amount (the ***total amount***) as a debt due to the Commonwealth under subsection 99ABC(1); and
  (b) the total amount consists of, or includes, an amount (the ***recoverable amount***) in respect of the benefit recoverable as a debt due to the Commonwealth from the person; and
  (c) the total amount is more than:

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(i) $2,500; or
(ii) if a higher amount is prescribed by the regulations—that higher amount.

99ABF Amount of administrative penalty

(1) The amount of the administrative penalty for a pharmaceutical benefit is worked out in accordance with this section.

(2) The amount (the ***base penalty amount***) of the administrative penalty for a pharmaceutical benefit is 20% of the recoverable amount mentioned in paragraph 99ABE(b) in respect of the benefit.

(3) However, a person's base penalty amount for a pharmaceutical benefit is reduced by 50% if:
(a) the Secretary gives a notice to the person under subsection 99ABB(2) relating to the benefit; and
(b) before the end of the period specified in the notice, the person voluntarily tells the Secretary, in the form approved in writing by the Secretary, that the amount paid to the person under this Act in respect of the benefit exceeds the amount (if any) that should have been paid.

99ABG Notice of administrative penalty and review of assessments

(1) The Secretary must give to a person who the Secretary has assessed, in accordance with sections 99ABE and 99ABF, is liable for an administrative penalty, or the person's estate, written notice of the assessment which includes the following:
(a) the person's liability to pay an administrative penalty in respect of one or more pharmaceutical benefits;
(b) the pharmaceutical benefit to which each administrative penalty relates;
(c) if there is more than one pharmaceutical benefit—the total of the administrative penalties;

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(d) the day by which the penalty becomes due for payment (which must be at least 14 days after the day on which the notice is given);

(e) the fact that the notice is given under this section.

(2) The notice may also deal with a debt due to the Commonwealth under subsection 99ABA(2) or 99ABB(4) arising in relation to the pharmaceutical benefit.

(3) If:

(a) a person is given a notice under subsection (1) of the person's liability to pay an administrative penalty; and

(b) the person does not pay the penalty by the day set out in the notice as the day by which the penalty becomes due for payment;

the amount set out in the notice is recoverable as a debt due to the Commonwealth from the person or the estate of the person.

Review of decisions

(4) Applications may be made to the Administrative Review Tribunal for review of assessment by the Secretary of liability to administrative penalties for which notice has been given under subsection (1).

(5) An application under subsection (4) may be made by a person, or a person's estate, only if:

(a) the person or estate has been given a notice under subsection (1) that the person is liable for an administrative penalty; and

(b) the decision to claim the debt to which the administrative penalty relates is a reconsidered decision under subsection 99ABD(6); and

(c) one or more garnishee notices have been given under subsection 99ABJ(2) in relation to the debt.

(6) Despite subsection 18(1) of the *Administrative Review Tribunal Act 2024*, an application under subsection (4) of this section must

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be made within the period of 28 days after the day the first garnishee notice is given.

99ABH Power to obtain information relating to a debt

(1A) This section applies in relation to an amount (a ***recoverable amount***) that is recoverable from a person, or from the estate of a person, as a debt due to the Commonwealth if the amount is one of the following:

(a) an amount for which notice has been served as mentioned in subsection 99ABC(4);

(b) an amount for which notice has been given as mentioned in subsection 99ABG(3).

(1) The Secretary may, by written notice given to the person or estate, require the person or estate to do either or both of the following:

(a) give to the Secretary information in writing that is relevant to the financial situation of the person or estate;

(b) produce to the Secretary a document that is in the custody or under the control of the person or estate and is relevant to the financial situation of the person or estate.

(2) The person must notify the Secretary of an address for the purposes of giving the person documents relating to the debt, within 14 days after the day:

(a) if paragraph (1A)(a) applies—notice is served as mentioned in subsection 99ABC(4); or

(b) if paragraph (1A)(b) applies—the amount becomes due for payment.

Civil penalty:

(a) for an individual—20 penalty units; and

(b) for a body corporate—100 penalty units.

(3) If the address of the person changes after notifying the address under subsection (2) or this subsection, the person must notify the Secretary of the change within 14 days after the change.

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Civil penalty:

(a) for an individual—20 penalty units; and

(b) for a body corporate—100 penalty units.

(4) If the Secretary reasonably believes that a person may have information or a document:

(a) that would help the Secretary locate another person or estate (the ***debtor***) from which a recoverable amount is recoverable; or

(b) that is relevant to the debtor's financial situation;

the Secretary may, by written notice given to the person, require the person to give the information in writing, or produce the document, to the Secretary.

(5) A notice under subsection (1) or (4) must specify the following:

(a) how the person or estate is to give the information in writing or produce the document;

(b) the period (which must be at least 14 days after the day the notice is given) within which the person or estate is to give the information in writing or produce the document;

(c) that the notice is given under subsection (1) or (4) (as the case requires).

(6) A person contravenes this subsection if:

(a) the person is given a notice under subsection (1) or (4) requiring the person to give information in writing or produce a document; and

(b) the person fails to comply with the requirement within the period specified in the notice.

Civil penalty: 20 penalty units.

(7) Subsection (2), (3) or (6) does not apply if the person has a reasonable excuse.

Note: A person who wishes to rely on this subsection bears an evidential burden in relation to the matters in this subsection (see section 96 of the Regulatory Powers Act).

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99ABI Amounts recoverable once only

To avoid doubt, an amount recoverable from a person, or an estate of a person, in respect of the supply, or purported supply, of a pharmaceutical benefit is recoverable under this Division once only.

99ABJ Garnishee notices

(1) This section applies in relation to an amount that is:
  (a) a debt due to the Commonwealth under subsection 99ABA(2), 99ABB(4) or 99ABG(3) (the ***debt***); and
  (b) recoverable from a person (the ***debtor***) or from the estate of that person; and
  (c) in relation to which any rights to review by the Secretary under section 99ABD have been exhausted or have expired.

(2) If a person (the ***third party***) owes or may later owe money to the debtor or estate, the Secretary may give a written notice (the ***garnishee notice***) to the third party.

Third party regarded as owing money in these circumstances

(3) The third party is taken to owe money (the ***available money***) to the debtor or estate if the third party:
  (a) is a person by whom the available money is due or accruing to the debtor or estate; or
  (b) holds the money for, or on account of, the debtor or estate; or
  (c) holds the money on account of some other person for payment to the debtor or estate; or
  (d) has authority from some other person to pay the money to the debtor or estate.

(4) The third party is taken to owe the available money to the debtor or estate even if:
  (a) the money is not due, or is not so held, or payable under the authority, unless a condition is fulfilled; and

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(b) the condition has not been fulfilled.

How much is payable under the notice

(5) The garnishee notice must:

(a) require the third party to pay to the Commonwealth the lesser of, or a specified amount not exceeding the lesser of:

(i) the debt; or

(ii) the available money; or

(b) if there will be amounts of the available money from time to time—require the third party to pay to the Commonwealth a specified amount, or a specified percentage, of each amount of the money, until the debt is satisfied.

When amount must be paid

(6) The garnishee notice must require the third party to pay an amount under paragraph (5)(a), or each amount under paragraph (5)(b), within the period specified in the notice.

Debtor must be notified

(7) The Secretary must send a copy of the garnishee notice to the debtor or estate.

Setting off amounts

(8) If a person other than the third party has paid an amount to the Commonwealth that satisfies all or part of the debt:

(a) the Secretary must notify the third party of that fact; and

(b) any amount that the third party is required to pay under the garnishee notice is reduced by that amount.

Indemnity

(9) If an amount is paid by the third party in accordance with the garnishee notice:

(a) the payment is taken to have been authorised by:

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(i) the debtor or estate; and
(ii) any other person who is entitled to all or a part of the amount; and

(b) the third party is indemnified for the payment.

Garnishee notice to Commonwealth, State or Territory

(10) If the third party is the Commonwealth, a State or a Territory, the Secretary may give the notice to a person who is (as the case requires):

(a) employed by the Commonwealth, State or Territory; and
(b) required, or authorised, to disburse public money under a law of the Commonwealth, State or Territory.

Section binds the Crown

(11) This section binds the Crown in right of the Commonwealth, of each of the States, of the Australian Capital Territory and of the Northern Territory.

(12) However, this section does not make the Crown liable to be prosecuted for an offence.

(13) To avoid doubt, this section does not imply that the Crown is, or is not, bound by any other provision of this Act.

Review of decisions

(14) The debtor or estate may apply to the Administrative Review Tribunal for review of a decision by the Secretary to give a garnishee notice to a person under subsection (2).

99ABK Failure to comply with garnishee notice

(1) A person commits an offence if:

(a) the person is given a garnishee notice under section 99ABJ; and
(b) the person fails to comply with the notice.

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Penalty: 20 penalty units.

(2) The court may, in addition to imposing a penalty on a person convicted of an offence against subsection (1) in relation to failing to pay an amount under the notice, order the person to pay to the Commonwealth an amount not exceeding that amount.

99ABL Recoverable amounts may be set off

(1) This section applies in relation to an amount (the ***recoverable amount***) if:

(a) the amount is recoverable from a person, or the estate of a person, as a debt due to the Commonwealth under subsection 99ABA(2), 99ABB(4) or 99ABG(3); and

(b) any review rights under section 99ABD in relation to the amount have been exhausted or have expired.

(2) The Secretary may, on behalf of the Commonwealth, set off the whole or a part of the recoverable amount against the whole or a part of an amount payable (the ***payable amount***) to the person or estate under this Act.

(3) To avoid doubt:

(a) an amount set off under subsection (2) may be equal to or less than 100% of the payable amount; and

(b) the payable amount is taken to have been paid in full to the person or estate if the payable amount, less any amount set off against the payable amount under this section, is paid to the person or estate.

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Division 3A—Price reductions

Subdivision A—Preliminary

99AC What this Division is about

This Division is about price reductions for listed brands of pharmaceutical items.

Subdivision B requires there to be a price reduction for the first new brand of a pharmaceutical item (other than a combination item) when the brand lists. The listing of the new brand of the pharmaceutical item also provides an automatic trigger for price reductions to occur under Subdivision E (see sections 99ACQ and 99ACR).

Subdivision C requires there to be a price reduction for the first new brand of a pharmaceutical item that is a combination item when the brand lists. The listing of the new brand of the pharmaceutical item also provides an automatic trigger for price reductions to occur under Subdivision E (see sections 99ACQ and 99ACR).

Subdivision D provides for other price reductions for pharmaceutical items. These price reductions include reductions that occur on a certain anniversary of the drug in the pharmaceutical item being a listed drug.

Subdivision E provides for price reductions that are automatically triggered when Subdivision B or C applies to require a first new brand price reduction for a brand of a pharmaceutical item.

Price reductions for listed brands of pharmaceutical items under this Division are subject to:

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(a) determinations made by the Minister to not apply, or reduce, the price reduction; or

(b) price reductions made under Subdivision E of Division 3B (see section 99ACG).

99ACA Definitions etc.

(1) In this Division:

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

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

(2) A listed component drug contained in a drug in a combination item has been subject to a ***12.5% price reduction*** if a pharmaceutical item that has:

(a) the listed component drug; and

(b) the same manner of administration as the combination item;

is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied.

(2A) A listed component drug contained in a drug in a combination item has been subject to a ***16% price reduction*** if a pharmaceutical item that has:

(a) the listed component drug; and

(b) the same manner of administration as the combination item;

is in a class of pharmaceutical items to which a 16% administrative price reduction has applied.

(2B) A listed component drug contained in a drug in a combination item has been subject to a ***25% price reduction*** if a pharmaceutical item that has:

(a) the listed component drug; and

(b) the same manner of administration as the combination item;

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is in a class of pharmaceutical items to which a 25% administrative price reduction has applied.

(3) The Minister may, by legislative instrument, determine that a 12.5% administrative price reduction has applied to a class of pharmaceutical items.

(4) A reference in this Division to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACF(2) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.

Subdivision B—First new brand price reductions for brands of pharmaceutical items that are not combination items

99ACB First new brand price reductions for brands of pharmaceutical items that are not combination items

When section applies to new brands

(1) Subject to subsections (2), (3), (3A) and (3B), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***) that is not a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger item was not a listed brand of the trigger item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the trigger item and existing item have the same drug and manner of administration.

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Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply

(2) This section does not apply in relation to the new brand of the trigger item if:

(a) the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(b) another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(c) if the drug that is in the trigger item is in a therapeutic group—a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item;

is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(d) on the day before the determination day:

(i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by 60% or more.

(2A) If the approved ex-manufacturer price mentioned in subparagraph (2)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity

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been the same as the pricing quantity on the day before the determination day.

(3) This section does not apply in relation to the new brand of the trigger item if:

(a) any of the following has applied:

(i) subsection (5) or (5A);

(ia) a determination under paragraph (6A)(b);

(ib) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1);

(ii) subsection 99ACF(1) or (2) because of repealed section 99ACH;

(iii) repealed subsection 99ACF(2AB) or (2AC);

(iv) section 99ACQ;

(v) subsection 99ACR(3) or (4);

in relation to:

(b) the new brand, or another listed brand, of the trigger item; or

(c) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item; or

(d) if the drug that is in the trigger item is in a therapeutic group—a listed brand of a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subparagraph (a)(i), subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (6B) of this section.

(3A) This section does not apply in relation to the new brand of the trigger item if:

(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

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(b) the determination day in relation to the new brand of the trigger item is on or before the fifth anniversary of the drug in the pharmaceutical item being on F1; and

(c) the responsible person for the new brand of the trigger item is the same person as the responsible person for the existing listed brand of the pharmaceutical item; and

(d) either of the following apply:

(i) there is not another brand of the pharmaceutical item that has the drug that is a listed brand;

(ii) the drug is not on F2.

(3B) This section does not apply in relation to the new brand of the trigger item if:

(a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and

(b) the Minister has made a determination under section 99ACBA in relation to the new brand of the trigger item; and

(c) the determination under section 99ACBA has not ceased to have effect.

First new brand price reduction

(4) The Minister:

(a) may, under section 85AD, make a price agreement for the new brand of the trigger item; and

(b) must not make a determination under section 85B in relation to the new brand of the trigger item.

(4A) If, on the day before the determination day:

(a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:

(c) 35% or less, subsection (5) applies; and

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(d) more than 35% but less than 60%, subsection (5A) applies.

Note: If previous price reductions have been 60% or more, see paragraph (2)(d).

(4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(5) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.

(5A) Subject to subsections (6) and (6A), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed:

(a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.

(5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

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Apportioning if pricing quantity changes

(6) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(6A) The Minister may, by notifiable instrument, determine that:

(a) the agreed price of the new brand of the trigger item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or

(b) the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result

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from the operation of subsection (5) or (5A) in relation to the determination day.

(6B) If the Minister makes a determination under paragraph (6A)(a), subsections (5) and (5A) are taken not to have applied to the trigger item.

(6C) In making a determination under subsection (6A):

(a) the Minister must take into account what the agreed price of the new brand of the trigger item would otherwise be under this section in relation to the particular determination day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

(7) This section does not limit the Minister's powers, after the determination day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brand of the trigger item.

99ACBA Ministerial determination—brand of pharmaceutical item that is not a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger item***) is not a combination item; and

(b) the brand of the trigger item:

(i) is not a listed brand of the trigger item; and

(ii) is a new presentation of an existing listed brand of a pharmaceutical item; and

(c) the Minister is satisfied that the determination day in relation to the brand of the trigger item is to be after the fifth anniversary, and before the tenth anniversary, of the drug in the pharmaceutical item being on F1;

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the Minister may determine, by notifiable instrument, that the brand of the trigger item is not a new brand for the purposes of section 99ACB.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger item, it must be made before the determination day in relation to the brand of the trigger item.

(3) In making a determination, the Minister may have regard to:
  (a) any advice given by the Pharmaceutical Benefits Advisory Committee; and
  (b) any information provided by the responsible person for the brand of the trigger item; and
  (c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:
  (a) the day that another brand of the pharmaceutical item becomes a listed brand;
  (b) the day that the drug in the pharmaceutical item does not satisfy all of the criteria for F1;
  (c) the tenth anniversary of the drug in the pharmaceutical item being on F1.

(5) In this section:

determination day has the same meaning as in paragraph 99ACB(1)(a).

Subdivision C—Price reductions for combination items

99ACC Price reductions for single brands of combination items

When section applies

(1) This section applies if:
  (a) subsection 85AB(5) applies to the drug in a combination item; and

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(b) there is only one listed brand (the ***single brand***) of the combination item; and

(c) there is an approved ex-manufacturer price for the single brand of the combination item; and

(d) any of the following apply:

(i) if the drug in the combination item contains only one listed component drug—that listed component drug becomes subject to a statutory price reduction on a day (the ***reduction day***); or

(ii) if the drug in the combination item contains 2 or more listed component drugs—one of the listed component drugs becomes subject to a statutory price reduction on a day (the ***reduction day***); or

(iii) if the drug in the combination item contains 2 or more listed component drugs—2 or more of the listed component drugs become subject to a statutory price reduction on the same day (the ***reduction day***); and

(e) on the reduction day, or on the day before that day, no listed brand of another combination item that has a drug that contains the same component drugs as the combination item:

(i) is bioequivalent or biosimilar to the single brand of the combination item; and

(ii) has the same manner of administration as the single brand of the combination item.

Price reduction

(2) Subject to subsections (5A), (5C) and (5E), on the reduction day, the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.

(3) Different methods may be prescribed by the regulations for different classes of combination items.

(4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.

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(5) Subject to subsections (5A) and (5C), if the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the single brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2).

Reduction cap

(5A) If:

(a) the approved ex-manufacturer price of the single brand of the combination item is to be reduced under subsection (2); and

(b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:

(i) 40% of the approved ex-manufacturer price of a listed brand of the combination item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the combination item;

the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced under subsection (2) to an amount equal to the capped price.

(5B) If the approved ex-manufacturer price mentioned in subparagraph (5A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(5C) In relation to the single brand of the combination item, the Minister may, by notifiable instrument, determine that:

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(a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or

(b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.

(5D) In making a determination under subsection (5C):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the single brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account:

(i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and

(ii) any other matter the Minister thinks is relevant.

(5E) If the Minister makes a determination under subsection (5C), the approved ex-manufacturer price of the single brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (5C).

Section does not limit Minister's powers

(5F) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the single brand of the combination item.

Subject to statutory price reduction etc.

(6) The following provisions have effect:

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(a) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if section 99ACB or 99ACQ or subsection 99ACR(3) or (4) or section 99ADH has applied to a listed brand of a pharmaceutical item that:
  (i) has the listed component drug; and
  (ii) has the same manner of administration as the combination item;

(b) whichever provision mentioned in paragraph (a) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that:
  (i) has the listed component drug; and
  (ii) has the same manner of administration as the combination item;

(c) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if subsection 99ACF(1) or (2) because of an item in the table in section 99ACF has applied to a listed brand of a pharmaceutical item that has the listed component drug;

(d) whichever provision mentioned in paragraph (c) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that has the listed component drug.

*Modified meaning of the **same manner of administration***

(7) For the purposes of subsection (6), a combination item whose drug contains a listed component drug has the same manner of administration as another pharmaceutical item that has (or whose drug contains) the listed component drug if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the listed component drug:

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(a) if the other pharmaceutical item is not a combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other pharmaceutical item; or

(b) if the other pharmaceutical item is another combination item—is the same as the manner of administration set out in a determination under subsection 85(5) for the other combination item, to the extent that the manner of administration relates to the listed component drug.

99ACD First new brand price reductions for brands of combination items

When section applies to new brands

(1) Subject to subsections (1A), (2) and (3), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger combination item***) that is a combination item if:

(a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger combination item on a day (the ***determination day***); and

(b) on the day before the determination day, the new brand of the trigger combination item was not a listed brand of the trigger combination item; and

(c) on the day before the determination day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(ii) the new brand of the trigger combination item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the drug in the trigger combination item and existing item contain the same component drugs; and

(iv) the trigger combination item and the existing item have the same manner of administration.

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Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger combination item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply to new brands

(1A) This section does not apply in relation to the new brand of the trigger combination item if:

(a) the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(b) another combination item that has the same drug and manner of administration as the new brand of the trigger combination item is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item;

is in a class of pharmaceutical items to which a 12.5%, 16% or 25% administrative price reduction has applied; or

(d) on the day before the determination day:

(i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by 60% or more.

(1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity

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been the same as the pricing quantity on the day before the determination day.

(2) This section does not apply in relation to the new brand of the trigger combination item if a listed provision (see subsection (2A)) has applied in relation to:

(a) the new brand, or another listed brand, of the trigger combination item; or

(b) a brand of another combination item that:

(i) has a drug that contains the same component drugs as the new brand of the trigger combination item; and

(ii) has the same manner of administration as the new brand of the trigger combination item; or

(c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the trigger combination item.

Note: For the purposes of this subsection, subsections (5) and (5A) of this section are taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI and subsection (7B) of this section.

(2A) For the purposes of subsection (2), ***listed provision*** means:

(a) subsection (5) or (5A); or

(b) a determination under paragraph (7A)(b); or

(c) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1); or

(d) section 99ACQ; or

(e) subsection 99ACR(3) or (4); or

(f) repealed section 99ACE.

(3) This section does not apply in relation to the new brand of the trigger combination item if:

(a) all of the following apply:

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(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;

(ii) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item;

(iii) the determination day in relation to the new brand of the trigger combination item is on or before the fifth anniversary of the declaration under subsection 85(2) being made;

(iv) the responsible person for the new brand of the trigger combination item is the same as the responsible person for the existing listed brand of the pharmaceutical item;

(v) the drug is not on F2; or

(b) all of the following apply:

(i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;

(ii) the Minister has made a determination under section 99ACEA in relation to the new brand of the trigger combination item;

(iii) the determination under section 99ACEA has not ceased to have effect.

First new brand price reduction

(4) The Minister:

(a) may, under a price agreement, agree an agreed price for the new brand of the trigger combination item that comes into force on the determination day; and

(b) must not make a determination under section 85B for the new brand of the trigger combination item.

(4A) If, on the day before the determination day:

(a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

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(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:

(c) 35% or less, subsection (5) applies; and

(d) more than 35% but less than 60%, subsection (5A) applies.

Note: If previous price reductions have been 60% or more, see paragraph (1A)(d).

(4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

(5) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by 25%.

(5A) Subject to subsections (7) and (7A), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed:

(a) 40% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the existing item.

(5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved

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ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

Apportioning if pricing quantity changes

(7) If the pricing quantity of the existing brand of the existing item on the day before the determination day is different from the pricing quantity of the existing brand of the existing item on the determination day, then, for the purposes of subsections (5) and (5A), the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the existing brand of the existing item on the day before the determination day.

PQ1 means the pricing quantity of the existing brand of the existing item on the day before the determination day.

PQ2 means the pricing quantity of the existing brand of the existing item on the determination day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(7A) The Minister may, by notifiable instrument, determine that:

(a) the agreed price of the new brand of the trigger combination item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or

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(b) the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.

(7B) If the Minister makes a determination under paragraph (7A)(a), subsections (5) and (5A) are taken not to have applied to the trigger combination item.

(7C) In making a determination under subsection (7A):

(a) the Minister must take into account what the agreed price of the new brand of the trigger combination item would otherwise be under this section in relation to the particular determination day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

Section does not limit Minister's powers

(8) This section does not limit the Minister's powers, after the determination day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brand of the trigger combination item.

99ACEA Ministerial determination—brand of pharmaceutical item that is a combination item is not a new brand

(1) If:

(a) a brand of a pharmaceutical item (the ***trigger combination item***) is a combination item; and

(b) the brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and

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(c) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item; and

(d) the Minister is satisfied that the determination day in relation to the brand of the trigger combination item is after the fifth anniversary, and before the tenth anniversary, of the declaration under subsection 85(2) being made;

the Minister may determine, by notifiable instrument, that the brand of the trigger combination item is not a new brand for the purposes of section 99ACD.

(2) If the Minister makes a determination under this section in relation to the brand of the trigger combination item, it must be made before the determination day in relation to the brand of the trigger combination item.

(3) In making a determination, the Minister may have regard to:

(a) any advice given by the Pharmaceutical Benefits Advisory Committee; and

(b) any information provided by the responsible person for the brand of the trigger combination item; and

(c) any other matter that the Minister considers relevant.

(4) A determination made under this section ceases to have effect on whichever is the earliest of the following:

(a) the tenth anniversary of the declaration under subsection 85(2) being made;

(b) the day that the drug is on F2.

(5) In this section:

determination day has the same meaning as in paragraph 99ACD(1)(a).

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Subdivision D—Other statutory price reductions

99ACF Statutory price reductions

Reduction equal to percentage etc.

(1) Subject to sections 99ACG and 99ADHC, if:

(a) a section or subsection referred to in column 2 of the table in this subsection applies to a listed brand of a pharmaceutical item on a day specified in the section or subsection (the ***reduction day***); and

(b) subsection (2) does not apply to the listed brand of the pharmaceutical item on the reduction day; and

(c) on the day before the reduction day, an approved ex-manufacturer price was, or one or more claimed prices were, in force for the listed brand of the pharmaceutical item;

then, subject to subsections (1A), (2A) and (3), the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, taken to be reduced, on the reduction day, by the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

Statutory price reductions table

Item	Section or subsection	Percentage or method
2	99ACHA	5%
2A	99ACHB	5%
3	99ACJ	10%
3A	99ACJA	5%
4	99ACK	5%
4A	99ACKA	26.1%
4B	99ACKB	30%
5	99ACL(1)	10%
6	99ACL(2)	(a) first, 10%; and

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Statutory price reductions table		
Item	**Section or subsection**	**Percentage or method**
		(b) second, using the price worked out under paragraph (a), by 5%
7	99ACM	5%
8	99ACN	The percentage referred to in paragraph 99ACN(1)(c)
9	99ACP	1.48%

Note: Subsection (1) does not apply if there is no determination under subsection 85(6) in respect of the pharmaceutical item in force on the specified day (whether or not the determination was revoked following a request by the responsible person for the pharmaceutical item).

Reduction cap

(1A) If:

(a) the approved ex-manufacturer price of a listed brand of a pharmaceutical item is to be reduced under subsection (1) because of an item in the table in subsection (1); and

(b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:

(i) 40% of the approved ex-manufacturer price of a listed brand of the pharmaceutical item on 1 January 2016; or

(ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the pharmaceutical item;

the approved ex-manufacturer price of the listed brand of the pharmaceutical item is taken to be reduced under subsection (1) because of that item to an amount equal to the capped price.

(1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is

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taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Reduction more than percentage

(2) This subsection applies if:

(a) a section or subsection referred to in column 2 of the table in subsection (1) applies to a listed brand of a pharmaceutical item on a reduction day; and

(b) subject to subsection (2A), on the reduction day, the approved ex-manufacturer price of the listed brand of the pharmaceutical item does not exceed:

(i) the approved ex-manufacturer price of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2; or

(ii) if subsection (1A) would have applied to the brand of the pharmaceutical item if paragraph (1)(b) were disregarded—the capped price of the brand of the pharmaceutical item that would be worked under subsection (1A) if paragraph (1)(b) were disregarded; and

(c) if, on the day before the reduction day and on the reduction day, a determination under subsection 85B(3) was in force in relation to a particular pack quantity of the listed brand of the pharmaceutical item—the claimed price for that pack quantity of the brand of the pharmaceutical item does not exceed the claimed price for the same pack quantity of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or method specified in column 3 of the table for the section or subsection referred to in column 2.

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Apportioning if pricing quantity changes

(2A) If the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day is different from the pricing quantity of the listed brand of the pharmaceutical item on the reduction day, then, for the purposes of subsection (1) and paragraph (2)(b), the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day is taken to be the amount worked out as follows:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ1 means the pricing quantity of the listed brand of the pharmaceutical item on the day before the reduction day.

PQ2 means the pricing quantity of the listed brand of the pharmaceutical item on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

(3) In relation to a listed brand of a pharmaceutical item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price is, or (if applicable) one or more claimed prices are, not to be reduced under a provision mentioned in an item of the table in subsection (1) (the ***specified provision***) in relation to a particular reduction day; or

(b) the approved ex-manufacturer price is, or (if applicable) one or more of the claimed prices are, to be reduced by a lower percentage than would otherwise apply under a provision

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mentioned in an item of the table in subsection (1) (the ***specified provision***) in relation to a particular reduction day.

(3A) In making a determination in relation to the application of an item of the table in subsection (1):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) each of the claimed prices, of the listed brand of the pharmaceutical item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account any other matter that the Minister considers relevant.

(3B) If the Minister makes a determination in relation to a specified provision, the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, not to be further reduced under that specified provision on any reduction day that occurs after the reduction day specified in the determination made under subsection (3).

Section does not limit Minister's powers

(4) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) further determinations under section 85B;

for the listed brand of the pharmaceutical item.

99ACG Other price reductions do not apply if a price disclosure reduction has applied

If:

(a) on a day, either:

(i) section 99ADH has applied to a listed brand of a pharmaceutical item (the ***first item***); or

(ii) the price of the first item is reduced under section 99ADHB; and

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(b) apart from this section, any of the following provisions would apply on or after that day to a listed brand of a pharmaceutical item that has the same drug and manner of administration as the first item:

(i) section 99ACB;

(ii) section 99ACD;

(iii) subsection 99ACF(1) or (2) because of item 4A, 4B, 7, 8 or 9 in the table in subsection 99ACF(1);

(iv) section 99ACQ;

(v) subsection 99ACR(3) or (4);

then none of the provisions mentioned in paragraph (b) apply, on or after that day, to:

(c) the first item; or

(d) a listed brand of the pharmaceutical item that has the same drug and manner of administration as the first item.

99ACHA 5% statutory price reduction for drugs on F1—fifth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:

(a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and

(b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and

(c) the approved ex-manufacturer price of a brand of a pharmaceutical item that has the drug has not been reduced under subsection 99ACF(1) or (2) because of repealed section 99ACH on a previous 5% price reduction day.

(2) In this section, each of the following is a ***5% price reduction day***:

(a) 1 April 2016;

(b) 1 April 2017;

(c) 1 April 2018;

(d) 1 April 2019;

(e) 1 April 2020;

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(f) 1 April 2021;
(g) 1 April 2022.

99ACHB 5% statutory price reduction for drugs on F1—fifth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
(a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
(b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and
(c) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
(d) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced:
(i) under subsection 99ACF(1) or (2); or
(ii) because of repealed section 99ACE or repealed section 99ACH; or
(iii) under section 99ACQ; or
(iv) under subsection 99ACR(3).

(2) In this section, each of the following is a ***5% price reduction day***:
(a) 1 April 2023;
(b) 1 April 2024;
(c) 1 April 2025;
(d) 1 April 2026;
(e) 1 April 2027.

99ACJ 10% statutory price reduction for drugs on F1—tenth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 10% price reduction day if:

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(a) the drug in the pharmaceutical item is on F1 on the 10% price reduction day; and
(b) the 10% price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
(c) the approved ex-manufacturer price of a brand of a pharmaceutical item that has the drug, on the day before the 10% price reduction day, has not been reduced under subsection 99ACF(1) or (2) because of:
(i) item 3 in the table in section 99ACF on a previous 10% price reduction day; or
(ii) item 5 in the table in section 99ACF on 1 June 2018.

(2) In this section, each of the following is a ***10% price reduction day***:
(a) 1 April 2019;
(b) 1 April 2020;
(c) 1 April 2021.

99ACJA 5% statutory price reduction for drugs on F1—tenth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
(a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
(b) the 5% price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
(c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
(i) item 3 in the table in section 99ACF; or
(ii) item 3A in the table in section 99ACF; or
(iii) item 5 in the table in section 99ACF; or
(iv) item 7 in the table in section 99ACF; and
(d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and

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(e) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced:
(i) because of repealed section 99ACE or repealed section 99ACH; or
(ii) under section 99ACQ; or
(iii) under subsection 99ACR(3).

(2) In this section, each of the following is a ***5% price reduction day***:
(a) 1 April 2023;
(b) 1 April 2024;
(c) 1 April 2025;
(d) 1 April 2026;
(e) 1 April 2027.

99ACK 5% statutory price reduction for drugs on F1—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
(a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
(b) the 5% price reduction day is on or after the 15th anniversary of the drug being a listed drug; and
(c) the approved ex-manufacturer price of a brand of a pharmaceutical item that has the drug, on the day before the 5% price reduction day, has not been reduced under subsection 99ACF(1) or (2) because of:
(i) item 4 in the table in section 99ACF on a previous 5% price reduction day; or
(ii) item 6 in the table in section 99ACF on 1 June 2018.

(2) In this section, each of the following is a ***5% price reduction day***:
(a) 1 April 2019;
(b) 1 April 2020;
(c) 1 April 2021.

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99ACKA 26.1% statutory price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on a 26.1% price reduction day if:

(a) the 26.1% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and

(b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:

(i) item 4 in the table in section 99ACF; or

(ii) item 4A in the table in section 99ACF; or

(iii) item 6 in the table in section 99ACF; or

(iv) item 8 in the table in section 99ACF; and

(c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 26.1% price reduction day:

(i) because of section 99ACB or 99ACD; or

(ii) because of repealed section 99ACE or repealed section 99ACH; or

(iii) under section 99ACQ; or

(iv) under subsection 99ACR(3); and

(d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 26.1% price reduction day; and

(e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

(2) In this section, each of the following is a ***26.1% price reduction day***:

(a) 1 April 2023;

(b) 1 April 2024;

(c) 1 April 2025;

(d) 1 April 2026.

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99ACKB 30% statutory price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on the 30% price reduction day if:

(a) the 30% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and

(b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:

(i) item 4 in the table in section 99ACF; or

(ii) item 4A in the table in section 99ACF; or

(iii) item 6 in the table in section 99ACF; or

(iv) item 8 in the table in section 99ACF; and

(c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 30% price reduction day:

(i) because of section 99ACB or 99ACD; or

(ii) because of repealed section 99ACE or repealed section 99ACH; or

(iii) under section 99ACQ; or

(iv) under subsection 99ACR(3); and

(d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 30% price reduction day; and

(e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

(2) In this section, the ***30% price reduction day*** is 1 April 2027.

99ACL Special rule—statutory price reduction for drugs on F1

Tenth anniversary of listing of drug falls on or before 1 June 2018

(1) This subsection applies to a brand of a pharmaceutical item if:

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(a) the drug in the pharmaceutical item is on F1 on 1 June 2018 (the ***price reduction day***); and
(b) the price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
(c) subsection (2) is not satisfied in relation to the brand of the pharmaceutical item.

15th anniversary of listing of drug falls on or before 1 June 2018

(2) This subsection applies to a brand of a pharmaceutical item if:
(a) the drug in the pharmaceutical item is on F1 on 1 June 2018 (the ***price reduction day***); and
(b) the price reduction day is on or after the 15th anniversary of the drug being a listed drug.

99ACM 5% statutory price reduction for drugs on F1—tenth anniversary

(1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
(a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
(b) the tenth anniversary of the drug being a listed drug occurred during the period:
(i) beginning at the start of 1 May 2021; and
(ii) ending at the end of 1 April 2022.

Note: See also section 99ACG.

(2) In this section, the ***5% price reduction day*** is 1 April 2023.

99ACN Catch-up price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on the catch-up price reduction day if:
(a) the 15th anniversary of the drug in the pharmaceutical item being a listed drug was on or before 1 April 2022; and

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(b) the pharmaceutical item is not an exempt item; and

(c) on the catch-up price reduction day, the percentage worked out using the formula in subsection (2) is greater than zero.

Note: See also section 99ACG.

(2) The formula mentioned in paragraph (1)(c) is:

$$100\% - \frac{63.18\%}{\text{Product of differential percentages}}$$

where:

product of differential percentages means:

(a) if there has been only one previous price reduction under this Division—the differential percentage for that price reduction; or

(b) if there have been 2 or more previous price reductions under this Division—the product of the differential percentages for those previous price reductions; or

(c) if there have not been any previous price reductions under this Division—100%.

Note 1: The effect of the formula is that, following the application of the price reduction which applies as a result of this section and item 8 of the table in section 99ACF(1), the cumulative impact of price reductions under this Division, applied successively, will be 36.82%. For example, if the brand of the pharmaceutical item has been subject to a 5% previous price reduction under this Division followed by a 16% previous price reduction under this Division, the product of the differential percentages will be (100% - 5%) x (100% - 16%) = 79.80%, and the percentage worked out using the formula will be 100% - 63.18%/79.80% = 20.83%.

Note 2: For rounding of the percentage worked out using the formula, see subsection (5).

(3) For the purposes of this section, ***previous price reduction under this Division*** has the meaning given by section 99ACNA.

(4) For the purposes of this section, the ***differential percentage*** for a previous price reduction under this Division means the difference

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between 100% and the previous price reduction under this Division.

(5) The percentage worked out using the formula in subsection (2) is to be calculated to 2 decimal places (rounding up if the third decimal place is 5 or more).

(6) In this section, the ***catch-up price reduction day*** is 1 April 2023.

99ACNA Catch-up price reduction for certain drugs—meaning of *previous price reduction under this Division*

(1) For the purposes of the application of section 99ACN to a brand (the ***relevant brand***) of a pharmaceutical item, ***previous price reduction under this Division*** means:

(a) a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under this Division (expressed as a percentage) (other than a reduction attributable to section 99ACN); or

(b) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACF(2)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACF(1) if paragraph (b) of that subsection were disregarded; or

(c) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACR(4)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACR(3) if subsection 99ACR(4) did not apply; or

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(d) a 12.5% administrative price reduction that applied, on or before the catch-up price reduction day, to the relevant brand or another brand of the pharmaceutical item.

(2) For the purposes of this section:

(a) a reduction in the agreed price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and

(b) a reduction in the determined price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and

(c) a reduction before 1 October 2012 in the approved price to pharmacists (within the meaning of this Part as it stood before 1 October 2012) of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item.

(3) A reference in this section to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACR(4) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.

(4) A reference in this section to this Division includes this Division as in force at any time before the commencement of this section.

(5) In this section, the ***catch-up price reduction day*** is 1 April 2023.

99ACP 1.48% statutory price reduction for certain drugs—15th anniversary

(1) This section applies to a brand of a pharmaceutical item on the 15th anniversary price reduction day if:

(a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) or section 99ACQ or subsection 99ACR(3) has applied to the brand of the pharmaceutical item; and

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(b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
  (i) item 4 in the table in section 99ACF; or
  (ii) item 4A in the table in section 99ACF; or
  (iii) item 8 in the table in section 99ACF; or
  (iv) item 9 in the table in section 99ACF; and
(c) the item is not an exempt item.

Note: See also section 99ACG.

(2) In this section, the ***15th anniversary price reduction day*** is the 15th anniversary of the drug in the pharmaceutical item being listed as a listed drug.

Subdivision E—Flow-on of first new brand price reductions to existing brands and related brands

99ACQ Flow-on of price reductions to existing brands of the same pharmaceutical item

(1) This section applies to a brand (the ***existing brand***) of a pharmaceutical item if:
(a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the ***new brand***) of the pharmaceutical item; and
(b) that price comes into force on a day (the ***reduction day***); and
(c) on the day before the reduction day, the existing brand of the item was a listed brand of the item.

Note: See also section 99ACG.

(2) On the reduction day, the approved ex-manufacturer price of the existing brand of the item is taken to be reduced to an amount equal to the approved ex-manufacturer price of the new brand.

(3) If the approved ex-manufacturer price of the existing brand of the item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand is taken to be

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reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the item is reduced under subsection (2).

Section does not limit Minister's powers

(4) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the existing brand of the item.

99ACR Flow-on of first new brand price reductions to related brands

(1) This section applies to a brand (the ***related brand***) of a pharmaceutical item (a ***related item***) mentioned in subsection (2) if:

(a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the ***new brand***) of a pharmaceutical item (the ***new item***); and

(b) that price comes into force on a day (the ***reduction day***); and

(c) on the day before the reduction day, the related brand of the related item was a listed brand of the related item; and

(d) the related item is not an exempt item.

Note: See also section 99ACG.

(2) For the purposes of this section, a related brand of a related item is any of the following:

(a) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new item;

(b) if the drug in the new item is in a therapeutic group—a listed brand of a pharmaceutical item that:

(i) has another drug that is in that group; and

(ii) has the same manner of administration as the new brand of the new item.

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(3) Subject to subsections (4) and (6), on the reduction day, the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item is taken to be reduced by a percentage equal to the percentage by which the agreed price for the new brand was reduced as a result of the application of the subsection mentioned in paragraph (1)(a).

(4) Subsection (3) does not apply to the related brand of the related item if:

(a) on the reduction day, the approved ex-manufacturer price of the related brand of the related item does not exceed the approved ex-manufacturer price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3); and

(b) if there is an applicable claimed price of the related brand of the related item—on the reduction day, the claimed price of the related brand of the related item does not exceed the claimed price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3).

Apportioning if pricing quantity changes

(5) If the pricing quantity of the related brand of the related item on the day before the reduction day is different from the pricing quantity of the related brand of the related item on the reduction day, then, for the purposes of subsection (3) and paragraph (4)(a), the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day is taken to be the amount worked out using the following formula:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

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AEMP1 means the amount that was the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day.

PQ1 means the pricing quantity of the related brand of the related item on the day before the reduction day.

PQ2 means the pricing quantity of the related brand of the related item on the reduction day.

Ministerial discretion not to apply, or to reduce, flow-on price reduction

(6) In relation to the related brand of the related item, the Minister may, by notifiable instrument, determine that:
   (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (3) in relation to a particular reduction day; or
   (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (3) in relation to a particular reduction day.

(7) If the Minister makes a determination under paragraph (6)(a), subsection (3) is taken not to have applied to the related brand of the related item.

(8) In making a determination under subsection (6):
   (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
   (b) the Minister may take into account any other matter the Minister thinks is relevant.

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Section does not limit Minister's powers

(9) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the related brand of the related item.

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Division 3B—Price disclosure

Subdivision A—Preliminary

99AD What this Division is about

This Division requires the responsible person for certain brands of pharmaceutical items to comply with the price disclosure requirements for each supply of those brands of pharmaceutical items.

- Subdivision B has the price disclosure requirements. It provides for regulations to set out the kind of information that is required to be provided for the brand of the pharmaceutical item, the form and manner in which that information is to be provided and when that information is to be provided.
- The price disclosure requirements generally apply in relation to brands of pharmaceutical items that have a drug on F2.
- Subdivision D provides for the consequences of failing to comply with the price disclosure requirements.

In addition, this Division reduces the approved ex-manufacturer price of the brand of the pharmaceutical item in specified circumstances (see Subdivision E). This reduction happens as a result of the price being adjusted based on information collected about brands of pharmaceutical items.

99ADA Division does not apply to exempt items

This Division does not apply to brands of exempt items.

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99ADB Definitions etc.

(1) In this Division:

adjusted approved ex-manufacturer price of a brand of a pharmaceutical item is the amount equal to the amount of the weighted average disclosed price of the brand of the pharmaceutical item.

applicable approved ex-manufacturer price: see subsection (3A).

data collection period, for a brand of a pharmaceutical item, has the meaning given by section 99ADBA.

originator brand has the meaning given by subsection (6B).

price disclosure requirements has the meaning given by section 99ADC.

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 means the day after the end of the period in respect of which the weighted average disclosed price of the brand of the pharmaceutical item is determined.

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

unadjusted price reduction for a brand of a pharmaceutical item is the difference between:

(a) the applicable approved ex-manufacturer price of the brand of the pharmaceutical item; and

(b) the weighted average disclosed price of the brand of the pharmaceutical item;

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expressed as a percentage of that applicable approved ex-manufacturer price.

weighted average disclosed price of a brand of a pharmaceutical item is the weighted average disclosed price of the brand of the pharmaceutical item determined by the Minister under subsection (4).

Applicable approved ex-manufacturer price

(3A) The ***applicable approved ex-manufacturer price*** of a brand of a pharmaceutical item is the approved ex-manufacturer price of the brand on the relevant day.

(3B) For the purposes of subsection (3A), if:

(a) apart from this subsection, the brand of the pharmaceutical item would not have an approved ex-manufacturer price on the relevant day; and

(b) the brand of the pharmaceutical item has an approved ex-manufacturer price before the first reduction day that:

(i) is determined under paragraph 99ADH(1)(aa) in relation to the brand of the pharmaceutical item; and

(ii) occurs after the relevant day;

then:

(c) the regulations may prescribe the approved ex-manufacturer price, or a method or formula for working out the approved ex-manufacturer price, of the brand of the pharmaceutical item on the relevant day; and

(d) if the regulations do so, the amount so worked out is taken to be the approved ex-manufacturer price of the brand of the pharmaceutical item on the relevant day.

Weighted average disclosed price

(4) The Minister may, by legislative instrument, determine the weighted average disclosed price of a brand of a pharmaceutical item in accordance with the regulations.

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(6) Without limiting subsection (4), the regulations may prescribe a method or formula for determining the weighted average disclosed price of a brand of a pharmaceutical item. The method or formula prescribed may take into account information (if any) that has been provided in compliance with the price disclosure requirements, and any other information, about:

(a) the brand of the pharmaceutical item; and

(b) other brands of the pharmaceutical item; and

(c) all brands (including the brand) of all pharmaceutical items that have the same drug and manner of administration as the pharmaceutical item.

(6A) The regulations may prescribe information that the method or formula must not take into account (including information that has been provided in compliance with the price disclosure requirements). Information prescribed for the purposes of this section may include information relating to originator brands.

(6B) The Minister may, by legislative instrument, determine that a brand of a pharmaceutical item that has a drug on F2 is an ***originator brand***.

(6C) In deciding whether to determine that a brand of a pharmaceutical item is an originator brand, the Minister must have regard to whether, when the brand of the pharmaceutical item was first determined under subsection 85(6):

(a) the drug in the pharmaceutical item was on F1; or

(b) subsection 85AB(5) applied to the drug.

(6D) Subsection (6C) does not apply if the drug is on F2 on 31 March 2016.

(7) A determination made under subsection (4) in relation to a brand of a pharmaceutical item may include the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item.

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99ADBA 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 brand's start day (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 2016, and the data collection period for a related brand ends on 30 September 2016:
  (a) the first data collection period starts on 1 July 2016; and
  (b) the first data collection period ends on 30 September 2016; and
  (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2016, 1 April 2017, 1 October 2017 and so on.

Example 2: If a brand to which subsection (3) applies has a start day of 1 August 2016:

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(a) the first data collection period starts on 1 August 2016; and
(b) the first data collection period ends on 31 March 2017; and
(c) subsequent data collection periods will be the 6 month periods that start on 1 April 2017, 1 October 2017, 1 April 2018 and so on.

Example 3: If a brand to which subsection (3) applies has a start day of 1 December 2016:
(a) the first data collection period starts on 1 December 2016; and
(b) the first data collection period ends on 30 September 2017; and
(c) subsequent data collection periods will be the 6 month periods that start on 1 October 2017, 1 April 2018, 1 October 2018 and so on.

Subdivision B—Price disclosure requirements

99ADC The price disclosure requirements

(1) The ***price disclosure requirements*** for a supply of a brand of a pharmaceutical item are:
(a) to provide information prescribed by the regulations in relation to the supply of the brand of the pharmaceutical item by the responsible person to a person or entity prescribed by the regulations; and
(b) to provide that information in the manner and form prescribed by the regulations; and
(c) to provide that information at the times prescribed by the regulations.

(2) Without limiting subsection (1), the regulations may prescribe information relating to:
(a) the price of the brand of the pharmaceutical item supplied, which may be by reference to the quantity or number of units of the pharmaceutical item supplied; and
(b) the volume of the supply; and
(c) the person to whom the supply was made; and
(d) when the supply was made; and
(e) the type and value of any benefit (whether monetary or otherwise) provided to persons by the responsible person in

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relation to the supply, whether or not the benefit also relates to another supply of a product (the ***related product***) that is:

(i) the brand of the pharmaceutical item; or

(ii) any other pharmaceutical item available in the brand or any other brand; or

(iii) any other product; and

(f) if the benefit referred to in paragraph (e) also relates to a supply of the related product—information relating to the supply of the related product (including the price and volume of the supply); and

(g) any other matter that is relevant in determining the weighted average disclosed price of the brand of the pharmaceutical item.

99ADD When the price disclosure requirements apply

The responsible person for a listed brand of a pharmaceutical item that has a drug on F2 is required to comply with the price disclosure requirements for each supply of the brand of the pharmaceutical item.

Subdivision D—Consequences for failing to comply with the price disclosure requirements

99ADF Offence for failing to comply with the price disclosure requirements

(1) A person commits an offence if:

(a) the person is required to comply with the price disclosure requirements for a supply of a brand of a pharmaceutical item; and

(b) the person fails to comply with those requirements for the supply of the brand of the pharmaceutical item.

Penalty: 60 penalty units.

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(2) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (1).

99ADG Other consequences for failing to comply with the price disclosure requirements

(1) This section applies if:

(a) a responsible person is required to comply with the price disclosure requirements for a supply of a brand (the ***disclosure brand***) of a pharmaceutical item (the ***disclosure item***); and

(b) the responsible person does not comply with those requirements for the supply of the disclosure brand of the disclosure item.

(2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:

(a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the disclosure brand of the disclosure item;

(b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:

(i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or

(ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or

(iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

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Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the disclosure brand, or a pharmaceutical item mentioned in those paragraphs may be the disclosure item.

(3) Without limiting the powers of the Minister under subsection (2), in exercising a power under that subsection, the Minister may have regard to:

(a) the number of times the responsible person did not comply with the price disclosure requirements for:

(i) the disclosure brand of the disclosure item; and

(ii) if, in addition to the disclosure brand of the disclosure item, the person was also required to comply with the price disclosure requirements for a brand of a pharmaceutical item—the brand of the pharmaceutical item; and

(b) the period in which the non-compliances occurred; and

(c) the duration of each non-compliance; and

(d) the reasons for the non-compliances; and

(e) whether those reasons are, in the Minister's opinion, reasonable; and

(f) any other matter the Minister thinks is relevant.

Note: For the purposes of subparagraph (a)(ii), a brand mentioned in that subparagraph may be the disclosure brand, or a pharmaceutical item mentioned in that subparagraph may be the disclosure item.

(4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Subdivision E—Price reduction

99ADH Price reduction based on information provided under the price disclosure requirements

When this section applies

(1) This section applies if:

(a) under section 99ADB, the Minister determines the weighted average disclosed price of a brand of a pharmaceutical item

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(the ***WADP brand***) in respect of a data collection period for the brand; and

(aa) the Minister, by legislative instrument, determines a day (the ***reduction day***) for the purposes of this section in relation to the brand of the pharmaceutical item; and

(b) a price agreement or price determination is in force in relation to the brand of the pharmaceutical item on the reduction day; and

(c) the unadjusted price reduction for the brand of the pharmaceutical item is:

(i) if section 99ADHC does not apply to the brand of the pharmaceutical item—at least 10%; or

(ii) subject to subparagraph (iii), if section 99ADHC applies to the brand of the pharmaceutical item and the approved ex-manufacturer price of the brand of the pharmaceutical item is more than $4—at least 30%; or

(iii) if section 99ADHC applies to the brand of the pharmaceutical item, the approved ex-manufacturer price of the brand of the pharmaceutical item is more than $4, and the brand of the pharmaceutical item has passed the 12.5% average unadjusted price reduction test set out in subsection (6) of this section—at least 10%.

(2) For the purposes of paragraph (1)(aa), the reduction day must be:

(a) 1 April or 1 October in any year; or

(b) another prescribed day.

Price reduction

(3) If, on the reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item would, apart from this section, be higher than the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item, then, on the reduction day, the amount of the approved ex-manufacturer price is taken to be reduced to the amount of the adjusted approved ex-manufacturer

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price for the purposes of the price agreement or price determination.

Note: If the pricing quantity of the brand of the pharmaceutical item on the relevant day is different from the pricing quantity on the reduction day, then, for the purposes of subsection (3), the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item is worked out under subsection (4A).

Claimed price reduction

(4) If, on the reduction day:

(a) a determination under subsection 85B(3) is in force in relation to a particular pack quantity of the brand of the pharmaceutical item; and

(b) the approved ex-manufacturer price of the brand of the pharmaceutical item is reduced because of subsection (3);

then, on the reduction day the claimed price for that pack quantity of the brand of the pharmaceutical item is taken to be reduced by the percentage worked out as follows:

$$\frac{\text{AEMP} - \text{AAEMP}}{\text{AEMP}} \times 100$$

where:

AAEMP means the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item.

AEMP means the amount that would have been the approved ex-manufacturer price of the brand of the pharmaceutical item on the reduction day if the reduction under subsection (3) had not occurred.

Note: If the pricing quantity of the brand of the pharmaceutical item on the relevant day is different from the pricing quantity on the reduction day, then, for the purposes of subsection (4), the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item is worked out under subsection (4A).

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Apportioning if pricing quantity changes

(4A) If the pricing quantity of the brand of the pharmaceutical item on the relevant day is different from the pricing quantity of the brand of the pharmaceutical item on the reduction day, then, for the purposes of subsections (3) and (4), the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item is taken to be the amount worked out as follows:

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

where:

PQ1 means the pricing quantity of the brand of the pharmaceutical item on the relevant day.

PQ2 means the pricing quantity of the brand of the pharmaceutical item on the reduction day.

WADP means the amount equal to the amount of the weighted average disclosed price of the brand of the pharmaceutical item.

Section not to limit Minister's powers

(5) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) other price agreements; or

(b) further determinations under section 85B;

for the brand of the pharmaceutical item.

12.5% average unadjusted price reduction test

(6) For the purposes of this section, a brand of a pharmaceutical item passes the ***12.5% average unadjusted price reduction test*** if there have been 3 consecutive data collection periods in respect of which a weighted average disclosed price has been determined for any brand of the pharmaceutical item, where:

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(a) the percentage obtained by dividing the total of the unadjusted price reductions for a brand of the pharmaceutical item in respect of each of those data collection periods by 3 is at least 12.5%; and

(b) this section did not apply to the brand of the pharmaceutical item in relation to any of those data collection periods; and

(c) those data collection periods include the data collection period mentioned in paragraph (1)(a).

Example: The 12.5% average unadjusted price reduction test was passed using data from the data collection periods ending on 30 September 2022, 31 March 2023 and 30 September 2023. A price reduction occurred on 1 April 2024. The next reduction day for which the 12.5% average unadjusted price reduction test could be passed would be 1 October 2025, using data from the data collection periods ending on 31 March 2024, 30 September 2024 and 31 March 2025.

(7) For the purposes of subsection (6), if the Minister determines the weighted average disclosed price of a brand of a pharmaceutical item in respect of a data collection period for the brand, the unadjusted price reduction for the brand of the pharmaceutical item in respect of the data collection period is the unadjusted price reduction for the brand of the pharmaceutical item when the determination came into force.

Note: See subsection 99ADB(4).

(8) For the purposes of paragraph (6)(b), this section did not apply to the brand of the pharmaceutical item in relation to any of those data collection periods if the approved ex-manufacturer price of the brand of the pharmaceutical item had not been reduced under subsection (3) as a result of calculations using data from any of those 3 data collection periods.

(9) Subsection (8) is included to avoid doubt.

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99ADHA Price reduction for brands listing after end of data collection period

When this section applies

(1) This section applies if:

(a) a determination under subsection 85(6) is in force on the reduction day in relation to a brand (the ***new brand***) of a pharmaceutical item (the ***existing item***); and

(b) the determination came into force:

(i) after the last day of the period in respect of which the weighted average disclosed price is determined for another brand (the ***existing brand***) of the existing item; and

(ii) before the reduction day; and

(c) the approved ex-manufacturer price of the existing brand of the existing item is reduced on the reduction day under subsection 99ADH(3).

Price reduction

(2) On the reduction day, the approved ex-manufacturer price of the new brand of the existing item is taken to be reduced to the same amount as the approved ex-manufacturer price of the existing brand of the existing item on that day.

Claimed price reduction

(3) If, on the reduction day:

(a) a determination under subsection 85B(3) is in force in relation to a particular pack quantity of the new brand of the existing item; and

(b) the approved ex-manufacturer price of the new brand of the existing item is reduced because of subsection (2);

then, on the reduction day the claimed price for that pack quantity of the new brand of the existing item is taken to be reduced by the percentage worked out as follows:

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$$\frac{\text{AEMP1} - \text{AEMP2}}{\text{AEMP1}} \times 100$$

where:

AEMP1 means the amount that would have been the approved ex-manufacturer price of the new brand of the existing item on the reduction day if the reduction under subsection (2) had not occurred.

AEMP2 means the approved ex-manufacturer price of the new brand of the existing item on the reduction day.

99ADHB Flow on price reductions for brands of combination items

When section applies

(1) This section applies if:

(a) there is an approved ex-manufacturer price (the ***existing price***) in force for a brand (the ***existing brand***) of a combination item; and

(b) the combination item is not an exempt item; and

(c) the combination item has a drug on F2; and

(d) a brand of a pharmaceutical item (the ***non-combination item***) that is not a combination item has a drug (the ***common drug***) that is in the combination item; and

(e) the combination item has the same manner of administration as the non-combination item; and

(f) on a day (the ***reduction day***) after the day the existing price came into force for the existing brand of the combination item, section 99ADH applied to the brand of the non-combination item.

Note: The meaning of ***the same manner of administration*** is modified for the purposes of this section by subsection (7).

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Price reduction

(2) Subject to subsections (6) and (6B), on the reduction day, the approved ex-manufacturer price of the existing brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.

(3) Different methods may be prescribed by the regulations for different classes of combination items.

(4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.

(5) Subject to subsection (6), if the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2).

Ministerial discretion not to apply, or to reduce, statutory price reduction

(6) In relation to the existing brand of the combination item, the Minister may, by notifiable instrument, determine that:

(a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or

(b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.

(6A) In making a determination under subsection (6):

(a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the existing brand of the combination item would

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otherwise be under this section in relation to the particular reduction day if a determination were not made; and

(b) the Minister may take into account:

(i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and

(ii) any other matter the Minister thinks is relevant.

(6B) If the Minister makes a determination under subsection (6), the approved ex-manufacturer price of the existing brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (6).

Section does not limit Minister's powers

(6C) This section does not limit the Minister's powers, on or after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the existing brand of the combination item.

Modified meaning of the ***same manner of administration***

(7) For the purposes of this section, the existing brand of the combination item has the same manner of administration as a pharmaceutical item that is not a combination item (the ***non-combination item***) if the manner of administration set out in a determination under subsection 85(5) for the combination item, to the extent that the manner of administration relates to the common drug, is the same as the manner of administration set out in a determination under subsection 85(5) for the non-combination item.

Section does not limit Minister's powers

(13) This section does not limit the Minister's powers, after the reduction day, to make further price agreements or determinations

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under section 85B in relation to the existing brand of the combination item.

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Division 3BA—Floor price of a brand of a pharmaceutical item

99ADHC Floor price of a brand of a pharmaceutical item

When this section applies

(1) Subject to subsection (3), this section applies to a brand (the ***designated brand***) of a pharmaceutical item if:

(a) both:

(i) the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months; and

(ii) at the end of the previous data collection period for the designated brand of the pharmaceutical item, at least 30 months have passed since the first price reduction under Division 3B of any listed brand of a pharmaceutical item that has the same drug and manner of administration of the pharmaceutical item; or

(b) the approved ex-manufacturer price of the designated brand of the pharmaceutical item is $4 or less; or

(c) both:

(i) the approved ex-manufacturer price of a brand of the pharmaceutical item has been increased on or after 1 July 2022 as a result of the making of a price agreement; and

(ii) a determination is in force under subsection (2) in relation to the designated brand of the pharmaceutical item; or

(d) the approved ex-manufacturer price of the designated brand of the pharmaceutical item has been increased under section 104B.

Note 1: Section 104B commences on 1 October 2022.

Note 2: There are various consequences of a brand being a designated brand, including the changed threshold in subparagraphs 99ADH(1)(c)(ii)

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and (iii), the limits on price reductions in subsections (4) and (5) of this section, the Minister's powers under Division 3CA of this Part relating to certain discounting and incentives, and the minimum stockholding requirements in Division 3CAA of this Part. For example, if a brand satisfies paragraphs (1)(a)(i) and (ii) of this section at the end of the data collection period ending on 31 March 2024, the brand will become a designated brand, and these consequences will apply to the brand, on and from 1 April 2025 (subject to subsection (3) of this section).

(2) If the approved ex-manufacturer price of a brand of a pharmaceutical item is increased on or after 1 July 2022 as a result of a new agreed price coming into force, the Minister may, by notifiable instrument, determine that paragraph (1)(c) applies to the brand of the pharmaceutical item.

(3) This section does not apply to a brand of a pharmaceutical item if:
  (a) the drug in the pharmaceutical item is included in Schedule 2 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989* and as in force from time to time) by reference to a quantity or amount of the drug; and
  (b) that quantity or amount of the drug is equal to or greater than the total quantity or amount of the drug contained in the quantity or number of units of the brand of the pharmaceutical item in any pack quantity of the brand of the pharmaceutical item.

Limits on price reductions

(4) The approved ex-manufacturer price of the designated brand of the pharmaceutical item is not to be reduced under this Part unless:
  (a) the reduction is the result of the making of a price agreement; or
  (b) the reduction is under section 99ADH as the result of subparagraph 99ADH(1)(c)(ii) or (iii).

(5) If, apart from this subsection:
  (a) the approved ex-manufacturer price of the designated brand of the pharmaceutical item is to be reduced under a provision of this Part; and

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(b) the reduction would result in the approved ex-manufacturer price being less than $4;

then:

(c) the approved ex-manufacturer price is not to be reduced under that provision to an amount less than $4; and

(d) the approved ex-manufacturer price is instead to be reduced by an amount that would result in the approved ex-manufacturer price being $4; and

(e) the reduction mentioned in paragraph (d) is taken to be a reduction under that provision.

When the drug and manner of administration of a pharmaceutical item is taken to have been on F2 for at least 42 months

(6) For the purposes of paragraph (1)(a), the drug and manner of administration of a pharmaceutical item is taken to have been on F2 for at least 42 months if:

(a) at end of the previous data collection period, the drug in the designated brand of the pharmaceutical item had been on F2 for at least 42 months; and

(b) on a day at least 42 months before the end of the previous data collection period:

(i) there was a related brand of the designated brand of the pharmaceutical item that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the designated brand of the pharmaceutical item; or

(ii) there were 2 or more related brands of the designated brand of the pharmaceutical item that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.

(7) For the purposes of this section, ***data collection period*** has the same meaning as in Division 3B.

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99ADHD Meaning of *previous data collection period*

(1) This section sets out, for the purposes of section 99ADHC, the meaning of the expression ***the previous data collection period*** for a brand of a pharmaceutical item.

(2) This section is included to avoid doubt.

General rule

(3) The ***previous data collection period***, for the brand of the pharmaceutical item, is the data collection period for the brand of the pharmaceutical item that immediately preceded the corresponding data collection period for the brand of the pharmaceutical item in the immediately preceding year.

Example 1: A data collection period ends on 30 September 2025. The corresponding data collection period in the immediately preceding year ends on 30 September 2024: see subsection (5). Therefore, the ***previous data collection period*** is the data collection period ending on 31 March 2024.

Example 2: A data collection period ends on 31 March 2025. The corresponding data collection period in the immediately preceding year ends on 31 March 2024: see subsection (5). Therefore, the ***previous data collection period*** is the data collection period ending on 30 September 2023.

Newly listed brands

(4) If, on the day before a determination under subsection 85(6) came into force for a brand of a pharmaceutical item (the ***new brand***) there are, or have previously been, any related brands of the new brand, the ***previous data collection period***, for the new brand's first data collection period and the 2 data collection periods immediately following the first data collection period, is taken to end:

(a) when the previous data collection period for the related brands ends; or

(b) if the previous data collection period cannot be ascertained under paragraph (a)—when the previous data collection

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period would have ended if a determination under subsection 85(6) had remained in force for the related brands.

Example: A new brand is listed (that is, a determination comes into force under subsection 85(6) for the brand) on 1 July 2024 and its first data collection period ends on 30 September 2024. The immediately following data collection period ends on 31 March 2025. So:

(a) on any day between 1 July 2024 and 30 September 2024, the corresponding data collection period for any related brand is the data collection period ending on 30 September 2023, and the ***previous data collection period*** for the related brand (and the new brand) is the data collection period ending on 31 March 2023; and

(b) on any day between 1 October 2024 and 31 March 2025, the corresponding data collection period for any related brand is the data collection period ending on 31 March 2024 and the ***previous data collection period*** for the related brand (and the new brand) is the data collection period ending on 30 September 2023.

Meaning of ***corresponds***

(5) A data collection period in a year ***corresponds*** to a data collection period in another year if begins on the same day of the same month in the other year.

(6) In this section, a reference to a related brand of a brand of a pharmaceutical item includes a reference to a brand of a pharmaceutical item that would be a related brand of the brand of pharmaceutical item (within the meaning of Division 3B) but for the fact that it is a brand of an exempt item.

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Division 3C—Guarantee of supply

Subdivision A—Preliminary

99AE What this Division is about

This Division is about guaranteeing the supply of certain brands of pharmaceutical items.

Subdivision B requires the responsible person for certain brands of pharmaceutical items to supply those brands of pharmaceutical items during a specified period.

Subdivision C sets out which brands of pharmaceutical items are required to be supplied, and the period in which they are required to be supplied.

Subdivision D provides for when the responsible person is considered to have failed to supply, or been unable to supply, the brand of the pharmaceutical item.

Subdivision E requires the responsible person to notify the Minister if the person will fail or be unable to supply, or has failed or been unable to supply, the brand of the pharmaceutical item.

Subdivision F sets out the possible consequences for the responsible person if the person fails, or is unable, to supply the brand of the pharmaceutical item.

Subdivision G sets out the possible consequences for other brands of pharmaceutical items that were affected by the brand of the pharmaceutical item, if the brand of the pharmaceutical item is delisted under Subdivision F.

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99AEA Definitions

In this Division:

fails to supply has the meaning given by section 99AEE.

guaranteed brand of a guaranteed item has the meaning given by sections 99AEC and 99AED.

guaranteed period, for a guaranteed brand of a guaranteed item, has the meaning given by:

(a) if the guaranteed brand of the guaranteed item is a brand of a pharmaceutical item to which subsection 99AEC(2) applies—subsection 99AEC(3); or

(b) if the guaranteed brand of the guaranteed item is a brand of a pharmaceutical item to which subsection 99AED(2) applies—subsection 99AED(3).

unable to supply has the meaning given by section 99AEF.

Subdivision B—Guarantee of supply

99AEB Guarantee of supply

The responsible person for a guaranteed brand of a guaranteed item must supply the guaranteed brand of the guaranteed item during the guaranteed period for the guaranteed brand of the guaranteed item.

Note 1: For the circumstances when a responsible person fails to supply, or is unable to supply, in the guaranteed period, see sections 99AEE and 99AEF.

Note 2: For the consequences for the responsible person for failing to supply, or being unable to supply, in the guaranteed period, see Subdivision F.

Subdivision C—Brands that are guaranteed brands

99AEC Guaranteed brand: new brand

(1) A brand of a pharmaceutical item is a ***guaranteed brand of a guaranteed item*** for the purposes of this Division (other than

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section 99AED) if subsection (2) applies to the brand of the pharmaceutical item.

(2) This subsection applies to a brand (the ***guaranteed brand***) of a pharmaceutical item (the ***guaranteed item***) if:

(a) a determination under subsection 85(6) comes into force in relation to the guaranteed brand of the guaranteed item on a day (the ***determination day***); and

(b) on the day before the determination day, the guaranteed brand was not a listed brand of the guaranteed item; and

(c) on the determination day, or on the day before that day:

(i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) is a listed brand of the existing item; and

(ii) the guaranteed brand of the guaranteed item is bioequivalent or biosimilar to the existing brand of the existing item; and

(iii) the guaranteed item and the existing item have the same drug and manner of administration.

Note: For the purposes of paragraph (c), the guaranteed brand and the existing brand may be the same brand, or the guaranteed item and the existing item may be the same pharmaceutical item.

Guaranteed period

(3) The ***guaranteed period*** for the guaranteed brand of the guaranteed item is the period that commences on the determination day and ends on the earliest of the following days:

(a) the last day of the 24 month period beginning on the determination day;

(b) if, after the determination day:

(i) a determination under subsection 85(6) comes into force on a day (the ***later determination day***) in relation to a brand (the ***later brand***) of a pharmaceutical item (the ***later item***); and

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(ii) the later brand of the later item is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item; and

(iii) on the day before the later determination day, the later brand was not a listed brand of the later item;

the later determination day;

(c) if, after the determination day, subsection 99AED(2) applies to:

(i) a brand of the guaranteed item; or

(ii) a brand of a pharmaceutical item that is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item;

the new price day referred to in paragraph 99AED(2)(d);

(d) the day that is the first whole day on which the guaranteed brand is not a listed brand of the guaranteed item.

Note 1: For the purposes of paragraph (b), the later brand and the guaranteed brand may be the same brand, or the later item and the guaranteed item may be the same item.

Note 2: For the purposes of paragraph (c), the brand mentioned in that paragraph and the guaranteed brand may be the same brand, or the pharmaceutical item mentioned in that paragraph and the guaranteed item may be the same pharmaceutical item.

99AED Guaranteed brand: first brand to offer a lower price

(1) A brand of a pharmaceutical item is a ***guaranteed brand of a guaranteed item*** for the purposes of this Division (other than section 99AEC) if subsection (2) applies to the brand of the pharmaceutical item.

(2) This subsection applies to a brand (the ***guaranteed brand***) of a pharmaceutical item (the ***guaranteed item***) if:

(a) the drug in the guaranteed item is on F2; and

(b) the guaranteed brand is a listed brand of the guaranteed item; and

(c) the Minister and the responsible person for the guaranteed brand of the guaranteed item agree, in a price agreement, an

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agreed price (the ***new price***) of the guaranteed brand of the guaranteed item; and

(d) on the day (the ***new price day***) the new price comes into force, the new price is less than what the approved ex-manufacturer price of the guaranteed brand of the guaranteed item would have been on that day if the new price had not come into force; and

(e) the responsible person was the first responsible person for a brand of the guaranteed item to offer the Minister the new price.

Guaranteed period

(3) The ***guaranteed period*** for the guaranteed brand of the guaranteed item is the period that commences on the new price day and ends on the earliest of the following days:

(a) the last day of the 24 month period beginning on the new price day;

(b) if, after the new price day:

(i) a determination under subsection 85(6) comes into force on a day (the ***later determination day***) in relation to a brand (the ***later brand***) of a pharmaceutical item (the ***later item***); and

(ii) the later brand of the later item is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item; and

(iii) on the day before the later determination day, the later brand was not a listed brand of the later item;

the later determination day;

(c) if, after the new price day, subsection (2) applies, in another application of that subsection, to:

(i) a brand of the guaranteed item; or

(ii) a brand of a pharmaceutical item that is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item;

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the day the new price referred to in that subsection under the other application comes into force;

(d) the day that is the first whole day on which the guaranteed brand is not a listed brand of the guaranteed item.

Note 1: For the purposes of paragraph (b), the later brand and the guaranteed brand may be the same brand, or the later item and the guaranteed item may be the same item.

Note 2: For the purposes of paragraph (c), the brand mentioned in that paragraph and the guaranteed brand may be the same brand, or the pharmaceutical item mentioned in that paragraph and the guaranteed item may be the same pharmaceutical item.

Subdivision D—Meaning of fails to supply and unable to supply

99AEE Meaning of *fails to supply*

(1) A responsible person for a guaranteed brand of a guaranteed item ***fails to supply*** the guaranteed brand of the guaranteed item if:

(a) a wholesaler or an approved pharmacist requests the responsible person to supply the wholesaler or pharmacist with an amount of the guaranteed brand of the guaranteed item; and

(b) the responsible person fails to supply that amount to the wholesaler or pharmacist within:

(i) a reasonable period; or

(ii) if the regulations prescribe a period—that period;

after receiving the request.

(2) The responsible person fails to supply the guaranteed brand of the guaranteed item on the day after the end of that period.

99AEF Meaning of *unable to supply*

A responsible person for a guaranteed brand of the guaranteed item is ***unable to supply*** the guaranteed brand of the guaranteed item on a day if the responsible person would be unable to supply any amount of the guaranteed brand of the guaranteed item within a reasonable period of being requested by a wholesaler or an

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approved pharmacist, on that day, to supply the guaranteed brand of the guaranteed item.

Subdivision E—Requirement to notify Minister of failure or inability to supply etc.

99AEG Requirement to notify Minister of failure to supply etc.

Notification of belief that responsible person will fail to supply or be unable to supply

(1) If, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item forms the belief that the person will fail to supply, or will be unable to supply, the guaranteed brand of the guaranteed item in the period, then, as soon as practicable after the person forms the belief, the person must notify the Minister, in writing, of that belief.

Notification of failure to supply or inability to supply

(2) If, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item fails to supply, or is unable to supply, the guaranteed brand of the guaranteed item, then, as soon as practicable after the failure or inability occurs, the person must notify the Minister, in writing, of that failure or inability unless the person notified the Minister about that supply under subsection (1).

Offence

(3) A person commits an offence if:
  (a) the person is required to notify the Minister under subsection (1) or (2); and
  (b) the person fails to do so.

Penalty: 60 penalty units.

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(4) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (3).

Subdivision F—Consequences for guaranteed brands of failure or inability to supply

99AEH Minister's powers if responsible person fails to supply, or is unable to supply, guaranteed brand

(1) This section applies if, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item fails to supply, or is unable to supply, the guaranteed brand of the guaranteed item on one or more occasions.

(2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:

(a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the guaranteed brand of the guaranteed item;

(b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:

(i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or

(ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or

(iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

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Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the guaranteed brand, or a pharmaceutical item mentioned in those paragraphs may be the guaranteed item.

(3) Without limiting the powers of the Minister under subsection (2), in exercising a power under that subsection, the Minister may have regard to:

(a) the number of times the responsible person failed to supply, or was unable to supply:

(i) the guaranteed brand of the guaranteed item; and

(ii) if, in addition to the guaranteed brand of the guaranteed item, the person was also required to supply other guaranteed brands of guaranteed items—those other guaranteed brands of guaranteed items; and

(b) the period in which those failures or inabilities occurred; and

(c) the duration of those failures or inabilities; and

(d) the reasons for those failures or inabilities; and

(e) whether those reasons are, in the Minister's opinion, reasonable; and

(f) any other matter the Minister thinks is relevant.

(4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Subdivision G—Consequences for other brands

99AEI Minister may increase approved ex-manufacturer price if guaranteed brand delisted

(1) This section applies if, under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the ***delisted brand***) of a pharmaceutical item (the ***existing item***).

(2) Without limiting any power the Minister may otherwise have under this Part, the Minister may:

(a) under section 85AD, make or vary a price agreement to increase the agreed price; or

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(b) under subsection 85B(2), make or vary a determination to increase the determined price; or

(ba) under subsection 85B(3), make or vary a determination to increase one or more claimed prices;

for a brand of a pharmaceutical item that has an approved ex-manufacturer price that was reduced because the delisted brand of the existing item was:

(c) the new brand of the trigger item referred to in section 99ACB; or

(d) the new brand of the trigger combination item referred to in section 99ACD; or

(e) the guaranteed brand of the guaranteed item under subsection 99AED(2).

(3) If the Minister exercises the power referred to in subsection (2), then the Minister may, by legislative instrument, determine that:

(a) if subsection 99ACB(5) applied to the delisted brand of the existing item—for the purposes of subsection 99ACB(3), subsection 99ACB(5) is taken not to have applied to the delisted brand of the existing item; or

(b) if subsection 99ACB(5A) applied to the delisted brand of the existing item—for the purposes of subsection 99ACB(3), subsection 99ACB(5A) is taken not to have applied to the delisted brand of the existing item; or

(c) if subsection 99ACD(5) applied to the delisted brand of the existing item—for the purposes of subsection 99ACD(2), subsection 99ACD(5) is taken not to have applied to the delisted brand of the existing item; or

(d) if subsection 99ACD(5A) applied to the delisted brand of the existing item—for the purposes of subsection 99ACD(2), subsection 99ACD(5A) is taken not to have applied to the delisted brand of the existing item.

(4) If the Minister makes a determination under subsection (3), the determination has effect on the day specified in the determination, being a day on or after the determination comes into force.

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99AEJ Minister may determine drug is on F1 if guaranteed brand delisted

The Minister may, by legislative instrument, determine that a listed drug is on F1 if:

(a) under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the ***delisted brand***) of a pharmaceutical item (the ***existing item***); and

(b) before the revocation or variation came into force, subsection 99AEC(2) applied to the delisted brand of the existing item; and

(c) after the revocation or variation comes into force, there is only one listed brand of a pharmaceutical item (the ***remaining item***) that is bioequivalent or biosimilar to the delisted brand of the existing item; and

(d) apart from paragraph 85AB(4)(c), the drug in the remaining item satisfies the criteria for F1 referred to in subsection 85AB(4); and

(e) the drug in the remaining item was on F1 on the day before subsection 99AEC(2) began to apply to the delisted brand of the existing item.

99AEK Minister may revoke or vary formulary determination if guaranteed brand delisted

Without limiting the power of the Minister under section 85AB, the Minister may, by legislative instrument, revoke or vary a determination under section 85AB if:

(a) under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the ***delisted brand***) of a pharmaceutical item (the ***existing item***); and

(b) before the revocation or variation came into force, subsection 99AEC(2) applied to the delisted brand of the existing item; and

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(c) after the revocation or variation comes into force, there is only one listed brand of a pharmaceutical item (the ***remaining item***) that is bioequivalent or biosimilar to the delisted brand of the existing item; and

(d) the remaining item is a combination item; and

(e) the drug in the remaining item was not on F1 or F2 on the day before subsection 99AEC(2) began to apply to the delisted brand of the existing item.

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Division 3CAA—Minimum stockholding requirement

99AEKA Brands subject to the minimum stockholding requirement

For the purposes of this Division, a brand of a pharmaceutical item is subject to the minimum stockholding requirement if section 99ADHC applies to the brand of the pharmaceutical item.

99AEKB Minimum stockholding requirement

(1) If a brand of a pharmaceutical item is subject to the minimum stockholding requirement, the responsible person for the brand of the pharmaceutical item must keep in stock in Australia at least the applicable quantity of the brand of the pharmaceutical item.

(2) For the purposes of this Division, if a quantity of a brand of a pharmaceutical item is not available for sale in Australia by the responsible person, that quantity of the brand of the pharmaceutical item is taken not to be kept in stock.

99AEKC Applicable quantity of a brand of a pharmaceutical item

(1) For the purposes of this Division, the ***applicable quantity*** of a brand of a pharmaceutical item is:

(a) if the approved ex-manufacturer price of the brand of the pharmaceutical item has not been increased on or after 1 July 2022:

(i) 4 months stock by reference to usual demand for the brand of the pharmaceutical item; or

(ii) if another quantity is ascertained in accordance with a determination under subsection (2)—that quantity; or

(b) if the approved ex-manufacturer price of the brand of the pharmaceutical item was increased on or after 1 July 2022:

(i) 6 months stock by reference to usual demand for the brand of the pharmaceutical item; or

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(ii) if another quantity is ascertained in accordance with a determination under subsection (2)—that quantity.

(2) The Minister may, by legislative instrument, make a determination for the purposes of either or both of the following:
(a) subparagraph (1)(a)(ii);
(b) subparagraph (1)(b)(ii).

(3) A quantity ascertained in accordance with a determination under subsection (2) may be a specified number of months stock by reference to usual demand for the brand of the pharmaceutical item.

(4) Subsection (3) does not limit subsection (2).

(5) For the purposes of this section, ***usual demand*** for a brand of a pharmaceutical item is to be ascertained in accordance with the regulations.

99AEKD Minister to be notified of breach of minimum stockholding requirements

Notification of likely breach of the minimum stockholding requirement

(1) If:
(a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and
(b) the responsible person for the brand of the pharmaceutical item forms the belief that the person is likely to breach section 99AEKB in relation to the brand of the pharmaceutical item;

the person must:
(c) give the Minister a written notice that:
(i) informs the Minister of that belief; and
(ii) sets out the person's reasons for that belief; and
(d) do so as soon as practicable after forming that belief.

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Notification of breach of the minimum stockholding requirement

(2) If:

(a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and

(b) the responsible person for the brand of the pharmaceutical item has breached section 99AEKB in relation to the brand of the pharmaceutical item;

the person must:

(c) give the Minister a written notice that:

(i) informs the Minister of the breach; and

(ii) sets out the person's reasons for the breach; and

(d) do so as soon as practicable after the breach.

Offence

(3) A person commits an offence if:

(a) the person is subject to a requirement under subsection (1) or (2); and

(b) the person omits to do an act; and

(c) the omission breaches the requirement.

Penalty: 60 penalty units.

(4) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (3) of this section.

99AEKE Minister's power if responsible person breaches minimum stockholding requirement

(1) This section applies if:

(a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and

(b) the responsible person for the brand of the pharmaceutical item has breached section 99AEKB in relation to the brand of the pharmaceutical item.

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(2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:

(a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the brand of the pharmaceutical item;

(b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:

(i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or

(ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or

(iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the brand referred to in subsection (1), or a pharmaceutical item mentioned in those paragraphs may be the item referred to in subsection (1).

(3) In exercising a power under subsection (2), the Minister must have regard to the following:

(a) both:

(i) the responsible person's reasons for the breach; and

(ii) whether those reasons are, in the Minister's opinion, reasonable;

(b) whether, in the Minister's opinion, the responsible person will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future;

(c) whether the responsible person for the brand of the pharmaceutical item has offered discounts or incentives in relation to sales of the brand of the pharmaceutical item;

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(d) whether the responsible person for the brand of the pharmaceutical item has previously breached section 99AEKB and, if so:
  (i) the person's reasons for the breach; and
  (ii) whether those reasons are, in the Minister's opinion, reasonable;
(e) whether the responsible persons for other brands of the pharmaceutical item have breached section 99AEKB in relation to those other brands of the pharmaceutical item;
(f) any other matter the Minister thinks is relevant.

(4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

(5) For the purposes of this section, ***discount or incentive*** has the same meaning as in section 99AEL.

99AEKF Stockholding disclosure requirements

(1) The ***stockholding disclosure requirements*** for a brand of a pharmaceutical item are:
(a) to provide information prescribed by the regulations in relation to the quantity of the brand of the pharmaceutical item kept in stock in Australia by the responsible person for the brand of the pharmaceutical item; and
(b) to provide that information in the manner and form prescribed by the regulations; and
(c) to provide that information at the times prescribed by the regulations.

When the stockholding disclosure requirements apply

(2) If a brand of a pharmaceutical item is subject to the minimum stockholding requirement, the responsible person for the brand of the pharmaceutical item is required to comply with the stockholding disclosure requirements for the brand of the pharmaceutical item.

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Offence for failing to comply with the stockholding disclosure requirements

(3) A person commits an offence if:

(a) the person is required to comply with the stockholding disclosure requirements for a brand of a pharmaceutical item; and

(b) the person fails to comply with those requirements for the brand of the pharmaceutical item.

Penalty: 60 penalty units.

(4) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (3) of this section.

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Division 3CA—Discounts and incentives

99AEL Minister's powers if responsible person offers discounts or incentives for certain brands of pharmaceutical items

When this section applies

(1) This section applies if:

(a) a brand of a pharmaceutical item has an approved ex-manufacturer price of $4 or less; and

(b) the responsible person offers a discount or incentive, in relation to sales of the brand of the pharmaceutical item, on one or more occasions; and

(c) section 99ADHC applies to the brand of the pharmaceutical item.

Minister's powers

(2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:

(a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the brand of the pharmaceutical item;

(b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

(d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:

(i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or

(ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or

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(iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the brand referred to in subsection (1), or a pharmaceutical item mentioned in those paragraphs may be the item referred to in subsection (1).

(3) In exercising a power under subsection (2), the Minister must have regard to any relevant information that:

(a) relates to discounts or incentives; and

(b) was disclosed in compliance with the price disclosure requirements referred to in Division 3B.

(4) In exercising a power under subsection (2), the Minister may have regard to the following:

(a) the extent to which the discount or incentive will compromise the responsible person's capacity to continue to supply the brand of the pharmaceutical item;

(b) whether the responsible person will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future;

(ba) whether the responsible person has breached section 99AEKB;

(c) the extent to which the discount or incentive will compromise another person's capacity to continue to supply another brand of the pharmaceutical item;

(d) any other matter the Minister thinks is relevant.

(5) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Meaning of discount or incentive

(6) For the purposes of this section, ***discount or incentive***, in relation to sales of a brand of a pharmaceutical item, means:

(a) anything that results in the net revenue for the brand of the pharmaceutical item for a data collection period for the brand of the pharmaceutical item falling below the amount that

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would have been the net revenue for the brand of the pharmaceutical item for the data collection period if the price charged for the brand of the pharmaceutical item had been equal to the approved ex-manufacturer price of the brand of the pharmaceutical item; or

(b) an incentive given in relation to sales of the brand of the pharmaceutical item.

(7) For the purposes of subsection (6), ***incentive*** and ***net revenue*** have the same respective meanings as they have when used in regulations made for the purposes of subsection 99ADB(6).

(8) For the purposes of subsection (6), ***data collection period*** has the same meaning as in Division 3B.

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Division 4—Provisions relating to members of the Pharmaceutical Benefits Remuneration Tribunal

99A Terms and conditions of appointment

(1) Subject to this Part, a member holds office for such period (not exceeding 3 years) as is, and on such terms and conditions as are, specified in the instrument of his or her appointment, but is eligible for re-appointment.

(2) If the holder of the office of Chairperson ceases to be a Deputy President of the Fair Work Commission he or she ceases to hold the office of Chairperson.

99B Remuneration and allowances

(1) The Chairperson shall not be paid remuneration or allowances in his or her capacity as Chairperson but, for the purposes of the payment of travelling expenses to him or her, his or her duties as Deputy President of the Fair Work Commission shall be deemed to include his or her duties as Chairperson of the Tribunal.

(2) An additional member shall be paid such remuneration as is determined by the Remuneration Tribunal, but, if no determination of that remuneration by that Tribunal is in operation, the additional member shall be paid such remuneration as is prescribed.

(3) An additional member shall be paid such allowances as are prescribed.

(4) Subsections (2) and (3) have effect subject to the *Remuneration Tribunal Act 1973*.

99C Resignation and removal from office

(1) A member may resign office by writing signed by the member and delivered:

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(a) in the case of the Chairperson—to the Governor-General; or
(b) in any other case—to the Minister.

(2) The Governor-General may remove the Chairperson from office for misbehaviour or physical or mental incapacity.

(3) The Minister may remove an additional member from office for misbehaviour or physical or mental incapacity.

(4) If an additional member becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his or her creditors or makes an assignment of his or her remuneration for their benefit, the Minister shall remove the member from office.

99D Acting Chairperson

(1) The Governor-General may appoint a person who holds office as a Deputy President of the Fair Work Commission to act as Chairperson of the Tribunal:
(a) during a vacancy in the office of Chairperson; or
(b) during any period, or during all periods, when the Chairperson is unavailable to perform the duties of Chairperson.

Note: For rules that apply to acting appointments, see section 33A of the *Acts Interpretation Act 1901*.

(4) Where the Tribunal as constituted for the purpose of a proceeding includes a person acting or purporting to be appointed under this section, or a person so acting or purporting to be appointed has done any act, the validity of any decision of, or of any direction given or other act done by, the Tribunal as so constituted, or of the act done by the person so acting or purporting to be appointed, shall not be called in question in any proceeding on the ground that the occasion for the person to act or for the appointment of the person had not arisen or that the occasion for the person's appointment had passed or the person's appointment had ceased to have effect.

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(7) Where, by virtue of an appointment under subsection (1), a person is acting as Chairperson during the unavailability of the Chairperson, the Governor-General may, by reason of the pending consideration of a matter by the Tribunal or other special circumstances, direct that the person so acting shall continue so to act until otherwise directed by the Governor-General notwithstanding that the Chairperson has ceased to be unavailable.

(8) Where a person is acting as Chairperson by virtue of a direction under subsection (7), the Chairperson shall take no part in the operations of the Tribunal.

(9) A person shall not continue to act as Chairperson by virtue of a direction under subsection (7) for a period of more than 12 months.

(10) The appointment of a person under subsection (1) and a direction in relation to a person under subsection (7) cease to have effect if the person ceases to hold office as a Deputy President of the Fair Work Commission.

99E Acting additional member

(1) The Minister may appoint a person to act as an additional member of the Tribunal:

(a) during a vacancy in an office of an additional member; or

(b) during any period, or during all periods, when an additional member is unavailable to perform his or her duties.

Note: For rules that apply to acting appointments, see section 33A of the *Acts Interpretation Act 1901*.

(4) Where the Tribunal as constituted for the purpose of a proceeding includes a person acting or purporting to be appointed under this section, or a person so acting or purporting to be appointed has done any act, the validity of any decision of, or of any direction given or other act done by, the Tribunal as so constituted, or of the act done by the person so acting or purporting to be appointed, shall not be called in question in any proceeding on the ground that the occasion for the person to act or for the appointment of the person had not arisen or that the occasion for the person's

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appointment had passed or the person's appointment had ceased to have effect.

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Division 4A—Indexation etc.

Subdivision A—Preliminary

99F Definitions

In this Division, unless the contrary intention appears:

concessional beneficiary charge means each amount of $4.60 referred to in paragraph 84C(4)(d), section 84CA, paragraph 87(2)(a) or subsection 99(2B).

concessional beneficiary safety net means the amount worked out by multiplying the concessional beneficiary charge by 36.

general patient charge means the amount specified in the definition of ***general patient charge amount*** in subsection 84(1).

general patient reduced charge means each amount of $4.60 referred to in paragraph 87(2)(b) or subsection 99(2AB).

general patient safety net means the amount of $1,457.10.

increased discounting upper Commonwealth price means the amount specified in subparagraph 87AA(c)(ii).

index number, in relation to a quarter, means the All Groups Consumer Price Index number that is the weighted average of the 8 capital cities and is published by the Australian Statistician in respect of that quarter.

Subdivision B—Indexation

99G Indexation

(1) An amount referred to in an item in the CPI Indexation Table below is to be indexed under this section in each year on the indexation day in that item, using the reference quarter in that item and rounding to the nearest multiple of 10 cents. However, if the

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amount is not a multiple of 10 cents but it is a multiple of 5 cents, the amount is to be increased by 5 cents.

CPI INDEXATION TABLE

Item	Amount	Indexation day	Reference quarter
1.	General patient charge	1 January	September
2.	General patient reduced charge	1 January	September
3.	Concessional beneficiary charge	1 January	September
4.	General patient safety net	1 January	September
5.	Increased discounting upper Commonwealth price	1 January	September

Certain charges not to be indexed

(1A) Despite subsection (1), the general patient charge is not to be indexed on 1 January 2026.

(1B) Despite subsection (1), the general patient reduced charge and the concessional beneficiary charge are not to be indexed on:

(a) 1 January 2025; and
(b) 1 January 2026; and
(c) 1 January 2027; and
(d) 1 January 2028; and
(e) 1 January 2029.

Effect of indexation

(2) Where an amount is to be indexed on an indexation day, this Act has effect as if the indexed amount were substituted for that amount on that day.

Note: The Department can tell you what the current indexed amounts are.

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Working out the indexed amount

(3) Subject to this section, the indexed amount for an amount to be indexed is worked out using the formula:

$$\text{Current figure} \times \text{Indexation factor}$$

where:

Current figure, as at a particular time in relation to an amount to be indexed, means:

(a) if the amount has not yet been indexed under this section before that time—the amount; and

(b) if the amount has been indexed under this section before that time—the amount most recently substituted for the amount under this section before that time.

Indexation factor means the figure worked out under subsection (4).

(4) Subject to subsections (5) and (6), the indexation factor for an amount to be indexed on an indexation day is worked out using the formula:

$$\frac{\text{Most recent index number}}{\text{Previous index number}}$$

where:

Most recent index number means the index number for the most recent reference quarter for the amount ending before the indexation day.

Previous index number means the index number for the reference quarter for the amount immediately preceding the most recent reference quarter for the amount ending before the indexation day.

(5) Subject to subsections (6) and (7), an indexation factor is to be worked out to 3 decimal places.

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(6) If an indexation factor worked out under subsection (5) would, if it were worked out to 4 decimal places, end in a number that is greater than 4, the indexation factor is to be increased by 0.001.

(7) If an indexation factor worked out under subsections (4), (5) and (6) would be less than 1, the indexation factor is to be increased to 1.

(8) Subject to subsection (9), if at any time (whether before or after the commencement of this section), the Australian Statistician publishes an index number for a quarter in substitution for an index number previously published by the Statistician for that quarter, the publication of the later index number is to be disregarded for the purposes of this section.

(9) If at any time (whether before or after the commencement of this section) the Australian Statistician changes the index reference period for the Consumer Price Index, regard is to be had, for the purposes of applying this section after the change takes place, only to index numbers published in terms of the new index reference period.

Subdivision C—Reduction of allowable discounts

99GA Definitions

In this Subdivision:

adjustment day means 1 January 2025 and each later 1 January.

current figure has the same meaning as in subsection 99G(3).

99GB Supplies to which this Subdivision applies

This Subdivision applies in relation to a supply of a pharmaceutical benefit that is made on or after 1 January 2025.

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99GD Reduction of allowable discounts relating to the general patient reduced charge and concessional beneficiary charge

Amount of reduction when charges are not indexed

(1) On each adjustment day before 1 January 2030, an allowable discount specified in column 1 of an item of the following table is reduced by the amount specified in column 2 of that item.

Item	Column 1 Allowable discount	Column 2 Amount by which allowable discount is reduced
1	Allowable discount for a supply of a pharmaceutical benefit covered by paragraph 87(2)(a)	The amount that is the difference between: (a) the current figure of the concessional beneficiary charge at the start of 1 January 2025 (the ***frozen CBC***); and (b) the indexed amount of the concessional beneficiary charge that would have been substituted under section 99G for the concessional beneficiary charge on the adjustment day if: (i) subsection 99G(1B) were not enacted; and (ii) the concessional beneficiary charge immediately before the adjustment day were equal to the frozen CBC
2	Allowable discount for a supply of a pharmaceutical benefit covered by paragraph 87(2)(b)	The amount that is the difference between: (a) the current figure of the general patient reduced charge at the start of 1 January 2025 (the ***frozen GPRC***); and (b) the indexed amount of the general patient reduced charge that would have been substituted under section 99G for the general patient reduced charge on the adjustment day if: (i) subsection 99G(1B) were not enacted; and (ii) the general patient reduced charge immediately before the adjustment day

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Item	Column 1 Allowable discount	Column 2 Amount by which allowable discount is reduced
		were equal to the frozen GPRC

Amount of reduction when charges are indexed

(2) On each adjustment day after 1 January 2029, an allowable discount specified in column 1 of an item of the following table is reduced by the amount specified in column 2 of that item.

Item	Column 1 Allowable discount	Column 2 Amount by which allowable discount is reduced
1	Allowable discount for a supply of a pharmaceutical benefit covered by paragraph 87(2)(a)	The amount that is the difference between: (a) the current figure of the concessional beneficiary charge immediately before the adjustment day; and (b) the indexed amount of the concessional beneficiary charge that is substituted under section 99G for the concessional beneficiary charge on the adjustment day
2	Allowable discount for a supply of a pharmaceutical benefit covered by paragraph 87(2)(b)	The amount that is the difference between: (a) the current figure of the general patient reduced charge immediately before the adjustment day; and (b) the indexed amount of the general patient reduced charge that is substituted under section 99G for the general patient reduced charge on the adjustment day

Allowable discount not to be less than nil

(3) However, if an allowable discount worked out under subsection (1) or (2) would be less than nil, the allowable discount is increased to nil.

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Sunset

(4) This section ceases to be in force in relation to an allowable discount for a kind of supply of a pharmaceutical benefit at the end of the first adjustment day on which the allowable discount for that kind of supply is adjusted to nil under this section.

99GE Effect of reduction in allowable discount

If an allowable discount is adjusted under section 99GD on a day, this Act has effect as if the adjusted allowable discount were substituted for that allowable discount on that day.

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Division 4B—Australian Community Pharmacy Authority

99H Interpretation

In this Division:

Chairperson means the Chairperson of the Authority.

member means a member of the Authority.

99J Establishment of Authority

(1) An Authority is established.

(2) The name of the Authority is the ***Australian Community Pharmacy Authority***.

99K Functions

(1) The functions of the Authority are:
  (a) to consider applications under section 90; and
  (b) to make, in respect of an application under section 90:
    (i) a recommendation whether or not the applicant should be approved under that section in respect of particular premises; and
    (ii) if an approval is recommended—recommendations as to the conditions (if any) to which the approval should be subject.

(2) In making a recommendation under subsection (1), the Authority must comply with the relevant rules determined by the Minister under section 99L.

(3) All recommendations of the Authority under subsection (1) are to be made to the Secretary.

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99L Determination of rules by Minister

The Minister must, by legislative instrument, determine the rules subject to which the Authority is to make recommendations under subsection 99K(1).

99M Powers

The Authority has power to do all things necessary or convenient to be done for, or in connection with, the performance of its functions.

99N Membership

(1) The Authority consists of the following part-time members:
   (a) a Chairperson;
   (b) 2 pharmacists who are to be chosen from 4 pharmacists nominated by the Pharmacy Guild of Australia;
   (c) one pharmacist who is to be chosen from 2 pharmacists nominated by the Pharmaceutical Society of Australia;
   (d) an officer of the Department;
   (e) a person who, in the Minister's opinion, is an appropriate person to represent the interests of consumers.

(2) The member referred to in paragraph (1)(d) is to be appointed by the Secretary.

(3) The other members are to be appointed by the Minister.

(4) The member referred to in paragraph (1)(d) holds office, subject to this Division, during the pleasure of the Secretary.

(5) Each member referred to in paragraph (1)(a), (b), (c) or (e) holds office, subject to this Division, for the period of 3 years from the date of his or her appointment, but is eligible for re-appointment.

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99P Terms and conditions not provided for by this Act

A member holds office on such terms and conditions (if any), in respect of matters not provided for by this Act, as are determined in writing by the Minister.

99Q Defective appointment not invalid

The appointment of a person as a member is not invalid because of a defect or irregularity in connection with the appointment.

99R Remuneration and allowances

(1) A member is to be paid such remuneration as is determined by the Remuneration Tribunal, but, if no determination of that remuneration by the Tribunal is in operation, a member is to be paid such remuneration as is prescribed.

(2) A member is to be paid such allowances as are prescribed.

(3) Subsections (1) and (2) have effect subject to the *Remuneration Tribunal Act 1973*.

(4) In this section:

member means a member other than the member referred to in paragraph 99N(1)(d).

99S Leave of absence

The Minister may grant to a member appointed by the Minister leave of absence on such terms and conditions as to remuneration or otherwise as the Minister determines.

99T Disclosure of interests

(1) A member who has a direct or indirect pecuniary interest in a matter being considered by the Authority must, as soon as possible after the relevant facts have come to the member's knowledge, disclose the nature of the interest at a meeting of the Authority.

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(2) A disclosure under subsection (1) must be recorded in the minutes of the meeting of the Authority and the member may not, unless the Minister otherwise determines:

(a) be present during any deliberation of the Authority with respect to that matter; or

(b) take any part in any decision of the Authority with respect to that matter.

99U Resignation

A member may resign by writing signed and delivered:

(a) if the member was appointed by the Secretary—to the Secretary; or

(b) otherwise—to the Minister.

99V Termination of appointment

(1) The Minister may terminate the appointment of a member for misbehaviour or physical or mental incapacity.

(2) If a member:

(a) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with creditors or makes an assignment of remuneration for the benefit of those creditors;

(b) fails, without reasonable excuse, to comply with an obligation imposed by section 99T; or

(c) is absent, except on leave of absence granted under section 99S, from 3 consecutive meetings of the Authority;

the Minister may terminate the appointment of the member.

(3) In this section:

member means a member appointed by the Minister.

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99W Meetings

(1) The Chairperson may convene such meetings of the Authority as the Chairperson considers necessary for the efficient performance of the Authority's functions.

(2) Meetings are to be held at such places as the Chairperson determines.

(3) The Chairperson presides at all meetings at which he or she is present.

(4) Where the Chairperson is not present at a meeting, the members present must appoint one of their number to preside at the meeting.

(5) Subject to this Act, the person presiding at a meeting may give directions regarding the procedure to be followed at or in connection with that meeting.

(6) At a meeting:
  (a) 3 members constitute a quorum; and
  (b) all questions are to be decided by a majority of votes of the members present and voting; and
  (c) the person presiding has a deliberative vote and, if necessary, also has a casting vote.

(7) The Authority must keep records of its meetings.

99X Committees

(1) The Authority:
  (a) may, with the approval in writing of the Minister, establish committees to assist it in performing its functions; and
  (b) must, if the Minister so requires in writing, establish a committee to assist it in advising the Minister on a particular matter referred to it by the Minister.

(2) A committee consists of the persons (whether or not members of the Authority) appointed by the Minister to be its members.

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(3) An appointment under subsection (2) is on a part-time basis.

(4) For the purposes of section 99R, the members of a committee who are not members of the Authority are taken to be members of the Authority.

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Division 4C—Cost recovery

Subdivision A—Preliminary

99YB What this Division is about

This Division enables fees to be charged for certain services provided by the Commonwealth in order to recover the cost to the Commonwealth of providing those services. Those services relate to the exercise of certain powers of the Minister under this Act.

Subdivision B provides for regulations to set out the fees that are payable for those services, as well as other matters relating to the payment of those fees and the provision of those services (including some consequences of failing to pay a fee).

Subdivision C sets out another possible consequence of failing to pay a fee by providing for the Minister to refuse to exercise certain powers until the fee is paid.

Subdivision D provides that the Minister must cause a review to be undertaken of the impact of cost-recovery measures provided for under this Division and any regulations made under this Division, and must table an annual report on related processes.

Subdivision B—Payment of fees etc. for certain services

99YBA Payment of fees etc. for certain services

(1) The regulations may make provision in relation to services provided by the Commonwealth in relation to the exercise of a power by the Minister under any of the following:
  (a) section 9B;
  (b) a provision in Part VII (other than a provision in that Part prescribed by the regulations).

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(2) Without limiting subsection (1), the regulations may make provision in relation to the following:
  (a) the making of applications for those services;
  (b) prescribing fees for those services;
  (c) the time that prescribed fees are due and payable (including extending the time for payment of the fees);
  (d) the manner of payment of prescribed fees (including payment by instalments);
  (e) the payment of penalties in respect of late payment of prescribed fees;
  (f) exemptions from prescribed fees;
  (g) the waiver, remission or refund of prescribed fees;
  (h) the refusal to provide those services until a prescribed fee is paid;
  (i) the review of decisions made under the regulations.

(3) A prescribed fee must not be such as to amount to taxation.

(4) A prescribed fee is payable to the Commonwealth.

(5) A prescribed fee that is due and payable may be recovered by the Commonwealth as a debt due to the Commonwealth.

Subdivision C—Consequences if fees not paid

99YBB Minister may refuse to exercise certain powers if prescribed fees not paid

(1) If:
  (a) a person applies for a service referred to in subsection 99YBA(1) in relation to the exercise of a power by the Minister; and
  (b) either:
    (i) a fee prescribed under paragraph 99YBA(2)(b) is payable by the person for the service; or

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(ii) a fee prescribed under paragraph 99YBA(2)(b) is payable by the person for another service referred to in subsection 99YBA(1) that the person has applied for;

then, without limiting any power the Minister may otherwise have under section 9B or this Part, the Minister may refuse to exercise the power until the prescribed fee is paid.

(2) A refusal referred to in subsection (1) is not a legislative instrument.

Subdivision D—Review of cost-recovery measures

99YBC Review of impact of cost-recovery measures

Review

(1) The Minister must cause an independent review of the impact of cost-recovery measures provided for under this Division and any regulations made under this Division to be undertaken as soon as possible after the second anniversary of the commencement of this Division and completed within 4 months of that anniversary.

(2) The review must report on:

(a) the average number of times a submission is presented before gaining approval and the reasons provided for requiring applicants to resubmit;

(b) the average fee for submissions by type of submission (major/minor/generic according to the Department's classifications);

(c) the number of applications where the population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted;

(d) the number of reviews requested by applicants;

(e) the number of fee waivers given to applicants and the reasons why waivers were given;

(f) the length of time taken for submissions to be approved;

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(g) the number of applications that fail to gain a listing, the reasons why and the types of drugs concerned;
(h) any increase in operating costs of the Pharmaceutical Benefits Advisory Committee;
(i) any increase in the cost of pharmaceutical benefits scheme medications to patients;
(j) any other matters considered relevant.

(3) The review must be conducted by a panel which must comprise not less than five persons, including:
(a) a medical professional nominated by the Minister;
(b) a nominee of the Consumers Health Forum of Australia;
(c) three other persons nominated by the Minister, each of whom must have relevant professional qualifications and must not be employed within the pharmaceuticals industry.

(4) The panel must give the Minister a written report of the review, and the Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of receiving the report.

Annual report on processes

(5) The Secretary must, as soon as practicable after 30 June in each year, prepare and give to the Minister a report on processes leading up to the Pharmaceutical Benefits Advisory Committee consideration, including:
(a) the extent and timeliness with which responsible persons are provided copies of documents relevant to their submission to the Pharmaceutical Benefits Advisory Committee;
(b) the extent to which responsible persons exercise their right to comment on these documents, including appearing at hearings before the Pharmaceutical Benefits Advisory Committee;
(c) the number of responsible persons seeking a review of a Pharmaceutical Benefits Advisory Committee recommendation.

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(6) The Minister must cause a copy of each report prepared under subsection (5) to be tabled in each House of the Parliament within 15 sitting days of receiving the report.

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Division 4D—Export restriction

99ZH Definitions

(1) In this Division, unless the contrary intention appears:

Commonwealth benefit means benefit paid or payable by the Commonwealth to an approved supplier of substances to which this Part applies.

Comptroller-General of Customs means the person who is the Comptroller-General of Customs in accordance with subsection 11(3) or 14(2) of the *Australian Border Force Act 2015*.

consign for export, in relation to an article containing drug like substances, means the initial act of placement of that article by one person in the physical possession of another person with the intention that the other person will, either directly or indirectly, arrange for the export of that article from Australia to a place outside Australia.

Customs declaration, in relation to an article that is consigned for export and that contains drug like substances, means:

(a) an export entry within the meaning of the *Customs Act 1901*; or

(b) a declaration that is attached to the article in accordance with the requirements of section 99ZK.

Customs documentation purposes means the purposes of enabling the Immigration and Border Protection Department to deal with any complaint made, or proceeding taken, against Customs officers in respect of their activities under this Division.

Customs officer means an officer of Customs within the meaning of subsection 4(1) of the *Customs Act 1901*.

drug like substance means a substance:

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(a) that is in the form of a tablet, capsule, or other similar preparation apparently suitable for taking by mouth; or
(b) that is apparently suitable for introduction into the nose or throat as an aerosol; or
(c) that is contained in an ampoule or vial apparently suitable for injection; or
(d) that is a cream, suppository, pessary, foam or other preparation apparently suitable for insertion in the rectum or vagina; or
(e) that is contained in a patch or other vehicle apparently suitable for the introduction of a medication through the skin;

and includes the packaging (if any) in which the substance, or the ampoule, vial, patch or other vehicle containing the substance, is contained.

exporter, in relation to drug like substances, means a person who:
(a) leaves Australia or attempts to leave Australia, carrying such substances; or
(b) consigns an article containing such substances for exportation.

Immigration and Border Protection Department means the Department administered by the Minister administering Part XII of the *Customs Act 1901*.

PBS monitoring purposes means monitoring by the Chief Executive Medicare of the operation of the pharmaceutical benefits scheme.

PBS regulatory purposes means:
(a) the purpose of enabling the Chief Executive Medicare to perform his or her functions in relation to drug like substances detained under this Division; and
(b) PBS monitoring purposes.

pharmaceutical benefits scheme means the scheme for the supply of pharmaceutical benefits established under this Part.

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prescription drug means a substance for the supply of which the prescription of a medical or dental practitioner is required:

(a) if the State or Territory in which the substance was supplied is known—under the law of that State or Territory relating to drugs or poisons; or

(b) in any other case—under the law of any State, of the Australian Capital Territory, or of the Northern Territory, relating to drugs or poisons.

prohibited export means a thing the exportation of which from Australia is prohibited under the *Customs Act 1901* or under any other law of the Commonwealth.

(2) In this Division, a reference to the making of a copy of a document means, in relation to a document that is in electronic form, the making of a hard copy of the text of the original document.

99ZI Restrictions on carriage or consignment of drug like substances

(1) A person must not leave Australia carrying drug like substances unless they:

(a) are not prescription drugs; or

(b) are prescription drugs but no Commonwealth benefit has been paid or is payable in respect of those drugs; or

(c) are prescription drugs but for the personal use of the person, of another person travelling in the company of the person or of a person covered by paragraph 86A(2)(a), (b) or (c).

(2) A person must not consign for export an article that contains drug like substances unless the substances:

(a) are not prescription drugs; or

(b) are prescription drugs but no Commonwealth benefit has been paid or is payable in respect of those drugs; or

(c) are prescription drugs but for the personal use of the person, of another person accompanying the person or of a person covered by paragraph 86A(2)(a), (b) or (c).

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(3) For the purposes of subsection (1), a person who attempts to leave Australia is taken to be carrying drug like substances if the substances are in baggage to which the person's documents for travel relate, whether or not that baggage is under the person's immediate physical control.

(4) The restriction imposed by subsections (1) and (2) on the carriage or consignment of drug like substances are in addition to, and not in derogation from, any other prohibition or restriction imposed on such activities, in relation to those substances, under any other law of the Commonwealth or any law of a State or Territory.

(5) The reference in subsection (3) to a person's documents for travel that relate to the person's baggage includes a reference to any document relating to the person's travel that contains information for use by the person in reclaiming that baggage.

99ZJ Detention of certain drug like substances being carried out of Australia and retention of related documents

(1) If:

(a) a person is attempting to leave Australia; and

(b) a Customs officer finds that the person is carrying drug like substances in the person's baggage; and

(c) the person cannot satisfy the officer of a matter referred to in paragraph 99ZI(1)(a), (b) or (c) in relation to the substances;

the officer may, in accordance with guidelines issued under section 99ZS, detain the substances for transfer to the Chief Executive Medicare for PBS regulatory purposes.

(2) If the drug like substances are claimed by the exporter not to be prescription drugs, the exporter may satisfy a Customs officer of that claim by providing to the officer:

(a) a signed declaration by the exporter to that effect; or

(b) any other evidence sufficient to satisfy the officer to that effect.

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(3) If the drug like substances are claimed by the exporter to be prescription drugs, the exporter may satisfy a Customs officer that no Commonwealth benefit has been paid or is payable in respect of the substances by providing to the officer:

(a) an approved supplier's letter to that effect; or

(b) a signed declaration by the exporter to that effect; or

(c) any other evidence sufficient to satisfy the officer to that effect.

(4) If the drug like substances are claimed by the exporter to be prescription drugs, the exporter may satisfy a Customs officer that they are for the personal use of the exporter (the ***applicable person***), of another person (the ***applicable person***) accompanying the exporter or of a person (the ***applicable person***) covered by paragraph 86A(2)(a), (b) or (c), by providing to the officer:

(a) a medical or dental practitioner's letter to that effect; or

(aa) an optometrist's letter signed on or after 1 January 2008 to that effect; or

(ab) a letter from an authorised midwife or an authorised nurse practitioner signed on or after 1 November 2010 to that effect; or

(b) a signed declaration by the exporter:

(i) stating that the substances are for the personal use of the applicable person; and

(ii) setting out the name and address of the medical or dental practitioner, or the optometrist, authorised midwife or authorised nurse practitioner, who prescribed the substances; and

(iii) setting out the name and address of the approved supplier of the substances; and

(iv) stating the quantity of the substances intended for export; and

(v) setting out the daily dosage of the substances for the applicable person and the time the applicable person is expected to be outside Australia; or

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(c) any other evidence sufficient to satisfy the officer that the substances are for the personal use of the applicable person.

(4A) For the purposes of subparagraph (4)(b)(ii), the substances must have been prescribed:

(a) for substances prescribed by an optometrist—on or after 1 January 2008; or

(b) for substances prescribed by an authorised midwife or an authorised nurse practitioner—on or after 1 November 2010.

(5) Nothing in subsection (2), (3) or (4) is intended to imply that the tendering to a Customs officer of a document of the kind described in paragraph (2)(a), (3)(a) or (b) or (4)(a), (aa), (ab) or (b) will necessarily be sufficient to satisfy the officer as required by that subsection.

(6) If drug like substances are detained by a Customs officer under subsection (1), the officer must:

(a) if a signed declaration is given to the officer under subsection (2), (3) or (4):

(i) make 2 copies of the declaration; and

(ii) retain the original declaration for transfer to the Chief Executive Medicare for PBS regulatory purposes; and

(iii) retain one copy of the declaration for Customs documentation purposes; and

(iv) return the other copy of the declaration to the exporter; and

(b) if any other document is given to the officer under that subsection:

(i) make 2 copies of that document; and

(ii) retain one copy for transfer to the Chief Executive Medicare for PBS regulatory purposes; and

(iii) retain the other copy for Customs documentation purposes; and

(iv) return the original document to the exporter.

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(7) Subject to subsection (8), if a drug like substance is not detained by a Customs officer under subsection (1), the officer must return to the exporter any document, including any signed declaration, given to the officer.

(8) If, on examination of a document, if any, given to a Customs officer under subsection (2), (3) or (4), the officer decides not to detain the drug like substances, but, having regard to:

(a) the quantity of the substances; or

(b) the manner of packaging or carrying of the substances; or

(c) any other circumstances relating to the carriage of the substances;

the officer considers it appropriate to retain information relating to the substances for transfer to the Chief Executive Medicare for PBS monitoring purposes, the officer must:

(d) if a signed declaration is given to the officer under that subsection:

(i) make 2 copies of the declaration; and

(ii) retain the original declaration for transfer to the Chief Executive Medicare for those monitoring purposes; and

(iii) retain one copy of the declaration for Customs documentation purposes; and

(iv) return the other copy of the declaration to the exporter; and

(e) if any other document is given to the officer under that subsection:

(i) make 2 copies of that document; and

(ii) retain one copy for transfer to the Chief Executive Medicare for those monitoring purposes; and

(iii) retain the other copy for Customs documentation purposes; and

(iv) return the original document to the exporter.

Note: The manner of dealing with documents, and copies of documents, retained under subsection (6) or (8) is dealt with in section 99ZN.

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99ZK Detention of certain drug like substances consigned for export and retention of related documents

(1) If:

(a) a person consigns an article for export; and

(b) a Customs officer finds drug like substances in the article; and

(c) the article:

(i) is not covered by a Customs declaration that discloses the substances; or

(ii) is covered by a Customs declaration disclosing the substances but the declaration is not sufficient to satisfy the officer of a matter referred to in paragraph 99ZI(2)(a), (b) or (c) in relation to the substances;

the officer may, in accordance with guidelines issued under section 99ZS, detain the substances for transfer to the Chief Executive Medicare for PBS regulatory purposes.

(2) If a person consigns an article containing drug like substances for export and the person is not required, under subsection 113(1) of the *Customs Act 1901*, to enter the goods for export, the exporter must attach to the article in which the substances are consigned a signed declaration stating:

(a) his or her name and address; and

(b) any one of the following:

(i) that the substances are not prescription drugs;

(ii) that they are prescription drugs but no Commonwealth benefit has been paid or is payable in respect of them;

(iii) that they are prescription drugs but for the personal use, outside Australia, of the exporter, of a person who travels from Australia in the company of the exporter or of a person covered by paragraph 86A(2)(a), (b) or (c).

(3) To satisfy a Customs officer of a matter referred to in paragraph (2)(b), the exporter may:

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(a) in the case of a statement under subparagraph (2)(b)(i)—include in the article any documentary evidence in support of that statement; or

(b) in the case of a statement under subparagraph (2)(b)(ii)—include in the article an approved supplier's letter or other evidence to support that statement; or

(c) in the case of a statement under subparagraph (2)(b)(iii)—include in the article:

(i) a medical practitioner's letter; or

(ii) a dental practitioner's letter; or

(iii) an optometrist's letter signed on or after 1 January 2008; or

(iiia) a letter from an authorised midwife or an authorised nurse practitioner signed on or after 1 November 2010; or

(iv) any other documentary evidence to support that statement.

(4) Nothing in subsection (3) is intended to imply that the inclusion within the article of a document of the kind described in paragraph (3)(a), (b) or (c) will necessarily be sufficient to satisfy the officer as required by that subsection.

(5) If drug like substances contained within an article consigned for export are detained by a Customs officer under subsection (1), the officer must:

(a) make a copy of the Customs declaration relating to that article; and

(b) retain that copy for transfer to the Chief Executive Medicare for PBS regulatory purposes; and

(c) retain the original declaration for Customs documentation purposes; and

(d) if the article is found to contain a document in support of a statement relating to the substances in the Customs declaration:

(i) make 2 copies of the document; and

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(ii) retain one copy for transfer to the Chief Executive Medicare for PBS regulatory purposes; and

(iii) retain the other copy for Customs documentation purposes; and

(iv) return the original document to the article.

(6) If, on examination of a declaration referred to in subsection (2) or any other document referred to in subsection (3), the Customs officer decides not to detain the drug like substances, but having regard to:

(a) the quantity of the substances; or

(b) the manner of packaging the substances; or

(c) any other circumstances in which the substances are being exported;

the officer considers it appropriate to retain information relating to the substances for transfer to the Chief Executive Medicare for PBS monitoring purposes, the officer must:

(d) make a copy of the Customs declaration relating to that article; and

(e) retain the copy for transfer to the Chief Executive Medicare for those monitoring purposes; and

(f) retain the original declaration for Customs documentation purposes; and

(g) if the article is found to contain a document in support of a statement relating to the substances in the Customs declaration:

(i) make 2 copies of the document; and

(ii) retain one copy for transfer to the Chief Executive Medicare for those monitoring purposes; and

(iii) retain the other copy for Customs documentation purposes; and

(iv) return the original document to the article.

Note: The manner of dealing with documents, and copies of documents, retained under subsection (5) or (6) is dealt with in section 99ZN.

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99ZL Examination and inspection powers

(1) A Customs officer may, in an examination place and with such assistance and using such force as is reasonable and necessary in the circumstances, examine, and inspect the contents of:

(a) any item of baggage, in that place, that is carried, or taken to be carried, by an exporter; or

(b) any article, in that place, that is consigned for export;

in order to determine, for the purposes of section 99ZJ or 99ZK:

(c) whether or not the baggage or article contains drug like substances; or

(d) if the presence of drug like substances in the baggage or article has been disclosed by the exporter—whether or not the drug like substances in the baggage or article are as so disclosed.

(2) A Customs officer must, in exercising the powers of examination and inspection referred to in subsection (1), act in accordance with guidelines issued under section 99ZS.

(3) In this section:

examination place means:

(a) a port, airport, wharf or boarding station appointed under section 15 of the *Customs Act 1901*; or

(b) a place that is the subject of a permission under section 58 of that Act; or

(c) an international mail centre approved for the purposes of subsection 77F(1) of that Act; or

(d) a place appointed under section 77G of that Act.

99ZM Detention of some drug like substances and not others

The power in section 99ZJ or 99ZK to detain drug like substances contained in an item of baggage, or in an article consigned for export, includes a power to detain some such substances while not detaining others, including others of the same kind as the substances that are detained.

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99ZN Treatment of detained substances and retained documents

(1) Drug like substances detained under section 99ZJ or 99ZK must, pending their transfer to the Chief Executive Medicare, be taken to a place of security specified by the Comptroller-General of Customs.

(2) If a Customs officer detains drug like substances under section 99ZJ or 99ZK, the officer must:

(a) give to the exporter a notice of such detention in accordance with subsections (4) and (5); and

(b) give to the Chief Executive Medicare a copy of that notice; and

(c) in accordance with the guidelines issued under section 99ZS, transfer to the Chief Executive Medicare, for PBS regulatory purposes:

(i) the substances so detained; and

(ii) any documents that relate to the substances and that were retained by the officer under subsection 99ZJ(6) or 99ZK(5) for such transfer; and

(d) in accordance with the guidelines issued under section 99ZS, transfer to a place of security specified by the Comptroller-General of Customs, for Customs documentation purposes, any documents relating to the substances that were retained by the officer under subsection 99ZJ(6) or 99ZK(5) for such purposes.

(3) If a Customs officer does not detain drug like substances under section 99ZJ or 99ZK but retains information relating to the substances under that section, the officer must, in accordance with the guidelines issued under section 99ZS:

(a) transfer to the Chief Executive Medicare, for PBS regulatory purposes, any documents that relate to the substances and that were retained by the officer under subsection 99ZJ(8) or 99ZK(6) for such transfer, accompanied by a brief statement of the circumstances in which the substances were being exported; and

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(b) transfer to such place of security as the Comptroller-General of Customs directs, for Customs documentation purposes, any documents relating to the substances that were retained by the officer under subsection 99ZJ(8) or 99ZK(6) for such purposes, accompanied by a copy of the statement referred to in paragraph (a).

(4) For the purposes of this Division, a notice of detention of drug like substances is taken to have been duly given to the exporter if the notice is:

(a) given to the exporter, if the exporter is present at the time of the detention; or

(b) if the exporter is not present but a postal address of the exporter is known—sent by post to the last known such address; or

(c) if the postal address of the exporter of a consignment is not known but the address of the consignee is known—sent by post to the address of the consignee; or

(d) in any other situation—published in the *Gazette*.

(5) The notice of detention of drug like substances must:

(a) set out a description of the substances detained; and

(b) provide a brief statement of the reasons for detention; and

(c) inform the exporter that the Chief Executive Medicare will examine the substances, and:

(i) if the Chief Executive Medicare is satisfied that they are not prescription drugs and not prohibited exports—return the substances to the exporter or reconsign them for export, as the case requires; and

(ii) if the Chief Executive Medicare is satisfied that they are prohibited exports—pass the substances to the agency nominated in the guidelines issued under section 99ZS to deal with prohibited exports of that kind; and

(iii) if the Chief Executive Medicare is satisfied that they are prescription drugs but not prohibited exports—notify the exporter in writing to that effect and invite the exporter to apply in writing to the Chief Executive

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Medicare, within 60 days after the notification, for their return on the basis that paragraph 99ZI(1)(b) or (c) or (2)(b) or (c) applies in relation to the substances; and

(d) inform the exporter that, if the exporter is notified by the Chief Executive Medicare in accordance with subparagraph (c)(iii) but no application for the return of the substances is received within 60 days after the notification, then, in accordance with subsection 99ZO(5), the Chief Executive Medicare will be taken to have seized the substances and the substances will have been taken to have been condemned as forfeited to the Commonwealth; and

(e) inform the exporter that, if the exporter is notified by the Chief Executive Medicare in accordance with subparagraph (c)(iii) and an application for the return of the substances is made within 60 days after the notification, the Chief Executive Medicare will consider the application and, within 120 days after the notification, will either:

(i) return the substances to the exporter or reconsign them for export; or

(ii) seize the substances and then seek an order of a magistrates court for their condemnation as forfeited to the Commonwealth; and

(f) inform the exporter of the possible implications of a criminal prosecution of the exporter in relation to the substances.

(6) If a copy of a document or statement is transferred by a Customs officer under subsection (3) to a place of security, the Comptroller-General of Customs must ensure:

(a) that the copy is not used for any other purposes than the purposes for which it was retained; and

(b) that, at the end of 12 months, or on completion of any complaint or proceeding initiated against Customs officers, whichever last occurs, the copy is destroyed.

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99ZO Treatment by the Chief Executive Medicare of detained substances and retained documents

(1) As soon as practicable after the Chief Executive Medicare takes possession of detained substances, they must, pending their return, reconsignment or disposal, be taken to a place of security specified by the Chief Executive Medicare.

(2) If the Chief Executive Medicare establishes, on examining detained substances, that they are not prescription drugs and not prohibited exports, the Chief Executive Medicare must, as soon as practicable:

(a) return the substances and any documents relating to the substances to the exporter; or

(b) reconsign the substances, and those related documents, for export;

as the case requires.

(3) If the Chief Executive Medicare establishes, on examining detained substances, that they are prohibited exports, the Chief Executive Medicare must forthwith pass the substances, and any documents relating to the substances, to the agency nominated in the guidelines issued under section 99ZS to deal with prohibited exports of that kind.

(4) If the Chief Executive Medicare establishes, on examining detained substances, that they are prescription drugs but not prohibited exports, the Chief Executive Medicare must:

(a) notify the exporter, in writing, to that effect; and

(b) invite the exporter to apply in writing to the Chief Executive Medicare, within 60 days after the notification, for the return of the substances on the basis that paragraph 99ZI(1)(b) or (c) or (2)(b) or (c) applies in relation to them.

(5) If the exporter does not make an application for their return within that period, then, at the end of that period and subject to subsection (6):

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(a) the Chief Executive Medicare is taken to have seized the substances; and

(b) the substances are taken to have been condemned as forfeited to the Commonwealth.

(6) If, before the day when substances would be taken to have been condemned as forfeited to the Commonwealth under subsection (5), proceedings for an offence involving those substances have been commenced, the substances are not to be taken to have been so condemned.

(7) If:

(a) the Chief Executive Medicare establishes, on examining detained substances, that they are prescription drugs but not prohibited exports; and

(b) within 60 days after notification to that effect was given to the exporter, an application is made for the return of the substances;

the Chief Executive Medicare must consider the application and, not later than 120 days after the notification was so given:

(c) if the Chief Executive Medicare decides that he or she is satisfied that paragraph 99ZI(1)(b) or (c) or (2)(b) or (c) applies to the substances—must return the substances to the exporter or reconsign them for export; and

(d) if the Chief Executive Medicare decides that he or she is not so satisfied—must seize the substances as forfeited to the Commonwealth.

(8) Despite the fact that substances are seized under subsection (7) as forfeited to the Commonwealth, the Chief Executive Medicare must, subject to subsection (9) and to any other law of the Commonwealth requiring their retention, destruction or disposal, return the substances to the exporter or reconsign them for export unless:

(a) not later than 60 days after the seizure, proceedings are commenced in a magistrates court for the condemnation of the substances as forfeited goods; and

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(b) on completion of the proceedings, that court makes an order that the substances are condemned as forfeited to the Commonwealth.

(9) A court must not make an order for condemnation of substances under subsection (8) if proceedings for an offence involving the substances have been commenced.

(10) In any proceeding for the condemnation of substances as forfeited to the Commonwealth, a certificate by the Chief Executive Medicare to the effect that the substances are prescription drugs within the meaning of this Division is prima facie evidence of that matter.

99ZP Right of compensation in certain circumstances for substances destroyed

(1) Despite the destruction of drug like substances that are taken to be condemned as forfeited to the Commonwealth under subsection 99ZO(5) because no application for their return was made, a person may apply to a court of competent jurisdiction under this section for compensation in respect of those substances.

(2) A right to compensation exists if:
(a) the substances are not prohibited exports; and
(b) the substances were not used or otherwise involved in the commission of an offence; and
(c) the person establishes, to the satisfaction of the court:
(i) that he or she would have had an entitlement to the return of the substances; and
(ii) that there were circumstances providing a reasonable cause for the failure to apply for that return within 60 days after the notice was given to the exporter.

(3) If a right to compensation exists under subsection (2), the court must order the payment by the Commonwealth to the person of an amount equal to the market value of the substances at the time of their destruction.

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99ZQ Disposal of forfeited substances

(1) If drug like substances:

(a) are taken to have been seized and condemned as forfeited to the Commonwealth under subsection 99ZO(5); or

(b) are actually seized under subsection 99ZO(7) and condemned as forfeited to the Commonwealth under subsection 99ZO(8);

the title to the substances vests in the Commonwealth to the exclusion of all other interests and cannot be called into question.

(2) Substances to which subsection (1) applies must be destroyed in accordance with the guidelines issued under section 99ZS.

99ZR Liability for acts done in good faith

(1) Subject to subsection (2), neither the Commonwealth, the Chief Executive Medicare nor any person performing duty as a Customs officer or as a Departmental employee (within the meaning of the *Human Services (Medicare) Act 1973*) is liable for any act done in good faith by such a Customs officer, by the Chief Executive Medicare, or by such an employee in the performance of functions or duties, or the exercise of powers, under this Division.

(2) If drug like substances that the Chief Executive Medicare would, but for the operation of this subsection, be obliged under subsection 99ZO(2) or (7) to return or reconsign:

(a) have ceased to be usable because of effluxion of time or otherwise; or

(b) have been lost;

the Chief Executive Medicare is not required to return or reconsign the substances but, if the exporter seeks compensation under this subsection, must pay the exporter such amount as is agreed between the exporter and the Chief Executive Medicare, or, failing agreement, as is determined by a court of competent jurisdiction, to cover the cost to the exporter:

(c) of replacing the substances; and

(d) if the substances would, but for their detention, have been carried or sent by the exporter to a place outside Australia

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and the exporter continues to require that the substances are sent to that place—of sending the substances to that place.

99ZS Guidelines for detention of, dealing with, and disposal of, substances

(1) The Comptroller-General of Customs may, by legislative instrument, issue guidelines for the performance of functions and duties, and for the exercise of powers, by Customs officers, in relation to matters arising under this Division including, in particular, matters relating to:

(a) the examination and inspection of items of baggage, and articles consigned for export, in the circumstances, and for the purposes, set out in subsection 99ZL(1); and

(b) the detention of some or all of the drug like substances found in the exercise of those powers of examination and inspection; and

(c) the transfer of detained drug like substances to the Chief Executive Medicare; and

(d) copying, retaining, transferring and otherwise dealing with, documents (including Customs declarations) provided in respect of drug like substances or in respect of items of baggage, or articles consigned for export, that are found to contain such substances.

(2) The Chief Executive Medicare may, by legislative instrument, issue guidelines for the performance of functions and duties, and for the exercise of powers, by the Chief Executive Medicare, or by Departmental employees (within the meaning of the *Human Services (Medicare) Act 1973*), in relation to matters arising under this Division including, in particular, matters relating to:

(a) dealing with drug like substances transferred to the Chief Executive Medicare by Customs officers; and

(b) dealing with claims for the return of such substances; and

(c) if it is required to dispose of such substances—the manner of their disposal; and

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(d) if such substances are found on examination to be prohibited exports—the transfer of those substances, and any documents relating to them, to the agency nominated in the guidelines to deal with prohibited exports of that kind.

(3) At any time, the Comptroller-General of Customs or the Chief Executive Medicare may, by legislative instrument, issue further guidelines that vary or revoke the existing guidelines.

(4) Guidelines take effect from:

(a) the first day they are no longer liable to be disallowed, or to be taken to have been disallowed, under section 42 of the *Legislation Act 2003*; or

(b) after that day, if the guidelines so provide.

99ZT Forfeiture of substances detained under section 99ZJ or 99ZK

All drug like substances that are transferred to the Chief Executive Medicare under section 99ZJ or 99ZK following their detention are forfeited to the Commonwealth unless:

(a) the substances are not prescription drugs; or

(b) the substances are prescription drugs and the exporter establishes:

(i) that no Commonwealth benefit has been paid or is payable; or

(ii) that the substances are for the personal use of the exporter, of a person accompanying the exporter or of a person covered by paragraph 86A(2)(a), (b) or (c).

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Division 5—General

100 Special arrangements

(1) The Minister may, by legislative instrument, make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

(a) who are living in isolated areas; or

(b) who are receiving treatment in circumstances in which pharmaceutical benefits (other than those to which subsection (1A) applies) are inadequate for that treatment; or

(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

(1A) This subsection applies to:

(a) pharmaceutical benefits to which subsection 85AA(1) or (2) applies; and

(b) pharmaceutical benefits supplied in the circumstances referred to in subsection 85AA(3).

(2) The Minister may, by legislative instrument, vary or revoke a special arrangement made under subsection (1).

(3) This Part, and regulations or other instruments made for the purposes of this Part, have effect subject to a special arrangement made under subsection (1).

Note: For example, for a drug declared under subsection 85(2), it does not matter if a special arrangement for its supply is inconsistent with a determination made under subsection 85(3) or section 85A for the drug.

100A Establishment and membership of the Pharmaceutical Benefits Advisory Committee

(1) There is to be a Committee called the Pharmaceutical Benefits Advisory Committee.

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(2) The Committee is to consist of the Chairperson and at least 11, but not more than 20, other members.

Note: One of the members of the Committee (other than the Chairperson) may be appointed as the Deputy Chairperson of the Committee: see subsection 100B(1D).

(3) Members forming at least 2/3 of the total membership of the Committee are to be selected from the following:

(aa) industry;

(a) consumers;

(b) health economists;

(c) practising community pharmacists;

(d) general practitioners;

(e) clinical pharmacologists;

(f) specialists;

with at least one member selected from each of the interests or professions mentioned in paragraphs (a) to (f).

(4) The remaining members (if any) of the Committee are to be persons whom the Minister is satisfied have qualifications or experience:

(a) in a field relevant to the functions of the Committee; and

(b) that would enable them to contribute meaningfully to the deliberations of the Committee.

(5) The Chairperson is a member of the Committee.

100B Appointment etc. of members of the Pharmaceutical Benefits Advisory Committee

(1) The members of the Pharmaceutical Benefits Advisory Committee are to be appointed by the Minister by written instrument.

(1AA) A person appointed under subsection 100A(3) in respect of paragraph 100A(3)(aa) must be appointed from nominations made by the following:

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(a) industry organisations prescribed by the regulations for the purposes of this paragraph;
(b) industry organisations that the Minister invites to make nominations for the appointment.

(1AB) A person appointed under subsection 100A(3) in respect of paragraph 100A(3)(a) must be appointed from nominations made by the following:
(a) consumer organisations prescribed by the regulations for the purposes of this paragraph;
(b) individuals or consumer organisations that the Minister invites to make nominations for the appointment.

(1A) A person appointed under subsection 100A(3) must be appointed from nominations made by the following bodies:
(b) in respect of paragraph 100A(3)(b)—professional associations of health economists;
(c) in respect of paragraph 100A(3)(c)—professional associations of pharmacists;
(d) in respect of paragraph 100A(3)(d)—professional associations of medical practitioners;
(e) in respect of paragraph 100A(3)(e)—professional associations of clinical pharmacologists;
(f) in respect of paragraph 100A(3)(f)—professional associations of specialists;
prescribed by the regulations for the purposes of this subsection.

(1B) The regulations may prescribe matters relating to nominations, including (but not limited to) the number of nominations to be considered by the Minister before making an appointment.

(1C) The Minister must appoint one of the members of the Committee as the Chairperson of the Committee.

(1D) The Minister may appoint one of the members of the Committee (other than the Chairperson) as the Deputy Chairperson of the Committee.

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(1E) The Chairperson and the Deputy Chairperson (if any) are to be appointed on a full-time or part-time basis.

(1F) The other members of the Committee are to be appointed on a part-time basis.

(2) A member of the Committee is eligible for reappointment.

(3) The performance of the functions and the exercise of the powers of the Committee are not affected merely because the number of members of the Committee falls below 12 for a period of not more than 6 months.

(4) The names and qualifications of the members of the Committee must be published in the *Gazette.*

100C Termination of appointment

A member of the Pharmaceutical Benefits Advisory Committee holds office during the Minister's pleasure.

100D Remuneration

(1) A member of the Pharmaceutical Benefits Advisory Committee is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed.

(2) A member is to be paid the allowances that are prescribed.

(3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

101 Functions of Pharmaceutical Benefits Advisory Committee

Functions relating to drugs and medicinal preparations

(3) The Pharmaceutical Benefits Advisory Committee shall make recommendations to the Minister from time to time as to the drugs

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and medicinal preparations which it considers should be made available as pharmaceutical benefits under this Part and shall advise the Minister upon any other matter concerning the operation of this Part referred to it by the Minister.

(3AA) The Pharmaceutical Benefits Advisory Committee must make recommendations to the Minister from time to time about what should be specified in a determination under subsection 84AAA(2).

(3AB) Subsection (3AA) does not limit subsection (3).

(3A) For the purpose of deciding whether to recommend to the Minister that a drug or medicinal preparation, or a class of drugs and medicinal preparations, be made available as pharmaceutical benefits under this Part, the Committee shall give consideration to the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations.

(3B) Without limiting the generality of subsection (3A), where therapy involving the use of a particular drug or medicinal preparation, or a class of drugs and medicinal preparations, is substantially more costly than an alternative therapy or alternative therapies, whether or not involving the use of other drugs or preparations, the Committee:

(a) shall not recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits under this Part unless the Committee is satisfied that the first-mentioned therapy, for some patients, provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies; and

(b) if the Committee does recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits under this Part, the Committee shall include in its recommendation a statement that the Committee is satisfied as mentioned in paragraph (a).

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(3BA) If the Committee is of the opinion that a drug or medicinal preparation should be made available as a pharmaceutical benefit under this Part, the Committee must, in its recommendation under subsection (3), specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis.

(3C) Where the Committee is of the opinion that a drug or medicinal preparation, or a class of drugs and medicinal preparations, should be made available as pharmaceutical benefits under this Part, but only in certain circumstances, the Committee shall, in its recommendation under subsection (3), specify those circumstances.

Functions relating to declarations under subsection 85(2)

(4) A drug or medicinal preparation shall not be declared, pursuant to paragraph 85(2)(a), to be a drug or medicinal preparation in relation to which this Part applies unless:

(a) the drug or medicinal preparation was, immediately before the commencement of this subsection, a pharmaceutical benefit; or

(b) the Committee has recommended to the Minister that it be so declared.

(4A) A class of drugs or medicinal preparations, or of drugs and medicinal preparations, shall not be declared, pursuant to paragraph 85(2)(a), to be a class of drugs or medicinal preparations, or of drugs and medicinal preparations, in relation to which this Part applies unless:

(a) each member of that class was, immediately before the commencement of this subsection, a pharmaceutical benefit; or

(b) the Committee has recommended to the Minister that the class be so declared.

(4AAA) The Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation.

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(4AAB) If:

(a) under subsection (4AAA), the Minister proposes to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation; and

(b) on and after the day the revocation or variation comes into force, the drug or medicinal preparation would cease to be a listed drug;

then, before making the revocation or variation, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

(4AAC) An advice under subsection (4AAB) must be laid before each House of the Parliament with the declaration under subsection (4AAA) to which the advice relates.

Functions relating to determinations under section 88

(4AACAA) The Pharmaceutical Benefits Advisory Committee may give advice to the Minister as to which PBS prescribers should be authorised to write prescriptions for the supply of a pharmaceutical benefit.

Functions relating to declarations under subsection 85(2AA)

(4AACA) The Pharmaceutical Benefits Advisory Committee must make recommendations to the Minister from time to time as to the drugs and medicinal preparations which it considers should only be supplied under one or more of the prescriber bag provisions.

(4AACB) The Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2AA) in relation to a drug or medicinal preparation.

(4AACC) If:

(a) under subsection (4AACB), the Minister proposes to revoke or vary a declaration under subsection 85(2AA) declaring that a drug or medicinal preparation (the ***drug***) can only be supplied under one or more of the prescriber bag provisions; and

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(b) on and after the day the revocation or variation comes into force, the drug could be supplied under this Part otherwise than under one or more of the prescriber bag provisions;

then the Minister can only make the revocation or variation if:

(c) the Minister also revokes or varies the declaration under subsection 85(2), in accordance with subsections (4AAA), (4AAB) and (4AAC) of this section, so that the drug ceases to be a listed drug on and after the day the revocation or variation of the subsection 85(2) declaration comes into force; or

(d) the Pharmaceutical Benefits Advisory Committee recommends against the Minister taking the action in paragraph (c).

Functions relating to determinations under subsection 85(6A)

(4AACD) The Pharmaceutical Benefits Advisory Committee may give advice to the Minister in relation to whether or not the Minister should determine that a brand of a pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items.

Functions relating to declarations under subsection 85(2A)

(4AAD) The Pharmaceutical Benefits Advisory Committee must make recommendations to the Minister from time to time as to the drugs and medicinal preparations which it considers should be made available only under special arrangements under section 100.

(4AAE) The Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2A) in relation to a drug or medicinal preparation.

(4AAF) If:

(a) under subsection (4AAE), the Minister proposes to revoke or vary a declaration under subsection 85(2A) in relation to a drug or medicinal preparation (the ***drug***); and

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(b) on and after the day the revocation or variation comes into force, the drug could be supplied under this Part otherwise than under special arrangements under section 100;

then the Minister can only make the revocation or variation if:

(c) the Minister also revokes or varies the declaration under subsection 85(2), in accordance with subsections (4AAA), (4AAB) and (4AAC) of this section, so that the drug ceases to be a listed drug on and after the day the revocation or variation of the subsection 85(2) declaration comes into force; or

(d) the Pharmaceutical Benefits Advisory Committee recommends against the Minister taking the action in paragraph (c).

Function relating to Minister's determination of therapeutic groups

(4AA) If the Committee is of the opinion that the Minister should, or should not, determine a therapeutic group, the Committee must advise the Minister accordingly.

Function relating to Minister's determination about exempt items

(4AB) If the Committee is of the opinion that the following circumstances exist in relation to a pharmaceutical item:

(a) the listed drug in the pharmaceutical item represents suitable therapy for a particular patient population;

(b) the pharmaceutical item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item;

(c) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item;

the Committee must advise the Minister that those circumstances exist in relation to the pharmaceutical item.

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Function relating to Minister's decisions about prices of combination items

(4AC) If the Committee is satisfied that therapy involving a combination item provides, for some patients:

(a) a significant improvement in patient compliance with the therapy; or

(b) a significant improvement in efficacy or reduction in toxicity;

over alternative therapies, then the Committee must advise the Minister accordingly.

Functions relating to determinations that brands are not new brands

(4AD) The Pharmaceutical Benefits Advisory Committee may give advice to the Minister in relation to whether the Minister should determine that a brand of a pharmaceutical item is not a new brand for the purposes of section 99ACB or 99ACD.

Functions relating to vaccines

(4B) The Pharmaceutical Benefits Advisory Committee must:

(a) make recommendations to the Minister from time to time about the vaccines it considers should be designated vaccines (see section 9B); and

(b) advise the Minister about any other matter concerning the operation of section 9B referred to it by the Minister.

(4C) For the purpose of deciding whether to recommend to the Minister that a vaccine be a designated vaccine, the Committee must give consideration to the effectiveness and cost of immunisation involving the use of the vaccine, including by comparing the effectiveness and cost of immunisation involving the use of the vaccine with the effectiveness and cost of alternative options, whether or not involving the use of other vaccines.

(4D) If immunisation involving the use of a particular vaccine (the ***first vaccine***) is substantially more costly than an alternative vaccine:

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(a) the Committee must not recommend to the Minister that the first vaccine be a designated vaccine unless the Committee is satisfied that the first vaccine, for some individuals, provides a significant improvement in efficacy or reduction of toxicity over the alternative vaccine; and

(b) if the Committee recommends to the Minister that the first vaccine be a designated vaccine—the Committee must include in its recommendation a statement that the Committee is satisfied as mentioned in paragraph (a).

(4E) Subsection (4D) does not limit subsection (4C).

(4F) If the Committee is of the opinion that a vaccine should be a designated vaccine, but should only be provided under subsection 9B(1) in certain circumstances, the Committee must, in its recommendation under subsection (4B), specify those circumstances.

Procedure

(5) The regulations may make provision for and in relation to the procedure of the Committee.

101A Sub-committees of the Pharmaceutical Benefits Advisory Committee

(1) The Pharmaceutical Benefits Advisory Committee:

(a) may establish such sub-committees as it thinks fit to assist it in performing its functions; and

(b) shall, if the Minister so requires in writing, establish a sub-committee to assist the Committee in advising the Minister on a particular matter referred to it by the Minister under subsection 101(3) or (4B).

(2) A sub-committee shall consist of the following persons (whether or not members of the Committee):

(a) persons appointed by the Committee as members of the sub-committee;

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(b) persons nominated by the Minister as members of the sub-committee.

(3) A person shall not be appointed by the Committee, or nominated by the Minister, as a member of a sub-committee unless the person has special qualifications or experience in relation to the matter referred to the sub-committee.

(4) For the purposes of section 140, a sub-committee shall be taken to be a committee established under this Act.

101B Use of computer programs to take administrative action

Computer programs for administrative action by Minister

(1) The Minister may arrange for the use, under the Secretary's control, of computer programs for any purposes for which the Minister may or must take administrative action under this Part or a legislative instrument made for the purposes of this Part.

Computer programs for administrative action by Secretary

(2) The Secretary may arrange for the use, under the Secretary's control, of computer programs for any purposes for which the Secretary may or must take administrative action under this Part or a legislative instrument made for the purposes of this Part.

Computer programs for administrative action by Chief Executive Medicare

(3) The Chief Executive Medicare may arrange for the use, under the Chief Executive Medicare's control, of computer programs for any purposes for which the Chief Executive Medicare may or must take administrative action under this Part or a legislative instrument made for the purposes of this Part.

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Responsible person for arrangement taken to have taken administrative action

(4) For the purposes of this Part or a legislative instrument made for the purposes of this Part, if administrative action is taken by the operation of a computer program under an arrangement under subsection (1), (2) or (3), the responsible person for the arrangement is taken to have taken the administrative action.

Substituted decisions

(5) The responsible person may, under a provision of this Part or a legislative instrument made for the purposes of this Part, make a decision in substitution for a decision he or she is taken to have made under subsection (4), if the responsible person is satisfied that the decision made by the operation of the computer program is incorrect.

Note: For review of a decision made in substitution, see Part VIIA.

Definitions

(6) In this section:

administrative action: each of the following constitutes taking ***administrative action*** for the purposes of this section:

(a) making a decision;
(b) exercising any power or complying with any obligation;
(c) doing anything else related to making a decision or exercising a power or complying with an obligation.

responsible person means:

(a) for an arrangement under subsection (1)—the Minister; or
(b) for an arrangement under subsection (2)—the Secretary; or
(c) for an arrangement under subsection (3)—the Chief Executive Medicare.

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102 Testing of drugs

The Secretary may make such arrangements as the Secretary considers necessary for the testing or analysis of pharmaceutical benefits or of drugs which may be used as pharmaceutical benefits.

103 Offences

(1) An approved pharmacist shall not give, promise or offer a gift, rebate or reward as an inducement to a person to present, or in consideration of a person's presenting, a prescription for the supply of a pharmaceutical benefit.

Penalty: 10 penalty units.

(2) Except as prescribed, a pharmacist to whom a prescription is presented shall not:

(a) supply, in purported pursuance of this Part, anything other than the pharmaceutical benefit that is directed to be supplied in the prescription; or

(b) in exchange for the prescription make a payment in money or give any other consideration to the person presenting the prescription.

Penalty: Imprisonment for 12 months or 20 penalty units, or both.

(2A) Paragraph (2)(a) does not prohibit a pharmacist from supplying, instead of the pharmaceutical benefit that is directed to be supplied in a prescription (the ***specified benefit***), another pharmaceutical benefit (the ***substitute benefit***) if:

(a) the person who prescribed the specified benefit did not indicate on the prescription that only that benefit was to be supplied; and

(b) the Schedule of Pharmaceutical Benefits issued by the Department states that the specified benefit and the substitute benefit are equivalent; and

(c) the substitute benefit is a listed brand of a pharmaceutical item; and

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(d) the supply of the substitute benefit is not prohibited by a law of the State or Territory in which the substitute benefit is supplied.

(3) An approved pharmacist, approved medical practitioner or approved hospital authority shall not permit a person other than a medical practitioner or pharmacist to dispense a pharmaceutical benefit except under the direct supervision of a medical practitioner or pharmacist.

Penalty: Imprisonment for 12 months or 20 penalty units, or both.

(4) A person for whom a prescription for the supply of a pharmaceutical benefit is written or to whom a pharmaceutical benefit is supplied shall not use, dispose of or otherwise deal with the pharmaceutical benefit supplied in a way other than that for which the prescription was written or the pharmaceutical benefit supplied.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(4AA) A person must not have in his or her possession, or consign for export, a quantity of a pharmaceutical benefit or pharmaceutical item that exceeds the designated quantity of that pharmaceutical benefit or pharmaceutical item unless:

(a) that first-mentioned quantity was supplied to the person (whether on prescription or otherwise) by an approved supplier for the medical, dental, optometrical or midwifery treatment, or the nurse practitioner treatment by an authorised nurse practitioner, of the person or of a person covered by paragraph 86A(2)(a), (b) or (c); or

(b) the person has some other reasonable excuse for possessing or consigning for export that first-mentioned quantity.

Penalty: Imprisonment for 2 years.

(4AB) In a prosecution for an offence against subsection (4AA), the defendant bears the evidential burden of proving the exception set out in paragraph (a) or (b) of that subsection.

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(4AC) For the purposes of subsection (4AA), the designated quantity of a pharmaceutical benefit or pharmaceutical item is the quantity of that pharmaceutical benefit or pharmaceutical item worked out using the formula:

$$MQ \times \left(RA + 1 \right) \times 2$$

where:

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

RA is the number (if any) that is determined by the Minister, under paragraph 85A(2)(b), to be the maximum number of occasions on which the supply of the pharmaceutical benefit, or a pharmaceutical benefit that has the pharmaceutical item, may, in one prescription, be directed to be repeated.

(4AD) In proceedings for an offence against subsection (4AA), a certificate by the Chief Executive Medicare to the effect that:

(a) a substance specified in the certificate is a particular pharmaceutical benefit or pharmaceutical item; and

(b) the quantity of the substance to which the offence relates exceeds the designated quantity in relation to a pharmaceutical benefit or pharmaceutical item of that kind;

is prima facie evidence of those matters.

(4AE) A person is not liable to be convicted of an offence against subsection (4) and subsection (4AA) in respect of the same action.

(4A) A person shall not, in purported compliance with the requirements of regulations made by virtue of subsection 84AA(1) or (1A), include, or cause or permit to be included, on a prescription written by a PBS prescriber any information connected with the status of

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the person to whom the prescription relates that is, to his or her knowledge, false or misleading in a material particular.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(4B) A person shall not, in purported compliance with the requirements of regulations made under subsection 84AA(2) or (3), in so far as those regulations relate to a prescription communicated to an approved pharmacist, communicate to that pharmacist any information connected with the status of the person to whom the prescription relates that is, to his or her knowledge, false or misleading in a material particular.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(5) A person shall not:

(b) obtain a pharmaceutical benefit to which the person is not entitled;

(ba) obtain the issue of a concession card or entitlement card to which the person is not entitled;

(d) not being a PBS prescriber, write a prescription for the purposes of this Part;

(f) supply as a pharmaceutical benefit a substance that does not conform to the standards of composition or purity prescribed in the regulations or that has as an ingredient a substance that does not conform to those standards;

(g) by means of impersonation, a false or misleading statement or a fraudulent device, obtain, or by any of those means aid or abet another person to obtain, a pharmaceutical benefit or a payment in respect of the supply of a pharmaceutical benefit; or

(h) contravene or fail to comply with a provision of this Part which is applicable to the person.

Penalty for contravention of this subsection: Imprisonment for 2 years or 50 penalty units, or both.

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104A Pharmacists to furnish statement of stocks

(1) The Secretary may require an approved pharmacist to furnish to the Secretary, within a time specified by the Secretary and in accordance with a form supplied by the Secretary and with any directions contained in the form, a statement, signed by or on behalf of the approved pharmacist, setting out particulars of stocks of drugs or medicinal preparations in the approved pharmacist's possession or under the approved pharmacist's control immediately before the date on which the statement is signed, being drugs or medicinal preparations that are, or are capable of being used as ingredients in pharmaceutical benefits.

(2) An approved pharmacist shall not:
  (a) refuse or fail to comply with a requirement under this section; or
  (b) in a statement under this section, furnish information that is false or misleading in a material particular.

104B Transitional—price increases on 1 October 2022

When this section applies

(1) Subject to subsections (2) and (3), this section applies to a brand of a pharmaceutical item if, immediately before the start of 1 October 2022:
  (a) the drug in the brand of the pharmaceutical item was on F2; and
  (b) the brand of the pharmaceutical item had an approved ex-manufacturer price that is less than $3.50.

(2) The Minister may, by writing, determine that this section does not apply in relation to all brands of a specified pharmaceutical item.

(3) This section does not apply to a brand of a pharmaceutical item if:
  (a) the drug in the pharmaceutical item is included in Schedule 2 to the current Poisons Standard (within the meaning of the

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Therapeutic Goods Act 1989 and as in force from time to time) by reference to a quantity or amount of the drug; and

(b) that quantity or amount of the drug is equal to or greater than the total quantity or amount of the drug contained in the quantity or number of units of the brand of the pharmaceutical item in any pack quantity of the brand of the pharmaceutical item.

Price increases

(4) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of $2 or less, the approved ex-manufacturer price is taken to be increased to $2.50 at the start of 1 October 2022.

(5) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of more than $2 but not more than $3, the approved ex-manufacturer price is taken to be increased by 50 cents at the start of 1 October 2022.

(6) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of more than $3 but less than $3.50, the approved ex-manufacturer price is taken to be increased to $3.50 at the start of 1 October 2022.

Apportioning if pricing quantity changes

(7) If the pricing quantity of the brand of the pharmaceutical item on the day before 1 October 2022 is more than the pricing quantity of the brand of the pharmaceutical item on 1 October 2022, then the approved ex-manufacturer price of the brand of the pharmaceutical item on 1 October 2022 is taken to be the amount worked out using the following formula:

$$\frac{\text{AEMP1}}{\text{PQ1}} \times \text{PQ2}$$

where:

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AEMP1 means the amount the approved ex-manufacturer price of the brand of the pharmaceutical item would be on 1 October 2022 if the pricing quantity had not changed.

PQ1 means the pricing quantity of the brand of the pharmaceutical item on the day before 1 October 2022.

PQ2 means the pricing quantity of the brand of the pharmaceutical item on 1 October 2022.

Section does not limit Minister's powers

(8) This section does not limit the Minister's powers, on or after 1 October 2022, to make:

(a) price agreements; or

(b) determinations under section 85B;

in relation to the brand of the pharmaceutical item.

105 Regulations

The regulations may:

(a) prescribe the terms and conditions subject to which pharmaceutical benefits shall be supplied;

(b) make provision for or in relation to the writing of prescriptions; and

(c) prescribe the standards of composition or purity of drugs, medicines or substances which may be supplied as pharmaceutical benefits or may be ingredients of pharmaceutical benefits.

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Part VIIA—Reviews by Administrative Review Tribunal

105AA Interpretation

In this Part:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024*.

Tribunal means the Administrative Review Tribunal.

105AB Application for review by Tribunal

(2) An application may be made to the Tribunal for review of a decision of the Secretary under paragraph 84AAD(2)(a) or (3)(a).

(3) An application may be made to the Tribunal for review of a decision of the Secretary under paragraph 84AAH(2)(a) or (3)(a) or 84AAL(2)(a) or (3)(a).

(6A) An application may be made to the Tribunal for review of a decision of the Secretary:

(a) under subsection 84DA(1) refusing to issue a concession card to a person; or

(b) under subsection 84E(1) refusing to issue an entitlement card to a person.

(6B) An application may be made to the Tribunal for review of a decision of the Secretary to give a notice under section 84K.

(7) An application may be made to the Tribunal for review of a decision of the Secretary under section 90 rejecting an application under that section.

Note: In certain circumstances, the Minister may substitute for a decision of the Secretary rejecting an application for approval under section 90

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(including a decision that has been affirmed by the Administrative Review Tribunal), a decision granting the approval (see section 90A).

(7AA) An application may be made to the Tribunal for review of a decision of the Secretary:

(a) under subsection 91(1) granting or refusing an application under section 91; or

(b) under subsection 91(5) treating an application under section 91 as having been withdrawn; or

(c) under subsection 91(12) revoking a permission granted under section 91.

(7AB) An application may be made to the Tribunal for review of a decision of the Secretary:

(a) under subsection 91A(1) refusing an application under section 91A; or

(b) under subsection 91A(5) treating an application under section 91A as having been withdrawn; or

(c) under subsection 91A(9) revoking a permission granted under section 91A.

(7AC) An application may be made to the Tribunal for review of a decision of the Secretary:

(a) under subsection 91B(1), (2) or (3) refusing to grant a permission; or

(b) under subsection 91B(6) treating an application under section 91B as having been withdrawn; or

(c) under subsection 91B(12) revoking a permission granted under section 91B.

(7A) An application may be made to the Tribunal for review of a decision of the Secretary under section 92.

(7B) An application may be made to the Tribunal for review of a decision of the Minister under section 94.

(7C) An application may be made to the Tribunal for review of a decision of the Secretary under subsection 94B(2).

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(8) An application may be made to the Tribunal for review of a decision of the Minister under section 95 suspending, further suspending or revoking the approval of a pharmacist.

(8A) An application may be made to the Tribunal for a review of a decision of the Secretary:

(a) under paragraph 98(2A)(c) to refuse to cancel an approval; or

(b) under subsection 98(3), (3AB) or (3A) to cancel an approval.

(8B) An application may be made to the Tribunal for a review of a decision of the Minister under subsection 98AA(3) to revoke an approval.

(12) An application may be made to the Tribunal for the review of a decision of the Secretary under subsection 99AAA(6) not to approve a claim for payment made under subsection 99AAA(2).

(13) An application may be made to the Tribunal for the review of a decision of the Secretary under subsection 99AAC(4).

105AC Statements to accompany notification of decisions

(1) Where the Minister, a delegate of the Minister, the Secretary or a delegate of the Secretary makes a decision of the kind referred to in section 105AB and gives, or causes to be given, to the person or persons whose interests are affected by the decision notification in writing of the decision, that notice shall include a statement to the effect that, subject to the *Administrative Review Tribunal Act 2024*, application may be made to the Tribunal for review of the decision to which the notice relates by or on behalf of the person or persons whose interests are affected by the decision.

(2) Any failure to comply with the requirements of subsection (1) in relation to a decision does not affect the validity of the decision.

105AD Application for review by Tribunal of decisions of the Australian Community Pharmacy Authority

(1) In this section:

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Authority means the Australian Community Pharmacy Authority.

reviewable recommendation means a recommendation of the Authority referred to in paragraph (2)(a) or (aa).

(2) An application may be made to the Tribunal for review of the following recommendations of the Authority:

(a) a recommendation made under subparagraph 99K(1)(b)(i) that an applicant under section 90 not be approved under that section in respect of particular premises;

(aa) a recommendation made under subparagraph 99K(1)(b)(ii) as to the conditions (if any) to which an approval under section 90 should be subject.

(3) If:

(a) a person (in this section called the ***applicant***) applies under section 90; and

(b) the Authority makes a reviewable recommendation in respect of that application;

the Chairperson of the Authority must, within 28 days after the Authority makes the recommendation, cause a notice to be given to the applicant containing the following material:

(c) the terms of the recommendation;

(d) a statement to the effect that, subject to the *Administrative Review Tribunal Act 2024*, application may be made to the Tribunal for review of that recommendation;

(e) a statement that the applicant may request a statement under section 268 of that Act.

(4) Failure to comply with subsection (3) does not affect the validity of the Authority's recommendation.

105AE Time limits

(1) This section applies if:

(a) section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist; and

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(b) the pharmacist makes a request under section 90B that the Minister exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision; and

(c) the Minister decides, or is taken to have decided, not to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.

(2) For the purpose of making an application to the Administrative Review Tribunal or a federal court in respect of the Secretary's decision, the Secretary's decision is taken to have been made on the day on which notice of the Minister's decision is given to the pharmacist under subsection 90B(6).

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Part VIII—Committees of Inquiry

Division 1—Preliminary

107 Interpretation

(1A) In this Part, ***approved pharmacist*** and ***PBS prescriber*** have the same respective meanings as in Part VII.

(2) For the purposes of this Part:

(a) the Australian Capital Territory and Norfolk Island shall be deemed to be part of the State of New South Wales; and

(b) the Northern Territory of Australia shall be deemed to be part of the State of South Australia.

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Division 3—Pharmaceutical Services Committees of Inquiry

113 Pharmaceutical Services Federal Committee of Inquiry

(1) The Minister may establish a committee, called the Pharmaceutical Services Federal Committee of Inquiry, which shall consist of the Secretary and 4 pharmacists appointed by the Minister.

(2) The Secretary may, from time to time, by writing signed by the Secretary, appoint an officer of the Department who is a medical practitioner or pharmacist to be a member of the Committee in his or her stead, and the person so appointed shall, until his or her appointment is revoked, be a member of the Committee.

114 Functions of Federal Committee

The Pharmaceutical Services Federal Committee of Inquiry shall inquire into and report to the Minister or the Secretary on any matter referred to the Committee by the Minister or the Secretary in respect of or arising out of the services or conduct of approved pharmacists in connection with the supply of pharmaceutical benefits under Part VII.

115 Pharmaceutical Services State Committees of Inquiry

(1) The Minister may establish in each State a committee, called the Pharmaceutical Services Committee of Inquiry for the State in which it is established, which shall consist of 4 pharmacists appointed by the Minister.

116 Functions of State Committee

A State Committee of Inquiry established under section 115 shall inquire into and report to the Minister or the Secretary on any matter referred to the Committee by the Minister or the Secretary in respect of or arising out of the services or conduct of approved

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pharmacists in connection with the supply in the State of pharmaceutical benefits under Part VII.

117 Reports not to relate to conduct of PBS prescribers

(1) Subject to subsection (2), nothing in the preceding provisions of this Division authorizes a Committee to report on the conduct of a PBS prescriber in relation to a matter upon which the Committee makes inquiry.

(2) Subsection (1) does not prevent a Committee from referring in a report to the conduct of a PBS prescriber where that reference is incidental to a report by the Committee on the conduct of an approved pharmacist.

(3) In this section, ***Committee*** means a Committee established under this Division.

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Division 4—Provisions applicable to Committees generally

118 Interpretation

In this Division, unless the contrary intention appears:

Chairperson, in relation to a Committee, includes a person elected to preside at a meeting of the Committee.

Committee means a Committee established under this Part.

119 Membership of Committees

(1) A member of a Committee appointed by the Minister shall hold office during the Minister's pleasure.

(2) A qualified person may be appointed to be a member of both a Federal Committee and a State Committee, and a person so appointed may hold both appointments at the same time.

119A Acting Member

If the Minister becomes aware that a member of a Committee will be unable to attend a meeting or meetings of the Committee, the Minister may appoint a qualified person to act in the stead of that member at the meeting or meetings from which the member will be absent, and the person so appointed shall, while so acting, be deemed to be a member of the Committee.

120 Chairperson

(1) A Committee shall elect one of its members to be Chairperson of the Committee.

(2) In the event of the absence of the Chairperson of a Committee from a meeting of the Committee, the members present shall elect one of their number to preside at the meeting during the absence of the Chairperson, and the member so elected shall have and may

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exercise and perform, during the absence of the Chairperson, all the powers and functions of the Chairperson.

120A Vacancies in Committees

The exercise or performance of the powers or functions of a Committee is not affected by reason only of there being a vacancy in the office of a member of the Committee.

121 Procedure of Committees

The regulations may make provision for and in relation to the procedure of Committees.

122 Evidence

A Committee is not bound by legal rules of evidence but may inform itself on a matter referred to it under this Part in such manner as it thinks fit.

123 Proceedings in private

The proceedings of a Committee shall be held in private.

124 Determination of questions at meetings

(1) All questions before a meeting of a Committee shall be decided by a majority of votes.

(2) The Chairperson of a Committee shall have a deliberative vote only.

(3) A member shall not have a vote on a question before a Committee unless the member has been present for the whole of the time for which the Committee received evidence on the matter concerning which the question arose.

(4) In the event of an equality of votes on a question before a meeting of a Committee, the question shall be deemed to be unresolved and

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the Chairperson may direct that the question be reconsidered at a time and place fixed by the Chairperson.

125 PBS prescriber or pharmacist affected by inquiry to be given notice

(1) Where a matter referred to a Committee concerns the conduct of a PBS prescriber or an approved pharmacist, as the case may be, the Chairperson of the Committee shall cause notice in writing of the matter so referred, and of the time and place at which the Committee intends to hold an inquiry into the matter, to be given to that PBS prescriber or an approved pharmacist at least 10 days before the date of the inquiry.

(2) For the purposes of ascertaining whether a matter referred to a Committee concerns the conduct of a PBS prescriber or an approved pharmacist, the Committee may, before causing notice to be given to any person, meet and examine any written evidence or allegation referred to the Committee by the Minister or the Secretary in relation to the matter.

(4) Subject to subsection (5), the Committee shall afford a PBS prescriber or an approved pharmacist to whom notice has been given in pursuance of subsection (1) an opportunity of examining witnesses, giving evidence and calling witnesses and of addressing the Committee.

(5) Where a PBS prescriber or an approved pharmacist to whom notice has been given in pursuance of subsection (1) fails to attend at the time and place specified in the notice, the Committee may, unless it is satisfied that the PBS prescriber or approved pharmacist is prevented by illness or other unavoidable cause from so attending, proceed to hold the inquiry in the absence of the PBS prescriber or approved pharmacist.

(6) For the purposes of this section, ***inquiry*** includes a reconsideration of a question by a Committee in pursuance of subsection 124(4) where that reconsideration involves the rehearing of evidence or the hearing of further evidence.

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(7) When a matter referred to a Federal Committee of Inquiry concerns a course of conduct of PBS prescribers or approved pharmacists generally or in a class of cases, the matter shall, for the purposes of this section, be deemed not to concern the conduct of a PBS prescriber or an approved pharmacist, as the case may be.

126 Summoning of witnesses

(1) The Chairperson of a Committee may cause a notice in writing signed by the Chairperson to be served on a person summoning the person to attend the Committee at a time and place specified in the summons and to give evidence and to produce books, documents and writings in the person's custody or control which the person is required by the summons to produce.

(3) A Committee may inspect books, documents or writings before it, and may retain them for such reasonable period as it thinks fit, and may make copies of such portions of them as are relevant to the inquiry.

127 Committee may examine upon oath or affirmation

(1) A Committee may examine on oath a person appearing as a witness before the Committee, whether the witness has been summoned or appears without being summoned, and for this purpose a member of the Committee may administer an oath to the witness.

(2) Where a witness conscientiously objects to take an oath, the witness may make an affirmation instead of taking an oath.

128 Failure to attend or produce documents

(1) A person served with a summons to attend a Committee shall not, after payment to the person of reasonable expenses fail to attend the Committee or to produce the books, documents or writings in the person's custody or control which the person is required by summons to produce.

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Penalty: Imprisonment for 6 months or 10 penalty units, or both.

(1A) Subsection (1) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (1A). See subsection 13.3(3) of the *Criminal Code*.

(2) Subsection (1) does not apply if the book, document or writing was not relevant to the matter that is the subject of the Committee's proceedings.

Note: The defendant bears an evidential burden in relation to the matter in subsection (2). See subsection 13.3(3) of the *Criminal Code*.

(3) An offence under subsection (1) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

129 Refusal to be sworn or give evidence

(1) A person appearing as a witness before a Committee shall not refuse to be sworn or to make an affirmation or to answer a question relevant to the proceedings put to the person by a member of the Committee.

Penalty: Imprisonment for 6 months or 10 penalty units, or both.

(2) A statement or disclosure made by a witness to a Committee is not admissible in evidence against the witness in civil or criminal proceedings in a court except in a prosecution for giving false testimony in the Committee's proceedings.

130 Protection of witnesses

A witness before a Committee has the same protection as a witness in a matter before the High Court.

131 Allowances to witnesses

A witness summoned to attend before a Committee shall be paid fees in accordance with the scales of fees payable in respect of

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attendance before the Supreme Court of the State or Territory in which the witness is required to attend or, in special circumstances, such fees as the Committee directs.

132 Protection of members

(1) An action or proceeding, civil or criminal, does not lie against a member of a Committee for or in respect of an act or thing done, or report made, in good faith by the member or the Committee in pursuance of the powers and duties conferred on the member or the Committee by this Part.

(2) An act or thing shall be deemed to have been done, or a report shall be deemed to have been made in good faith, if the member or Committee by whom the act or thing was done or the report was made was not actuated by ill will to the person affected or by any other improper motive.

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Part VIIIA—Data-matching

132A Definitions

In this Part:

authorised Commonwealth entity means a Commonwealth entity that is authorised under subsection 132B(2) to match information under subsection 132B(1) on the Chief Executive Medicare's behalf.

Commonwealth entity has the same meaning as in the *Public Governance, Performance and Accountability Act 2013*.

general treatment has the same meaning as in the *Private Health Insurance Act 2007*.

Health Practitioner Regulation National Law means:

(a) for a State or Territory other than Western Australia—the Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld), as it applies (with or without modification) as a law of the State or Territory; or

(b) for Western Australia—the *Health Practitioner Regulation National Law (WA) Act 2010* (WA), so far as that Act corresponds to the Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld).

inappropriate practice has the same meaning as in Part VAA of the *Health Insurance Act 1973*.

My Health Record information means health information (within in the meaning of the *My Health Records Act 2012*) disclosed by the System Operator (within the meaning of that Act) under section 70AA of that Act.

permitted purpose: see section 132AB.

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Note: The *Privacy Act 1988* contains provisions relevant to the use and disclosure of information under this Act.

personal information has the same meaning as in the *Privacy Act 1988*.

share by default service means a professional service specified in upload rules made for the purposes of subsection 19AD(1) of the *Health Insurance Act 1973* rendered by or on behalf of a person specified for the service in the upload rules for the purposes of that subsection.

132AB Meaning of *permitted purpose*

(1) For the purposes of this Part, each of the following is a ***permitted purpose*** for the matching of data other than data that includes My Health Record information:

(a) identifying whether a person may have, under a medicare program, claimed or been paid a benefit that exceeds the amount of the benefit that was payable to the person;

(b) recovering overpayments of benefits under a medicare program;

(c) detecting or investigating contraventions of a law of the Commonwealth relating to a medicare program;

(d) detecting or investigating whether a person may have engaged in inappropriate practice;

(e) analysing services, benefits, programs or facilities that are provided for under a medicare program, in connection with the purposes mentioned in paragraphs (a) to (d);

(f) educating healthcare providers about medicare program requirements.

(2) For the purposes of this Part, each of the following is a ***permitted purpose*** for the matching of data that includes My Health Record information:

(a) identifying whether a person may have, under a medicare program, claimed or been paid a benefit in relation to a share

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by default service that exceeds the amount of the benefit that was payable to the person;

(b) recovering overpayments of benefits under a medicare program in relation to share by default services;

(c) detecting or investigating contraventions of a law of the Commonwealth relating to share by default services;

(d) analysing services, benefits, programs or facilities that are provided for under a medicare program, in connection with the purposes mentioned in paragraphs (a) to (c);

(e) educating healthcare providers about requirements in relation to share by default services.

Note: The *Privacy Act 1988* contains provisions relevant to the use and disclosure of information under this Act.

132B Data-matching by the Chief Executive Medicare

(1) Subject to this Part, the Chief Executive Medicare may, for a permitted purpose, match any of the following information:

(a) information that is held or has been obtained by the Chief Executive Medicare for the purpose of a medicare program;

(b) therapeutic goods information (within the meaning of subsection 61(1) of the *Therapeutic Goods Act 1989*) that has been disclosed under subsection 132C(1) of this Act;

(c) information that has been disclosed to the Chief Executive Medicare under section 132D;

(d) information that has been provided to the Chief Executive Medicare in accordance with the Health Practitioner Regulation National Law for a State or Territory;

(e) information that has been provided to the Chief Executive Medicare in accordance with any of the following Acts:

(i) the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006*;

(ii) the *Military Rehabilitation and Compensation Act 2004*;

(iii) the *Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988*;

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(iv) the *Treatment Benefits (Special Access) Act 2019;*

(v) the *Veterans' Entitlements Act 1986*;

(ea) My Health Record information;

(f) any other information that may be lawfully provided to the Chief Executive Medicare (other than information that may only be obtained by the Chief Executive Medicare for the purpose of performing functions under the *My Health Records Act 2012*).

Note 1: For the purposes of paragraph (1)(a)—to avoid doubt, information that is held or has been obtained by the Chief Executive Medicare for the purpose of a medicare program includes information in a document that has been produced to the Chief Executive Medicare or to a Departmental employee (within the meaning of the *Human Services (Medicare) Act 1973*) in accordance with section 129AAD of the *Health Insurance Act 1973*.

Note 2: This subsection constitutes an authorisation for the purposes of the *Privacy Act 1988*.

Data-matching by authorised Commonwealth entity on Chief Executive Medicare's behalf

(2) Subject to this Part, the Chief Executive Medicare may, in writing, authorise a Commonwealth entity to match information under subsection (1) on the Chief Executive Medicare's behalf for a permitted purpose.

Note: This subsection constitutes an authorisation for the purposes of the *Privacy Act 1988*.

(3) An authorised Commonwealth entity:

(a) must comply with any other terms and conditions relating to the matching of the information that are determined, in writing, by the Chief Executive Medicare; and

(b) must, if requested to do so by the Chief Executive Medicare, disclose the results of the matching to the Chief Executive Medicare.

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Information must not be matched until Minister's principles have commenced

(4) Information must not be matched under subsection (1) by the Chief Executive Medicare or an authorised Commonwealth entity until after the principles made by the Minister under subsection 132F(1) have commenced.

132C Secretary may disclose therapeutic goods information to the Chief Executive Medicare

(1) The Secretary may disclose to the Chief Executive Medicare therapeutic goods information (within the meaning of subsection 61(1) of the *Therapeutic Goods Act 1989*) for the purpose of facilitating the matching of that information under subsection 132B(1).

Note: This subsection constitutes an authorisation for the purposes of the *Privacy Act 1988*.

(2) The Chief Executive Medicare may use information disclosed in accordance with subsection (1) for the purpose of facilitating the matching of that information under subsection 132B(1).

132D Private health insurer may disclose information about hospital or general treatment to the Chief Executive Medicare

(1) A private health insurer may disclose to the Chief Executive Medicare information relating to hospital treatment or general treatment provided to a person who is insured under an insurance policy of the insurer, for the purpose of facilitating the matching of that information under subsection 132B(1), if:

(a) the insurance policy was taken out after the commencement of this section; or

(b) the insurance policy provided that information of that kind may be disclosed if the disclosure is authorised under an Australian law; or

(c) the insurer had notified the person under subclause 5.1 of the Australian Privacy Principles in Schedule 1 to the *Privacy*

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Act 1988 that information of that kind may be disclosed if the disclosure is authorised under an Australian law.

Note: This subsection constitutes an authorisation for the purposes of the *Privacy Act 1988*.

(2) A private health insurer may disclose the information under subsection (1) on the private health insurer's own initiative, or on request by the Chief Executive Medicare.

(3) If information is disclosed to the Chief Executive Medicare in accordance with subsection (1), the disclosure is taken to be an authorised disclosure for the purposes of section 323-1 of the *Private Health Insurance Act 2007*.

132E Breach of provision of this Part is an interference with privacy

A breach of a provision of this Part in relation to an individual constitutes an act or practice involving interference with the privacy of the individual for the purposes of section 13 of the *Privacy Act 1988*.

Note: The act or practice may be the subject of a complaint under section 36 of the *Privacy Act 1988*.

132F Data-matching principles

(1) The Minister must, by legislative instrument, make principles in relation to the matching of information under subsection 132B(1) by:

(a) the Chief Executive Medicare; and

(b) an authorised Commonwealth entity.

(2) Without limiting subsection (1), the principles must:

(a) require the Chief Executive Medicare to establish and maintain a publicly available register of the kinds of information matched by the Chief Executive Medicare or an authorised Commonwealth entity under subsection 132B(1); and

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(b) require the Chief Executive Medicare to keep records of information matched by the Chief Executive Medicare under subsection 132B(1); and

(c) require an authorised Commonwealth entity to keep records of information matched by the Commonwealth entity under subsection 132B(1); and

(d) require the Chief Executive Medicare and an authorised Commonwealth entity to take reasonable steps to destroy personal information that has been matched under subsection 132B(1) if the information is no longer needed for any purpose for which the information was matched; and

(e) require the Chief Executive Medicare and an authorised Commonwealth entity to take reasonable steps to ensure that personal information that is matched under subsection 132B(1) is accurate, complete and up to date; and

(f) require the Chief Executive Medicare and an authorised Commonwealth entity not to match information for a permitted purpose under subsection 132B(1) unless the Chief Executive Medicare is satisfied that the matching is reasonably necessary for that purpose.

(3) In making principles under subsection (1), the Minister must take into account the guidelines (if any) on data-matching in Australian Government administration made by the Information Commissioner under paragraph 28(1)(a) of the *Privacy Act 1988*.

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Part VIIIB—COVID-19 vaccines and treatments

132G Provision of COVID-19 vaccines and treatments

(1) The Minister may provide or arrange for the provision of:
  (a) COVID-19 vaccines (including boosters); and
  (b) treatments for COVID-19; and
  (c) consumables related to the use of such vaccines and treatments.

(2) To avoid doubt:
  (a) subsection (1) covers payments for vaccines, treatments or consumables even if arrangements to purchase those vaccines, treatments or consumables were made before this Part commenced; and
  (b) this Part does not limit the provision of vaccines, treatments or consumables for COVID-19 or any other disease or ailment under another provision of this Act or any other law.

(3) This Part has no effect after 30 June 2022.

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Part IX—Miscellaneous

133 Effect of prosecution for offence

Effect of being charged

(1) Where a medical practitioner, other PBS prescriber or an approved pharmacist (a ***defendant***) is charged before a court with having committed an offence against this Act or the regulations or against another law of the Commonwealth, of a State, of an internal Territory, of Norfolk Island, of the Territory of Cocos (Keeling) Islands or of the Territory of Christmas Island, being an offence that arises out of or is connected with the supply of pharmaceutical benefits under Part VII, the Secretary may, if the Secretary thinks fit, by notice in writing:

(a) in the case of a defendant who is a medical practitioner—suspend:

(i) the authority to write a prescription for the supply of pharmaceutical benefits conferred upon that medical practitioner by section 88;

(ii) any approval of that medical practitioner under section 92; or

(iii) the authority to supply prescribed pharmaceutical benefits conferred upon that medical practitioner by section 93;

(b) in the case of a defendant who is a participating dental practitioner—suspend the approval of that dental practitioner as a participating dental practitioner under section 84A; or

(ba) in the case of a defendant who is an authorised optometrist—suspend the approval of that person under section 84AAB; or

(bb) in the case of a defendant who is an authorised midwife—suspend:

(i) the approval of that person under section 84AAF; or

(ii) the authority to supply prescribed pharmaceutical benefits conferred upon that person by section 93AA; or

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(bc) in the case of a defendant who is an authorised nurse practitioner—suspend:

(i) the approval of that person under section 84AAJ; or

(ii) the authority to supply prescribed pharmaceutical benefits conferred upon that person by section 93AB; or

(c) in the case of a defendant who is an approved pharmacist—suspend the approval of that pharmacist under section 90.

Effect of conviction

(2) If a person is convicted of an offence referred to in subsection (1), the Minister may, by notice in writing:

(a) where the Secretary has, under subsection (1), suspended an authority or approval that relates to the person—remove that suspension; and

(b) suspend, or further suspend, for such period as the Minister specifies in the notice, or revoke, any authority or approval referred to in a paragraph of subsection (1), being an authority or approval that relates to the person.

(3) For the purposes of subsection (2), a person shall be deemed to have been convicted of an offence if the court concerned thought that the charge in relation to the offence was proved but, without proceeding to conviction, discharged the person conditionally on the person's entering into a recognizance.

(4) The Minister may, at any time, by notice in writing:

(a) remove a suspension, or further suspension, imposed under subsection (2); or

(b) restore any approval or authority revoked under subsection (2).

Effect of acquittal

(5) If, upon the hearing of a charge for an offence referred to in subsection (1), the person is acquitted, any suspension under subsection (1) in relation to him or her ceases to have effect.

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Effect on Committees of Inquiry

(6) If a medical practitioner, a dental practitioner, an optometrist, a midwife, a nurse practitioner or a pharmacist is charged before a court with an offence referred to in subsection (1):

(a) any act or conduct to which the charge relates shall not be referred for investigation or report by a Committee of Inquiry; and

(b) any investigation by a Committee of Inquiry into any such act or conduct shall cease.

Extended operation for approved pharmacist corporations

(6A) If a person that is a director of an approved pharmacist corporation is charged before a court with having committed an offence referred to in subsection (1), then this section applies in relation to the approved pharmacist corporation:

(a) as if the approved pharmacist corporation were charged before the court with having committed the offence; and

(b) if:

(i) the person is convicted of the offence; or

(ii) the court concerned thinks that the charge in relation to the offence is proved but, without proceeding to conviction, discharges the person conditionally on the person's entering into a recognizance;

as if the approved pharmacist corporation were convicted of the offence; and

(c) if:

(i) the person ceases to be an ineligible director at a particular time; and

(ii) at that time, there is no other director of the approved pharmacist corporation that is an ineligible director;

as if the approved pharmacist corporation were acquitted of the offence.

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Definitions

(7) In this section:

approved pharmacist has the same meaning as in Part VII.

approved pharmacist corporation means an approved pharmacist that is a body corporate.

authorised midwife has the same meaning as in Part VII.

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

authorised optometrist has the same meaning as in Part VII.

ineligible director: a director of an approved pharmacist corporation is an ***ineligible director*** if:

(a) the director has been charged before a court with having committed an offence referred to in subsection (1); and

(b) the director has not been acquitted of the offence; and

(c) the charge has not been withdrawn or otherwise disposed of.

PBS prescriber has the same meaning as in Part VII.

pharmacist includes a person to whom subsection 90(6) applies.

133A Territories

There are payable towards the maintenance of a public hospital in a Territory such sums as are agreed upon between the Finance Minister and the Minister.

134 Effect of suspension or cancellation of approval or authority

(1) Where:

(a) the authority conferred upon a medical practitioner by section 88 is suspended or revoked; or

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(b) the approval of a dental practitioner as a participating dental practitioner under section 84A is suspended or revoked; or

(c) the approval of an optometrist as an authorised optometrist under section 84AAB is suspended or revoked; or

(d) the approval of a person as an authorised midwife under section 84AAF is suspended or revoked; or

(da) the approval of a person as an authorised nurse practitioner under section 84AAJ is suspended or revoked;

the person to whom the authority or approval relates shall not, during the period of suspension or after the revocation takes effect, write a prescription for the purposes of Part VII, and an approved pharmacist, approved medical practitioner or approved hospital authority shall not supply for the purposes of that Part a pharmaceutical benefit on a prescription written by the person to whom the authority or approval relates.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(2) Where the approval of a medical practitioner under section 92 is suspended or revoked, that medical practitioner shall not, during the period of suspension or after the revocation takes effect, supply a pharmaceutical benefit for the purposes of Part VII.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(3) Upon the revocation of an authority or approval referred to in subsection (4), the person to whom the authority or approval relates must deliver to a person specified by the Secretary all drugs and medicinal preparations in the first-mentioned person's possession which he or she has obtained for the purposes of Part VII.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(4) The authorities and approvals are as follows:

(a) an authority conferred upon a medical practitioner by section 88 or 93;

(b) an approval of a person as an authorised midwife under section 84AAF;

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(c) an approval of a person as an authorised nurse practitioner under section 84AAJ;

(d) an authority conferred upon an authorised midwife by section 93AA;

(e) an authority conferred upon an authorised nurse practitioner by section 93AB.

134A Publication of particulars of certain action taken under this Act

(1) The Minister may, if the Minister thinks fit, cause to be published in the *Gazette* particulars of or relating to any action that the Minister or the Secretary has taken under section 34, 35, 95 or 133, including a statement of the reason for that action, which may take the form of, or include, a reference to, or an abstract from, any relevant report by a Committee of Inquiry.

(2) A publication in the *Gazette* shall not be made in pursuance of subsection (1) until:

(a) the period within which an appeal may be brought against the action referred to in that subsection has expired; and

(b) if such an appeal is brought, judgment has been given on that appeal.

(3) The Minister or the Secretary may, in any report or statement on or relating to the administration of this Act or the operation of this Act or a part of this Act, publish such particulars of, or comments on, cases or matters referred to in subsection (1) as he or she considers necessary or desirable in the public interest, and for that purpose the public interest shall be taken to extend to the prevention or discouragement of conduct that involves contravention of any provision of this Act or the regulations or an abuse of those provisions or failure to discharge conscientiously duties or obligations under those provisions.

(4) An action or proceeding, civil or criminal, does not lie against a person for publishing in good faith a copy of, or a fair extract from,

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or a fair abstract of, a publication made in accordance with the preceding provisions of this section.

(5) A publication shall be deemed to be made in good faith if the person by whom it is made is not actuated by ill will to the person affected by the publication or by any other improper motive.

(6) Nothing in this section authorizes publication of the name of a patient or particulars that would enable a patient to be identified.

134B Time for commencing prosecutions

A prosecution in respect of an offence against this Act or the regulations may be commenced at any time within 3 years after the commission of the offence.

134C Defence in certain prosecutions

In a prosecution under this Act of a person for making a statement, or issuing or presenting a document, that is false or misleading in a material particular it is a defence if the person did not know and had no reason to suspect that the statement or document was false or misleading, as the case may be.

Note: The defendant bears an evidential burden in relation to the matter in this section. See subsection 13.3(3) of the *Criminal Code*.

134D Civil penalty provisions

Enforceable civil penalty provisions

(1) Each civil penalty provision of this Act is enforceable under Part 4 of the Regulatory Powers Act.

Note: Part 4 of the Regulatory Powers Act allows a civil penalty provision to be enforced by obtaining an order for a person to pay a pecuniary penalty for the contravention of the provision.

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Authorised applicant and relevant court

(2) For the purposes of Part 4 of the Regulatory Powers Act, as that Part applies in relation to the civil penalty provisions of this Act:

(a) the Secretary is an authorised applicant; and

(b) each of the following is a relevant court:

(i) the Federal Court of Australia;

(ii) the Federal Circuit and Family Court of Australia (Division 2);

(iii) a court of a State or Territory that has jurisdiction in relation to matters arising under this Act.

134E Obligations not affected by State or Territory laws

Nothing contained in a law of a State or a Territory, or in the general law, operates to prevent a person from:

(a) giving information; or

(b) producing a document; or

(c) giving evidence;

that the person is required, or authorised, to give or produce under a provision of this Act.

134F Conduct by directors, employees or agents

(1) Where it is necessary, for the purposes of this Act, to establish the state of mind of a body corporate in respect of conduct engaged in, or deemed by subsection (2) to have been engaged in, by the body corporate, it is sufficient to show that a director, employee or agent by whom the conduct was engaged in within the scope of his or her actual or apparent authority, had that state of mind.

(2) Any conduct engaged in on behalf of a body corporate:

(a) by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority; or

(b) by any other person at the direction or with the consent or agreement (whether express or implied) of a director, employee or agent of the body corporate, where the giving of

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the direction, consent or agreement is within the scope of the actual or apparent authority of the director, employee or agent;

shall be deemed, for the purposes of this Act, to have been engaged in also by the body corporate.

(3) Where it is necessary, for the purposes of this Act, to establish the state of mind of a person in relation to conduct deemed by subsection (4) to have been engaged in by the person, it is sufficient to show that an employee or agent of the person, being an employee or agent by whom the conduct was engaged in within the scope of his or her actual or apparent authority, had that state of mind.

(4) Conduct engaged in on behalf of a person other than a body corporate:

(a) by an employee or agent of the person within the scope of his or her actual or apparent authority; or

(b) by any other person at the direction or with the consent or agreement (whether express or implied) of an employee or agent of the first-mentioned person, where the giving of the direction, consent or agreement is within the scope of the actual or apparent authority of the employee or agent;

shall be deemed for the purposes of this Act to have been engaged in also by the first-mentioned person.

(5) A reference in this section to the state of mind of a person includes a reference to the knowledge, intention, opinion, belief or purpose of the person and the person's reasons for the person's intention, opinion, belief or purpose.

(6) A reference in this section to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth, of a State or of a Territory.

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135 Right of Commonwealth officers to practise

(1) An employee of the Commonwealth who is registered as a medical practitioner, dentist, nurse, pharmaceutical chemist, pharmacist, physiotherapist or optometrist under the law of a State or Territory is entitled to perform, on behalf of the Commonwealth, the duties of the employee's profession in any other State or Territory notwithstanding that the employee is not registered in that other State or Territory.

(2) In subsection (1), ***Territory*** includes Norfolk Island, the Territory of Cocos (Keeling) Islands and the Territory of Christmas Island.

135A Officers to observe secrecy

Offence—use or disclosure by officer outside course of duty

(1) A person (the ***relevant person***) commits an offence if:

(a) the relevant person is or has been an officer; and

(b) the relevant person uses or discloses information; and

(c) the information:

(i) relates to the affairs of a person other than the relevant person; and

(ii) is obtained or generated by the relevant person in the performance of duties or functions, or in the exercise of powers, under this Act.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(1A) Subsection (1) does not apply if the use or disclosure is:

(a) authorised or exempted under a provision of this Act; or

(b) otherwise required or authorised under an Australian law.

Note 1: The defendant bears an evidential burden in relation to the matter in this subsection. See subsection 13.3(3) of the *Criminal Code*.

Note 2: For the purposes of this subsection, examples of provisions of this Act that authorise the use or disclosure of information include sections 135ABA, 135ABB and 135ABC.

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Authorisation—performance of functions

(2) An officer may use or disclose information of a kind referred to in paragraph (1)(c):

(a) in the performance of duties or functions, or in the exercise of powers, under this Act or any other Act; or

(b) for the purpose of enabling the officer or any other person to perform duties or functions, or exercise powers, in relation to a medicare program; or

(c) in the case of disclosure to the Minister—for the purposes of the Minister's performance of the Minister's functions.

Authorisations—use or disclosure in public interest

(3) An officer may use or disclose information of a kind referred to in paragraph (1)(c) if:

(a) the Secretary or the Chief Executive Medicare certifies, by instrument in writing, that it is in the public interest to disclose the information to a specified person or body for a specified purpose; and

(b) the officer:

(i) discloses the information to the person or body for that purpose; or

(ii) uses the information for purposes related to such a disclosure.

Note: Information disclosed to a person under this subsection for a specified purpose must only be further used or disclosed for that purpose (see subsection (3G)).

(3A) The Secretary or the Chief Executive Medicare may, by instrument in writing, specify terms and conditions subject to which the information may be used or disclosed by the person.

(3B) Without limiting subsection (3A), the instrument may require the person to give an undertaking in writing with respect to the use or disclosure of the information by the person, which may include an undertaking not to disclose any of the information to any other person or body.

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(3C) An instrument under paragraph (3)(a) or subsection (3A) is not a legislative instrument.

(3D) Subsection (3) has effect subject to rules made under subsection (3E) (if any).

(3E) The Minister may, by legislative instrument, make rules for the purposes of subsection (3D).

Authorisation—disclosing to prescribed person or body

(3F) An officer may disclose information of a kind referred to in paragraph (1)(c) to a person or body for a specified purpose if regulations made for the purposes of this subsection provide that:

(a) the person or body is a prescribed person or body; and

(b) the information is prescribed information; and

(c) the information may be provided to the person or body for that purpose.

Note: Information disclosed to a person or body under this subsection for a specified purpose must only be further used or disclosed for that purpose (see subsection (3G)).

Obligation on further use or disclosure of disclosed information

(3G) A person or body that receives information under subsection (3) or (3F) for a specified purpose must ensure that any further use or disclosure of the information is only for that purpose.

Authorisation—use or disclosure by officer in certain circumstances

(4) An officer may use or disclose information of a kind referred to in paragraph (1)(c) if:

(a) the information is lawfully in the public domain; or

(b) the person to whom the information relates has expressly or impliedly consented to the use or disclosure; or

(c) the use or disclosure is for the purpose of obtaining or providing legal advice; or

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(d) if the disclosure is to a person or body—the information relates to that person or body; or

(e) if the disclosure (the ***present disclosure***) is to a person or body—the information has lawfully been disclosed to that person or body previously (the ***previous disclosure***), and the present disclosure is for the same purpose as the previous disclosure.

Authorisation—statistical information

(5) An officer may use or disclose information of a kind referred to in paragraph (1)(c) for the purpose of deriving or publishing statistics that do not enable the identification of any person (other than the Commonwealth, a State or a Territory).

(5A) Statistics relating to the supply of pharmaceutical benefits may be published in spite of the fact that the manufacturer of any of those benefits may be identified through those statistics.

Authorisation—data-matching by a Commonwealth entity

(5D) Notwithstanding anything in subsection (1), the Secretary or the Chief Executive Medicare may provide information to an authorised Commonwealth entity (within the meaning of Part VIIIA) for the purpose of facilitating the matching of that information by the Commonwealth entity under subsection 132B(1).

Authorisation—disclosing information relating to convictions etc.

(6) Notwithstanding anything contained in subsection (1), where:

(a) a person has been convicted of:

(i) an offence against this Act; or

(ii) an offence against section 6 of the *Crimes Act 1914*, or section 11.1, 11.4 or 11.5 of the *Criminal Code*, that relates to an offence against this Act; or

(b) an order has been made in relation to a person under section 19B of the *Crimes Act 1914* in relation to an offence referred to in subparagraph (a)(i) or (ii); or

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(c) a Committee of Inquiry reports adversely on the conduct of a practitioner or pharmacist in relation to a matter upon which the Committee makes inquiry;

the Secretary may disclose any information acquired by an officer in the performance of duties or functions, or in the exercise of powers, under this Act that concerns a matter referred to in paragraph (a), (b) or (c) to:

(d) the Secretary of the Department of Social Security; or

(e) the Secretary of the Veterans' Affairs Department; or

(ea) the Chief Executive Centrelink or a person engaged (whether as an employee or otherwise) by Services Australia; or

(f) a person or persons who, under a law of a State or Territory that provides for the registration or licensing of hospitals, nursing homes or similar institutions, is or are, responsible for the administration of that law or who is, or are, empowered to investigate persons in connection with contraventions of that law; or

(g) a person or persons who, under a law of a State or Territory that provides for the registration or licensing of practitioners, pharmacists or pharmaceutical chemists is, or are, empowered to take disciplinary action with respect to practitioners, pharmacists or pharmaceutical chemists or to investigate practitioners, pharmacists or pharmaceutical chemists in connection with the taking of such disciplinary action; or

(ga) a person or persons who, under a law of a State or Territory that provides for the registration of midwives, or the authorisation (however described) of persons to practise midwifery, are empowered to:

(i) take disciplinary action with respect to midwives; or

(ii) investigate midwives in connection with the taking of such disciplinary action; or

(gb) a person or persons who, under a law of a State or Territory that provides for the registration of nurse practitioners, or the authorisation (however described) of persons to practise as nurse practitioners, are empowered to:

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(i) take disciplinary action with respect to nurse practitioners; or

(ii) investigate nurse practitioners in connection with the taking of such disciplinary action; or

(h) a person or persons who, under a law of the Commonwealth, a State or a Territory relating to drugs or poisons, is, or are, responsible for the administration of that law or who is, or are, empowered to investigate persons in connection with contraventions of that law; or

(j) a director, secretary or employee of a private health insurer who is authorized by the Secretary, by instrument in writing, for the purposes of this subsection.

Authorisation—disclosing certified information for purposes of certain laws or private health insurance

(7) Notwithstanding anything contained in subsection (1), where the Minister, by instrument in writing, certifies that it is desirable for such of the following purposes as the Minister specifies in the certificate, that is to say:

(b) the administration of an Act administered by the Veterans' Affairs Minister;

(c) the administration of a specified law of a State or Territory, being a law that provides for the registration or licensing of hospitals, nursing homes or similar institutions;

(d) the administration of a specified law of a State or Territory, being a law that provides for the registration or licensing of practitioners or pharmacists;

(da) the administration of a specified law of a State or Territory, being a law that provides for the registration of midwives, or the authorisation (however described) of persons to practise midwifery; or

(db) the administration of a specified law of a State or Territory, being a law that provides for the registration of nurse practitioners, or the authorisation (however described) of persons to practise as nurse practitioners; or

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(e) the administration of a specified law of the Commonwealth, a State or a Territory relating to drugs or poisons; or

(f) the carrying on of the business of a specified private health insurer or a private health insurer included in a specified class of private health insurers;

that information of a kind referred to in the certificate, being information acquired by an officer in the performance of duties or functions, or in the exercise of powers, under this Act, should be disclosed, the Secretary may disclose information of that kind:

(h) if the certificate specifies a purpose of the kind referred to in paragraph (b)—to the Secretary of the Veterans' Affairs Department;

(j) if the certificate specifies a purpose in relation to a specified law of the kind referred to in paragraph (c) or (e)—to the person or persons who, under that law is, or are, responsible for the administration of that law or is, or are, empowered to investigate persons in connection with contraventions of that law;

(k) if the certificate specifies a purpose in relation to a specified law of the kind referred to in paragraph (d)—to the person or persons who, under that law is, or are, empowered to take disciplinary action with respect to practitioners or pharmacists or to investigate practitioners or pharmacists in connection with the taking of such disciplinary action; or

(l) if the certificate specifies a purpose in relation to a specified law of the kind referred to in paragraph (da)—to the person or persons who are empowered to:

(i) take disciplinary action with respect to midwives; or

(ii) investigate midwives in connection with the taking of such disciplinary action; or

(la) if the certificate specifies a purpose in relation to a specified law of the kind referred to in paragraph (db)—to the person or persons who are empowered to:

(i) take disciplinary action with respect to nurse practitioners; or

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(ii) investigate nurse practitioners in connection with the taking of such disciplinary action; or

(m) if the certificate specifies a purpose of the kind referred to in paragraph (f)—to a director, secretary or employee of each private health insurer to which the certificate relates, being a director, secretary or employee who is authorized by the Secretary, by instrument in writing, for the purposes of this subsection.

Restrictions on disclosing information relating to rendering of certain professional services

(8) Information relating to the rendering of a medical service, a dental service or an optometrical service, the provision of hospital treatment or the supply of a pharmaceutical benefit must not be disclosed in pursuance of subsection (6) or (7) in a manner that is likely to enable the identification of the person to whom that service was rendered, that treatment or care was provided or that benefit was supplied (in this subsection referred to as the ***patient***) unless:

(a) the patient:

(i) is a person referred to in paragraph (6)(a) or (b); or

(ii) consents in writing to the disclosure of the information; or

(b) the Minister certifies that there are reasonable grounds for suspecting that the patient has committed, or is committing, an offence of the kind referred to in subparagraph (6)(a)(i) or (ii).

Offence—recipients of information relating to convictions etc. or certified information

(9) A person to whom information is disclosed under subsection (6) or (7) and any person under the control of the first-mentioned person shall not, directly or indirectly, except:

(aa) in the case of the Chief Executive Centrelink or a person engaged (whether as an employee or otherwise) by Services Australia—in the performance of duties or functions, or in

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the exercise of powers, under an Act administered by the Minister administering the *Human Services (Centrelink) Act 1997*; or

(b) in the case of the Secretary of the Veterans' Affairs Department or a person under the control of the Secretary—in the performance of duties or functions, or in the exercise of powers, under an Act administered by the Veterans' Affairs Minister; or

(c) in the case of a person or persons referred to in paragraph (6)(f), (g), (ga), (gb) or (h), or (7)(j), (k), (l) or (la), or a person under the control of such a person or persons—in the performance of duties or functions, or in the exercise of powers, under the law referred to in that paragraph; or

(d) in the case of a director, secretary or employee of a private health insurer or a person under the control of such a person—in the performance of duties or functions, or in the exercise of powers, in relation to the carrying on of the business of the insurer;

and while the person is, or after the person ceases to be, such a person, use, or further disclose to any person, any information so disclosed.

Penalty: Imprisonment for 2 years or 50 penalty units, or both.

(12A) Despite subsection (1), any of the following persons may disclose information about a person's compliance with a share by default provision (within the meaning of the *My Health Records Act 2012*) to the Australian Commission on Safety and Quality in Health Care:

(a) the Secretary;

(b) the Secretary of the Department administered by the Minister administering the *My Health Records Act 2012*;

(c) the Chief Executive Medicare.

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Offences—solicitation of certain information held by Department

(13) Where:

(a) a person solicits the disclosure of protected information from an officer or another person; and

(b) the disclosure would be in contravention of this section; and

(c) the first-mentioned person knows or ought reasonably to know that the information is protected information;

the first-mentioned person commits an offence, whether or not any protected information is actually disclosed.

(16) Where:

(a) a person is convicted of an offence under subsection (13); and

(b) the person acted as an employee or agent of another person in soliciting the disclosure of the information;

the other person commits an offence.

(16A) An offence under subsection (16) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(17) It is a defence to a prosecution for an offence against subsection (16) if the employee or agent was acting outside the scope of his or her authority as an employee or agent in soliciting the disclosure of the information.

Note: The defendant bears an evidential burden in relation to the matter in subsection (17). See subsection 13.3(3) of the *Criminal Code*.

Offence—conduct relating to information unlawfully disclosed

(17A) A person commits an offence if:

(a) protected information is disclosed to the person; and

(b) the disclosure contravenes this section; and

(c) the person:

(i) in any way solicited the disclosure of the information to the person; or

(ii) discloses the information to another person; or

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(iii) uses the information otherwise than by disclosing it to another person.

(18) Where:

(a) a person is convicted of an offence under subsection (17A); and

(b) the person acted as an employee or agent of another person in obtaining the information;

the other person commits an offence.

(18A) An offence under subsection (18) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(19) It is a defence to a prosecution for an offence against subsection (18) if the employee or agent's action described in subsection (17A) was outside the scope of his or her authority as an employee or agent.

Note: The defendant bears an evidential burden in relation to the matter in subsection (19). See subsection 13.3(3) of the *Criminal Code*.

Offences—offer to supply certain information held by Department

(20) A person who:

(a) offers to supply (whether to a particular person or otherwise) information about another person; and

(b) knows that the information is protected information;

commits an offence.

(21) A person who:

(a) holds himself or herself out as being able to supply (whether to a particular person or otherwise) information about another person; and

(b) knows that the information is protected information;

commits an offence.

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Penalty for offences against solicitation, conduct relating to information unlawfully disclosed or offer to supply

(22) The penalty for an offence against subsection (13), (16), (17A), (18), (20) or (21) is imprisonment for a period not exceeding 2 years.

Definitions

(24) In this section:

Chief Executive Centrelink has the same meaning as in the *Human Services (Centrelink) Act 1997*.

officer means any of the following:

(a) a person performing duties or functions, or exercising powers, under or in relation to this Act or a medicare program;

(b) any other person employed or engaged by the Commonwealth to provide services to the Commonwealth in connection with a relevant Department or Services Australia;

(c) any other person employed or engaged (however described) by a person described in paragraph (b) to provide services in connection with the services mentioned in that paragraph.

pharmaceutical benefit has the same meaning as in Part VII.

protected information means information about a person that is held in the records of the Department.

135AAA Prescribers and approved suppliers must observe secrecy in relation to medicare numbers and expiry dates provided for pharmaceutical benefit scheme purposes

(1) If:

(a) a medicare number, or a medicare number and the expiry date in relation to that number, are provided, as a result of a request under section 88, or under section 88AA, to a person who is a PBS prescriber; and

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(b) that number, or number and date, are provided solely for either or both of the following purposes:

(i) enabling the person to write or communicate a prescription for the supply of a pharmaceutical benefit;

(ii) enabling the person to record and retain that number, or number and date, to facilitate the writing of future prescriptions for the supply of pharmaceutical benefits;

the person commits an offence if, while the person is, or after the person ceases to be, a PBS prescriber, the person directly or indirectly makes an unauthorised disclosure or an unauthorised use of that number or that date.

Penalty: 50 penalty units or imprisonment for 2 years, or both.

(2) For the purposes of subsection (1):

(a) the disclosure by a person referred to in that subsection of a medicare number, or of the expiry date in relation to a medicare number, to another person is an unauthorised disclosure of that number or that date; and

(b) the use by a person referred to in that subsection of a medicare number, or of the expiry date in relation to a medicare number, is an unauthorised use of that number or that date;

if that disclosure or use is not made or undertaken:

(c) in the performance of the duties or functions, or in the exercise of the powers, of that person as a PBS prescriber under this Act in relation to the Pharmaceutical Benefits Scheme; or

(d) for the purpose of enabling a person to perform functions in relation to a medicare program in relation to that Scheme.

(3) If:

(a) a medicare number, or a medicare number and the expiry date in relation to that number, are provided, as a result of a request under section 86B or 86C, or under section 86D, to a person or body that is an approved supplier; and

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(b) that number, or number and date, are provided solely for one or more of the following purposes:

(i) enabling the person or body to supply a pharmaceutical benefit;

(ii) enabling the person or body to record and retain that number, or number and date, in order to facilitate the supply of pharmaceutical benefits at a later time or times;

(iii) enabling the person or body to record and retain that number, or number and date, in order to complete the written version of a prescription that has been previously communicated;

the person or body commits an offence if, while the person or body is, or after the person or body ceases to be, such an approved supplier, the person or body directly or indirectly makes an unauthorised disclosure or an unauthorised use of that number or that date.

Penalty: 50 penalty units or imprisonment for 2 years, or both.

(4) For the purposes of subsection (3):

(a) the disclosure by a person or body referred to in that subsection of a medicare number, or of the expiry date in relation to a medicare number, to another person is an unauthorised disclosure of that number or that date; and

(b) the use by a person or body referred to in that subsection of a medicare number or of the expiry date in relation to a medicare number is an unauthorised use of that number or that date;

if that disclosure or use is not made or undertaken:

(c) in the performance of the duties or functions, or in the exercise of the powers, of the person or body as an approved supplier under this Act in relation to the Pharmaceutical Benefits Scheme; or

(d) for the purpose of enabling a person to perform functions in relation to a medicare program in relation to that Scheme.

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(5) If a medicare number, or a medicare number and the expiry date in relation to that number, are provided:

(a) to a person who is employed or engaged by:

(i) a PBS prescriber; or

(ii) a company that provides services in support of a PBS prescriber;

solely for a purpose or purposes referred to in paragraph (1)(b); or

(b) to a person who is employed or engaged by:

(i) an approved supplier; or

(ii) a company that provides services in support of an approved supplier;

solely for a purpose or purposes referred to in paragraph (3)(b);

that person is, while the person is, and after the person ceases to be, so employed or engaged, subject to the same obligations and liabilities as apply under subsection (1) or (3), as the case requires, in relation to the person or body by whom the person is or was so employed or engaged.

(6) A person to whom a medicare number, or a medicare number and the expiry date in relation to that number, are disclosed in contravention of subsection (1), (3) or (5) commits an offence if:

(a) the person knows or ought reasonably to know that the disclosure of the number, or number and date, was in contravention of that subsection; and

(b) the person directly or indirectly discloses that number or that date to any person, or otherwise makes use of that number or that date.

Penalty: 50 penalty units or imprisonment for 2 years, or both.

(7) Despite subsection (1), (3) or (5), a person or body to whom a medicare number, or a medicare number and the expiry date in relation to that number, are provided solely for a purpose set out or referred to in that subsection may disclose that number or expiry

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date to another person for another specified purpose with the express authority of:

(a) the person in respect of whom that number was provided; or

(b) the legal guardian of that person; or

(c) another person identified in a determination made by the Minister under section 86D or 88AA as capable of authorising the recording and retention of such number or number and date, on behalf of the person to whom the number applies.

(8) A person to whom a medicare number, or a medicare number and the expiry date in relation to that number, are disclosed in accordance with an express authority under subsection (7) commits an offence if the person:

(a) directly or indirectly discloses that number or that date to another person; or

(b) makes use of that number or that date;

other than for the purpose specified by the person giving the authority.

Penalty: 50 penalty units or imprisonment for 2 years, or both.

(9) Nothing in subsection (1), (3), (5), (6) or (8) prevents a medicare number or an expiry date in relation to such a number from being communicated to a court for the purpose of proceedings under this section.

(10) In this section:

approved supplier has the same meaning as in Part VII.

expiry date, in relation to a medicare number, has the same meaning as in Part VII.

medicare number, in relation to a person, has the same meaning as in Part VII.

PBS prescriber has the same meaning as in Part VII.

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(11) A reference in this section to a number, or number and date, provided to an approved supplier or to a person engaged or employed by an approved supplier, includes a reference to such a number, or number and date, that are informed under section 86D to the approved supplier by a PBS prescriber communicating a prescription to the supplier.

135ABA Authorisations—dealings with certain information relating to pharmaceutical benefits for program integrity etc.

(1) This section applies to information that:

(a) relates to a person; and

(b) is held by an agency (whether or not the information was obtained by that agency, or any other agency, after the commencement of this section); and

(c) is any of the following:

(i) information obtained by the agency, or any other agency, in connection with a claim for payment of a benefit under the Pharmaceutical Benefits Program;

(ii) information obtained by the agency, or any other agency, in connection with a supply of a pharmaceutical benefit;

(iii) information relating to a person's eligibility or entitlement to receive a pharmaceutical benefit, to receive payment in respect of the supply of a pharmaceutical benefit or to be paid a benefit under the Pharmaceutical Benefits Program.

Authorised collection, use and disclosure of information

(2) Information to which this section applies may be collected, used or disclosed for one or more of the purposes specified in subsection (3) in any of the following circumstances:

(a) the disclosure is by an officer (within the meaning of section 135A) to an entrusted public official;

(b) the collection, use or disclosure is by an entrusted public official;

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(c) if the information was previously disclosed to a person (the ***recipient***) by an entrusted public official:

(i) the disclosure of the information is by the recipient to an entrusted public official; or

(ii) the use of the information is by the recipient for the purpose for which it was previously disclosed; or

(iii) the disclosure of the information is by the recipient to any other person for the purpose for which it was previously disclosed.

Note 1: Collection, use or disclosure authorised by this subsection is not prohibited by subsection 135A(1) (see subsection 135A(1A)).

Note 2: This subsection also constitutes an authorisation for the purposes of other laws, such as the *Privacy Act 1988*.

(3) The collection, use or disclosure is authorised if it is for one or more of the following purposes:

(a) the integrity or sustainability of a medicare program;

(b) the protection of a person from a risk arising from, or in connection with, the provision of a benefit or service under a medicare program;

(c) statistical analysis;

(d) medical research;

(e) research and development in relation to health, disability or aged care;

(f) development, analysis, administration and review of, and reporting related to, government policy and programs in relation to health, disability or aged care;

(g) a disclosure of information that is required or authorised under an Australian law.

Note 1: For paragraph (a), section 135ACC extends the meaning of the integrity or sustainability of a medicare program.

Note 2: For paragraphs (c), (d) and (e), additional requirements apply to disclosures for the purposes of statistical analysis, medical research, or research and development in relation to health, disability or aged care (see subsections (4) and (5)).

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Additional matters for disclosures relating to research or statistics

(4) However, this section does not authorise a disclosure for the purposes of medical research if:

(a) a person (the ***identifiable person***) is reasonably identifiable from the information that is proposed to be disclosed; and

(b) the person disclosing the information is not satisfied that:

(i) the identifiable person has given informed consent to the use and disclosure of the information for that research; or

(ii) the research is to be conducted in accordance with guidelines issued by the National Health and Medical Research Council under section 95 of the *Privacy Act 1988*.

(5) Before disclosing information under this section for the purposes of statistical analysis, medical research, or research and development in relation to health, disability or aged care, the person disclosing the information must consider the extent to which the disclosure complies with the data minimisation principle.

No interference with information handling for My Heath Record or data-matching

(6) Nothing in this section prevents:

(a) the My Health Record System Operator including information to which this section applies in the My Health Record of a healthcare recipient; or

(b) the matching of information under subsection 132B(1) or the operation of Part VIIIA generally.

Definitions

(7) In this section:

agency has the same meaning as in the *Privacy Act 1988*.

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data minimisation principle means the principle of only using or disclosing as much information to which this section applies as is reasonably needed to achieve the purpose of the use or disclosure of the information.

My Health Record has the same meaning as in the *My Health Records Act 2012*.

My Health Record System Operator has the same meaning as System Operator has in the *My Health Records Act 2012*.

Pharmaceutical Benefits Program means the program for supplying pharmaceutical benefits under Part VII of this Act.

135ABB Authorisations—dealings with officer obtained or generated information for program integrity etc.

(1) This section applies to information that:

(a) is obtained or generated by an officer (within the meaning of section 135A) in the performance of duties or functions, or in the exercise of powers, under this Act; and

(b) relates to the affairs of a person.

(2) Information to which this section applies may be collected, used or disclosed for one or more of the purposes specified in subsection (3) in any of the following circumstances:

(a) the disclosure is by a person who is or has been an officer (within the meaning of section 135A) to an entrusted public official;

(b) the collection, use or disclosure is by an entrusted public official;

(c) if the information was previously disclosed to a person (the ***recipient***) by an entrusted public official:

(i) the disclosure of the information is by the recipient to an entrusted public official; or

(ii) the use of the information is by the recipient for the purpose for which it was previously disclosed; or

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(iii) the disclosure of the information is by the recipient to any other person for the purpose for which it was previously disclosed.

Note 1: Collection, use or disclosure authorised by this subsection is not prohibited by subsection 135A(1) (see subsection 135A(1A)).

Note 2: This subsection also constitutes an authorisation for the purposes of other laws, such as the *Privacy Act 1988*.

(3) The collection, use or disclosure is authorised if it is for one or more of the following purposes:

(a) the integrity or sustainability of a medicare program;

(b) the protection of a person from a risk arising from, or in connection with, the provision of a benefit or service under a medicare program;

(c) the administration of a centrelink program (within the meaning of the *Human Services (Centrelink) Act 1997*);

(d) the administration of the following Acts:

(i) the *Child Support (Assessment) Act 1989*;

(ii) the *Child Support (Registration and Collection) Act 1988*.

Note: For paragraph (a), section 135ACC extends the meaning of the integrity or sustainability of a medicare program.

(4) However, this section does not authorise the following disclosures:

(a) disclosure by any of the following persons of information obtained as a result of a review or investigation under Part VAA of the *Health Insurance Act 1973*:

(i) a person appointed under Division 2 of that Part;

(ii) a member of staff or a consultant engaged under section 106ZM or 106ZP of that Act;

(iii) a person whose services are made available under section 106ZN of that Act;

(iv) a person providing services under section 106ZPL of that Act;

(v) any other person engaged (whether as an employee or otherwise) by the Professional Services Review to

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provide services in connection with the performance of duties or functions, or the exercise of powers, under that Part;

(b) disclosure, by a person consulted under section 90 of that Act, of information obtained in connection with that consultation.

Note: For paragraph (a), such persons include the Director or an Associate Director of Professional Services Review or a Panel member of the Professional Services Review Panel (all within the meaning of Part VAA of the *Health Insurance Act 1973*).

135ABC Authorisations—dealings with information for enforcement, public revenue or integrity purposes

(1) This section applies to information that:

(a) is obtained or generated by an officer (within the meaning of section 135A) in the performance of duties or functions, or in the exercise of powers, under this Act; and

(b) relates to the affairs of a person.

(2) An entrusted public official may use or disclose information for a purpose specified in subsection (3) if:

(a) the official reasonably believes that using or disclosing the information is necessary for that purpose; and

(b) for a disclosure of information—the disclosure is to an agency (within the meaning of the *Privacy Act 1988*) whose functions are directed at that purpose.

(3) The use or disclosure is authorised if it is for one or more of the following purposes:

(a) the enforcement of the criminal law;

(b) the enforcement of a law imposing a pecuniary penalty;

(c) the protection of the public revenue;

(d) an integrity purpose (within the meaning of the *Crimes Act 1914*).

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135AC Authorisation—collection of particular health information under health law

(1) If:

(a) particular health information is disclosed to an organisation; and

(b) the disclosure is authorised by or under a health law;

then the collection of the information by the organisation to whom the information is disclosed is taken to be authorised by or under this Act for the purposes of subparagraph 16B(1)(b)(i) of the *Privacy Act 1988*.

(2) In this section:

health law means any of the following:

(a) an Act administered by the Minister;

(b) the *Human Services (Medicare) Act 1973*.

organisation has the same meaning as in the *Privacy Act 1988*.

135ACA Authorisation—use for authorised disclosure

(1) This section applies to information that:

(a) is obtained or generated by an officer (within the meaning of section 135A) in the performance of duties or functions, or in the exercise of powers, under this Act; and

(b) relates to the affairs of a person.

(2) A person may use information to which this section applies for the purpose of disclosing the information under section 135A, 135ABA, 135ABB or 135ABC.

135ACB Authorisations and exemptions do not limit each other

An authorisation or exemption (however described) under section 135A, 135AAA, 135ABA, 135ABB, 135ABC, 135AC or 135ACA does not limit, and is not limited by, any other authorisation or exemption under:

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(a) that section or any other of those sections; or
(b) any other section of this Act.

135ACC References to the integrity or sustainability of a medicare program

(1) This section is made for the purposes of the following provisions:
(a) paragraph 135ABA(2)(a);
(b) paragraph 135ABB(3)(a).

(2) For the purposes of each of those provisions, and the section in which the provision is located:
(a) a reference in the section to the purposes of the integrity or sustainability of a medicare program includes a reference to the need to ensure that access to the program is limited to circumstances where requirements or parameters (whether or not statutory) relating to the program are met; and
(b) a reference in the section to a collection, use or disclosure being for those purposes is taken to include a reference to the collection, use or disclosure being for the purposes of ensuring that the delivery of the program is not compromised by mistakes, misconduct, fraud or non-compliance, including in relation to those requirements or parameters.

135ACD Information relating to deceased persons

Sections 135A, 135AAA, 135ABA, 135ABB, 135ABC, 135AC, 135ACA, 135ACB and 135ACC apply in relation to information relating to a deceased person in the same way as they apply in relation to information relating to a person who is not deceased.

135B Prosecution of offences

(1) Subject to subsection (2), an offence against section 84L, 103, 134 or 135A is an indictable offence.

(2) A court of summary jurisdiction may hear and determine proceedings in respect of an offence referred to in subsection (1) if

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the court is satisfied that it is proper to do so and the defendant and the prosecutor consent.

(3) Where, in accordance with subsection (2), a court of summary jurisdiction convicts a person of an offence referred to in that subsection, the penalty that the court may impose is imprisonment for a period not exceeding 6 months.

136 Committees

(1) In addition to the committees for the establishment of which express provision is made in the preceding provisions of this Act, the Minister may establish such other committees as the Minister thinks fit for the purposes of this Act, of the *Health Insurance Act 1973* or of both this Act and that Act.

(2) The regulations may make provision for and in relation to the constitution, powers, functions, duties and procedure of committees established in pursuance of subsection (1).

136A Filling of vacancies on committees

(1) Whenever a vacancy occurs in the office of a member of a Committee who was appointed by the Minister from among persons of a specified description nominated by a specified body, the Minister may request the appropriate body to nominate a specified number of persons of that description and may fill the vacancy by appointing a person from among the persons so nominated.

(2) In this section, ***Committee*** means a committee constituted under this Act.

137 Moneys from which payments under this Act are to be made

(1) Subject to this section, payments for the purposes of this Act (other than Part VII) shall be made out of the Consolidated Revenue Fund, which is appropriated accordingly.

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Note: For payments for the purposes of Part VII of this Act, see the *Medicare Guarantee Act 2017*.

(2) Expenditure of a capital nature (other than expenditure incurred under section 9A or paragraph 9C(2)(a)) and expenditure in respect of administrative expenses (including the remuneration of members of committees established under this Act) incurred by or on behalf of the Commonwealth for the purposes of this Act shall be paid out of moneys from time to time appropriated by the Parliament for the purpose.

138 Exercise of Secretary's powers subject to directions of Minister

The exercise of a power by the Secretary, or a delegate of the Secretary, under this Act is subject to the directions (if any) of the Minister.

138A Telephone access to offices

The Minister shall direct the Secretary to make provision for the development of a service which will enable a person to make a telephone call to an office that is under the general control of the Secretary, at no greater cost than the cost of a local telephone call.

139 Judicial notice of signature of Secretary

(1) For the purposes of any proceeding under this Act or a prosecution for an offence against a law of the Commonwealth, every Australian court is to take judicial notice of the signature of the person who holds or a person who has held the office of Secretary and of the fact that that person holds or has held that office.

(2) In this section:

Australian court has the same meaning as in the *Evidence Act 1995*.

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139A Evidence

(1) The Secretary may, by writing signed by the Secretary, certify that, during a period or on a date specified in the certificate:

(a) any premises were or were not an approved hospital for the purposes of this Act;

(d) a medical practitioner was or was not authorized under section 88 to write a prescription for the supply of pharmaceutical benefits or was or was not authorized under section 93 to supply pharmaceutical benefits specified in the certificate;

(da) a dental practitioner was or was not approved as a participating dental practitioner under section 84A;

(db) a person was or was not an authorised optometrist under section 84AAB;

(dc) a person was or was not an authorised midwife under section 84AAF;

(dd) a person was or was not an authorised nurse practitioner under section 84AAJ;

(de) a person was or was not authorised under section 93, 93AA or 93AB to supply pharmaceutical benefits specified in the certificate;

(e) a person was or was not approved under section 90 for the purpose of supplying pharmaceutical benefits at premises specified in the certificate;

(f) a medical practitioner was or was not approved under section 92 for the purpose of supplying pharmaceutical benefits to persons in an area specified in the certificate;

(g) a hospital authority was or was not approved under section 94 for the purpose of its supplying pharmaceutical benefits to patients receiving treatment in or at a hospital specified in the certificate.

(1A) The Secretary may, by writing signed by the Secretary, certify:

(a) that a document annexed to the certificate is a true copy of a determination by the Minister under this Act or of any other document made or issued under this Act;

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(b) that:

(i) a document annexed to the certificate is a true copy of a determination by the Minister under this Act or of any other document made or issued under this Act; and

(ii) the determination or other document of which the annexed document is certified to be a true copy had effect during a period or on a date specified in the certificate; or

(c) that:

(i) the document annexed to the certificate is a true copy of an approval, determination, certificate or variation that has or had effect as if it were given or made under this Act; and

(ii) the approval, determination, certificate or variation had such effect during the period or on a date specified in the certificate.

(2) In proceedings under this Act, in a prosecution for an offence against a law of the Commonwealth and in an investigation or inquiry conducted or made under this Act, a certificate purporting to have been given under this section:

(a) is prima facie evidence of the facts stated in the certificate; and

(b) shall, unless the contrary is proved, be deemed to have been given by the person purporting to give the certificate.

139C Information with respect to concessional beneficiaries

In spite of sections 202 to 210 of the *Social Security (Administration) Act 1999*, the Secretary of the Department of Family and Community Services or an officer authorised by him or her for the purpose may communicate to the Secretary or an officer authorised by him or her any information with respect to the operation of Part 2A.1 of the *Social Security Act 1991*.

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140 Regulations

The Governor-General may make regulations, not inconsistent with this Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to this Act, and, in particular, for prescribing:

(a) the fees and allowances payable to members of a committee established under this Act, other than members who are officers of the Public Service of the Commonwealth or of a State; and

(b) penalties not exceeding a fine of 20 penalty units for offences against the regulations.

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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

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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.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

C[x] = Compilation No. x

ch = Chapter(s)

cl = clause(s)

cont. = continued

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

div = Division(s)

ed = editorial change

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

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)

Ord = Ordinance

orig = original

p = page(s)

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

pres = present

prev = previous

(prev…) = previously

pt = Part(s)

r = regulation(s)/Court rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s) /rule(s)/subrule(s)/order(s)/suborder(s)

sch = Schedule(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

sub ch = Sub-Chapter(s)

sub div = Subdivision(s)

sub pt = Subpart(s)

underlining = whole or part not commenced or to be commenced

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Act 1953	95, 1953	18 Dec 1953	Parts I and II (ss. 1–11): Royal Assent Part VII (ss. 83–105): 12 May 1954 (*see Gazette* 1954, p. 1179) Remainder: 14 Apr 1954 (*see Gazette* 1954, p. 1055)	
National Health Act 1955	68, 1955	4 Nov 1955	s. 13: 14 Apr 1954 ss. 22, 24 and 28: 12 May 1954 ss. 23, 25–27 and 32: 1 July 1956 (*see Gazette* 1956, p. 1835) s. 44: 1 Jan 1956 (*see Gazette* 1955, p. 4237) Remainder: Royal Assent	s. 36(2)
National Health Act 1956	55, 1956	30 June 1956	s. 4: 14 Apr 1954 Remainder: Royal Assent	—
National Health Act (No. 2) 1956	95, 1956	15 Nov 1956	1 Sept 1957 (*see* s. 2 and *Gazette* 1957, p. 2631)	—
National Health Act 1957	92, 1957	12 Dec 1957	1 Jan 1958 (*see Gazette* 1957, p. 4105)	—
National Health Act 1958	68, 1958	8 Oct 1958	s. 6: 11 Sept 1958 Remainder: Royal Assent	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Act 1959	72, 1959	1 Dec 1959	ss. 3–6, 10, 23 and 24: 1 Jan 1960 s. 8(1): 1 Jan 1959 ss. 12–22: 1 Mar 1960 (*see Gazette* 1960, p. 785) Remainder: Royal Assent	ss. 2(2), 8(2) and 25 s. 3 (rep. by 16, 1961, s. 10)
as amended by				
National Health Act 1961	16, 1961	11 May 1961	ss. 3, 6, 7 and 10: 1 July 1961 Remainder: Royal Assent	—
National Health Act 1961	16, 1961	11 May 1961	ss. 3, 6, 7 and 10: 1 July 1961 Remainder: Royal Assent	—
National Health Act 1962	82, 1962	12 Dec 1962	ss. 3(b), (c), 4, 5, 12–19, 28 and 29: 1 Jan 1963 Remainder: Royal Assent	ss. 10(2) and 24
National Health Act 1963	77, 1963	31 Oct 1963	1 Jan 1964	s. 4(2)
National Health Act 1964	37, 1964	28 May 1964	s. 3(1): 1 July 1964 ss. 3(2), 5–13, 15, 16 and 24: 1 June 1964 Remainder: Royal Assent	ss. 7(2), 18(2) and 20(2)
National Health Act 1965	100, 1965	13 Dec 1965	13 Dec 1965	s. 2
National Health Act (No. 2) 1965	146, 1965	18 Dec 1965	14 Feb 1966	—
National Health Act 1966	44, 1966	18 Oct 1966	18 Oct 1966	ss. 3(2), 5(2) and 6(2)
National Health Act 1967	14, 1967	8 May 1967	21 Apr 1967 (*see* s. 2)	s. 4
National Health Act (No. 2) 1967	100, 1967	10 Nov 1967	ss. 4 and 5: 1 Mar 1968 (*see Gazette* 1968, p. 1117) Remainder: Royal Assent	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Act 1968	100, 1968	26 Nov 1968	ss. 1, 2, 5 and 22: Royal Assent Remainder: 1 Jan 1969	ss. 22(2) and 27
National Health Act 1969	102, 1969	27 Sept 1969	27 Sept 1969	—
National Health Act 1970	41, 1970	24 June 1970	Part I (ss. 1–3), ss. 4, 6, 7, 59 and 60: Royal Assent ss. 35 and 48: 1 July 1971 Remainder: 1 July 1970 (*see Gazette* 1970, p. 4143)	ss. 40(2), 50(2), 51(2) and 59–64
National Health Act 1971	85, 1971	20 Oct 1971	s. 3: 21 Oct 1971 ss. 4–6 and 11: 1 Nov 1971 (*see Gazette* 1971, p. 6701) Remainder: Royal Assent	ss. 7(2), 8(2), 10 and 11
National Health Act 1972	114, 1972	31 Oct 1972	ss. 1, 2, 5, 6, 31–36, 38 and 39: Royal Assent ss. 3(1), 14 and 30: 1 Mar 1973 (*see Gazette* 1972, No. 135) Remainder: 1 Jan 1973 (*see Gazette* 1972, No. 135)	ss. 31(2), 32(2), 33(2), 34(2), 35(2) and 39–41
National Health Act 1973	49, 1973	14 June 1973	3 July 1973	—
National Health Act (No. 2) 1973	202, 1973	18 Dec 1973	s. 17: 1 Jan 1974 Remainder: Royal Assent	ss. 31(2), 32(2), 34(2), 36(2), 37(2) and 38(2)
National Health Act 1974	37, 1974	7 Aug 1974	7 Aug 1974	ss. 5 and 6

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Act 1975	1, 1975	15 Feb 1975	ss. 3(2), 7, 9, 10(2), 11–14, 17–20, 32 and 34: 1 Jan 1975 Remainder: Royal Assent	ss. 3(3), 4(2), 22(2), 33(2) and 34
National Health Act (No. 2) 1975	13, 1975	9 Apr 1975	9 Apr 1975	—
National Health (Pharmaceutical Benefits Charges) Act 1975	93, 1975	28 Aug 1975	1 Sept 1975	—
National Health Act 1976	1, 1976	29 Feb 1976	ss. 1, 2, 4 and 7: Royal Assent Remainder: 1 Mar 1976	s. 16
National Health Amendment Act 1976	60, 1976	5 June 1976	ss. 1, 2, 28, 31, 41 and 42: Royal Assent Remainder: 1 Oct 1976	ss. 25(2), 29(2), 33(2), 35(2), 36(2) and 42 s. 43 (am. by 99, 1976, s. 24)
as amended by				
Administrative Changes (Consequential Provisions) Act 1976	91, 1976	20 Sept 1976	s 4 and Sch: 20 Sept 1976 (s 2(1), (5))	s 4
National Health Amendment Act (No. 2) 1976	99, 1976	29 Sept 1976	1 Oct 1976	—
Administrative Changes (Consequential Provisions) Act 1976	91, 1976	20 Sept 1976	s 4: 20 Sept 1976 (s 2(1)) Sch (amdts to National Health Act 1953): 22 Dec 1975 (s 2(7))	s 4
National Health Amendment Act (No. 2) 1976	99, 1976	29 Sept 1976	1 Oct 1976	s. 23(2)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment Act (No. 3) 1976	108, 1976	29 Oct 1976	25 Nov 1976	ss. 4 and 5
Federal Court of Australia (Consequential Provisions) Act 1976	157, 1976	9 Dec 1976	1 Feb 1977 (*see* s. 2 and *Gazette* 1977, No. S3)	s. 4
National Health Amendment Act (No. 4) 1976	177, 1976	13 Dec 1976	1 Jan 1977 (*see Gazette* 1976, No. S240)	s. 10
National Health Amendment Act 1977	98, 1977	30 Sept 1977	1 Nov 1977 (*see Gazette* 1977, No. S266)	—
National Health Acts Amendment Act 1977	100, 1977	30 Sept 1977	ss. 1, 2 and 32: Royal Assent Remainder: 1 Oct 1977	ss. 9(2), 11(2), 14(2), 21(2) and 32(2)
Administrative Changes (Consequential Provisions) Act 1978	36, 1978	12 June 1978	12 June 1978	s. 8
National Health Amendment Act 1978	88, 1978	22 June 1978	s 3, 5–7 and 15: repealed before commencing (s 2(2), (4)) s 4 and 12: 1 Oct 1978 (s 2(3) and gaz 1978, No G38, p 2) s 11: 1 July 1978 (s 2(5)) Remainder: 22 June 1978 (s 2(1))	—
as amended by				
National Health Amendment Act (No. 2) 1978	132, 1978	31 Oct 1978	s 44: 31 Oct 1978 (s 2(2))	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment Act (No. 2) 1978	132, 1978	31 Oct 1978	ss. 1, 2, 3(1)(b), 3(2) and 44: Royal Assent ss. 20–42: 16 Feb 1979 (*see Gazette* 1979, No. S27) Remainder: 1 Nov 1978	s. 3(2)
National Health Amendment Act (No. 3) 1978	189, 1978	4 Dec 1978	4 Dec 1978	—
National Health Amendment Act 1979	54, 1979	14 June 1979	ss. 3(1)(b)–(d) and 16: 1 Sept 1979 Remainder: Royal Assent	ss. 3(2), 9(2), 13(2), 14(2), 15 and 16
National Health Amendment Act (No. 2) 1979	91, 1979	31 Aug 1979	1 Sept 1979	—
National Health Amendment Act (No. 3) 1979	122, 1979	29 Oct 1979	1 Nov 1979	—
National Health Amendment Act 1980	117, 1980	8 Sept 1980	8 Sept 1980	s. 11(2)
National Health Amendment Act (No. 2) 1980	131, 1980	19 Sept 1980	ss. 1, 2, 7–10 and 15: 4 Sept 1980 s. 3: 1 Nov 1980 ss. 4–6 and 14: 1 Oct 1980 Remainder: 1 Dec 1980 (*see Gazette* 1980, No. S261)	ss. 4(2) and 15
National Health (Pharmaceutical Benefits) Amendment Act 1981	40, 1981	12 May 1981	12 May 1981	ss. 9 and 10

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Commonwealth Functions (Statutes Review) Act 1981	74, 1981	18 June 1981	s 177 and 264: 18 June 1981 (s 2(1))	s 264
Companies (Miscellaneous Amendments) Act 1981	92, 1981	18 June 1981	Part I (ss. 1, 2): Royal Assent Div. 1 of Part XI (s 36): 1 July 1981 (*see* s. 2(2) and *Gazette* 1981, No. S118) Remainder: 1 July 1982 (*see* s. 2(3) and *Gazette* 1982, No. S124)	—
Health Acts Amendment Act 1981	118, 1981	25 June 1981	ss. 1–3, 20, 24–31, 33 and 34: Royal Assent ss. 4(1), 6, 37 and 41: 3 Aug 1981 ss. 48 and 51–54: 1 Jan 1981 Part V (ss. 81–97): 1 Apr 1982 (*see Gazette* 1982, No. G12, p. 3) Remainder: 1 Sept 1981	ss. 55(2), (3), 70(2) and 75(2)
National Health Amendment Act 1981	163, 1981	26 Nov 1981	s. 3: 1 Dec 1981 Remainder: Royal Assent	s. 4(2)
Statute Law (Miscellaneous Amendments) Act 1981	176, 1981	2 Dec 1981	s 49: 1 Sept 1981 (s 2(8)) Sch 1: 30 Dec 1981 (s 2(12))	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act 1982	49, 1982	9 June 1982	s 41: repealed before commencing (s 2(2)) s 42–44: 9 June 1982 (s 2(1)) s 45: 1 Nov 1982 (s 2(2) and gaz 1982, No S227, p 2)	s 45(2)
as amended by				
Health and Community Services Legislation Amendment Act 1991	211, 1991	24 Dec 1991	s 29: 24 Dec 1991 (s 2(1))	—
Statute Law (Miscellaneous Amendments) Act (No. 2) 1982	80, 1982	22 Sept 1982	s 280(2), (3) and Sch 12: 22 Sept 1982 (s 2(1))	s 280(2) and (3)
Health Legislation Amendment Act (No. 2) 1982	112, 1982	8 Nov 1982	ss. 4(1), (4) and 14(2), (4): 1 Nov 1982 ss. 4(2), 5(1), 7, 9, 24(1), 25, 26, 29(2), 31, 32(2) and 40: 1 Jan 1983 ss. 4(3), 5(2), 14(3) and 24(2): 1 Mar 1983 s. 6(2): 1 Apr 1983 s. 6(3): 1 May 1983 s. 8: 1 Nov 1982 (*see* s. 2(7) and *Gazette* 1982, No. S227, p. 2) Remainder: Royal Assent	ss. 2(8), 14(4), 17(2), 35(3), (4) and 40
National Health Amendment Act 1983	35, 1983	19 June 1983	ss. 6, 7, 9 and 10: 18 July 1983 (*see Gazette* 1983, No. S151) Remainder: Royal Assent	ss. 2(2) and 10

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act 1983	54, 1983	1 Oct 1983	ss. 1–3, 4(1), 31(1), 32(4)–(8), 39, 45, 64–67, 70–82, 83(1), 85–88, 89(2), 95–99, 115(1), 119(1), 120(1), 123, 124, 126, 128 and 129: Royal Assent Remainder: 1 Feb 1984	ss. 2(3), 95(2), 96(2), 98(2), 100(2), 102(2), 103(2), (3), 105(2), 113(2), 116 (2), 119(3), 120(3), 133, 134(2) and 136

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act (No. 2) 1983	139, 1983	22 Dec 1983	s 24, 26, 27, 28(1), (3)–(7), (9), 29–33, 35(2), (5)–(8), 36(1), (3)–(5), 37, 38(1), (3), 39, 40(1), 41(1), 42–47, 49, 50(1), 51, 53, 54(1), (4), 55(1), 56 and 57: 22 Dec 1983 (s 2(1)) s 25 and 52: 1 Dec 1983 (s 2(2)) s 28(2) and (8): 1 Feb 1984 (s 2(7)) s 34, 35(3), (9)–(11), 36(2), 38(2), 48, 50(2), 54(2) and 55(2): 23 May 1984 (s 2(9) and gaz 1984, No S183) s 35(1): 1 Jan 1975 (s 2(10)) s 35(4), 40(2)–(4), 41(2) and 54(3), (5): repealed before commencing s 2(9))	s 26(2), 28(3)–(9), 29(2), 30(2), 31(2), 33(2), 35(5)–(11), 36(3)–(5), 37(2), 38(3), 39(2), 44(2), (3), 45(2), (3), 46(2), 51(2) and 54(4), (5)
as amended by				
Statute Law (Miscellaneous Provisions) Act (No. 2) 1984	165, 1984	25 Oct 1984	s 9(5) and (8): 13 Dec 1984 (s 2(29)) Sch 1: never commenced (s 2(11))	s 9(5) and (8)
Nursing Homes and Hostels Legislation Amendment Act 1986	115, 1986	24 Nov 1986	Part V (s 40, 41): 24 Nov 1986 (s 2(5))	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Cocos (Keeling) Islands Self-Determination (Consequential Amendments) Act 1984	46, 1984	25 June 1984	Part VII (ss. 22–26): 6 Apr 1984 Remainder: Royal Assent	—
Public Service Reform Act 1984	63, 1984	25 June 1984	s 151(1) and Sch 4: 1 July 1984 (*see Gazette* 1984, No. S245)	s. 151(9)
Statute Law (Miscellaneous Provisions) Act (No. 1) 1984	72, 1984	25 June 1984	s 3 and Sch 1: 23 July 1984 (s 2(1))	s. 5(7)
Christmas Island Administration (Miscellaneous Amendments) Act 1984	120, 1984	18 Oct 1984	Part VIII (ss. 27–31): 1 Oct 1984 Remainder: Royal Assent	—
Health Legislation Amendment Act 1984	135, 1984	25 Oct 1984	s. 7: 1 Feb 1984 ss. 11, 12, 15–21 and 26: 1 July 1985 (*see Gazette* 1985, No. S235) Remainder: Royal Assent	ss. 22(2), (3), 23(2)–(4) and 24(2), (3)
Statute Law (Miscellaneous Provisions) Act (No. 2) 1984	165, 1984	25 Oct 1984	s 3 and Sch 1: 23 July 1984 (s 2(15))	ss. 2(32), 6(1) and 9
National Welfare Fund Repeal Act 1985	24, 1985	22 May 1985	ss. 1, 2 and 5: Royal Assent Remainder: 1 July 1985 (*see Gazette* 1985, No. S232)	s. 5
National Health Amendment Act 1985	53, 1985	4 June 1985	1 July 1985	s. 6(2) and (3)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Statute Law (Miscellaneous Provisions) Act (No. 1) 1985	65, 1985	5 June 1985	s 3: 3 July 1985 (s 2(1))	—
Health Legislation Amendment Act 1985	70, 1985	5 June 1985	ss. 1–3 and 11: Royal Assent ss. 6, 8, 9 and 12–21: 1 Sept 1985 Remainder: 1 Sept 1985 (*see Gazette* 1985, No. S346)	s. 21(2) and (3)
Social Security and Repatriation Legislation Amendment Act 1985	95, 1985	5 Sept 1985	Part XI (s 60–62): 1 July 1985 (s 2(5))	—
Social Security and Repatriation (Budget Measures) Amendment Act 1985	127, 1985	28 Oct 1985	s 7 and 10(2): 28 Oct 1985 (s 2(1)) s 8 and 11: 1 Nov 1985 (s 2(5)) s 9 and 10(1): 1 July 1985 (s 2(2))	—
Health Legislation Amendment Act (No. 2) 1985	167, 1985	16 Dec 1985	ss. 1–25, 26(2), 27, 37, 38, 42, 43, 55, 57, 65–70 and 72–74: Royal Assent s. 28: 1 Feb 1984 s. 30: 5 Sept 1985 ss. 58–64: 1 May 1985 Remainder: 22 Feb 1986 (*see Gazette* 1986, No. S64)	—
Veterans' Entitlements (Transitional Provisions and Consequential Amendments) Act 1986	28, 1986	19 May 1986	s. 61: Royal Assent Remainder: 22 May 1986 (*see Gazette* 1986, No. S225)	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act 1986	75, 1986	24 June 1986	s 57 and 61–71: 22 July 1986 (s 2(1)) s 58 and 59: 1 July 1986 (s 2(2)) s 60: 16 Feb 1979 (s 2(5))	s 71
Health Legislation Amendment Act (No. 2) 1986	94, 1986	13 Oct 1986	ss. 4(1), 6–8, 10, 12, 14(2) and 36: 1 Oct 1986 ss. 4(2), 17(2), 20, 22 and 29: 1 Apr 1987 (*see Gazette* 1987, No. S57) ss. 5, 14(3), 17(1), 18, 19, 21, 23–28, 30, 32 and 35: 1 Nov 1986 ss. 16, 31, 33 and 38(2)–(4): 1 Jan 1987 Remainder: Royal Assent	ss. 21(2), 27(2), 28(2), 34(2) and 38
as amended by				
Statute Law (Miscellaneous Provisions) Act 1987	141, 1987	18 Dec 1987	s 5(1): 18 Dec 1987 (s 2(1)) Sch 1: 13 Oct 1986 (s 2(16))	s 5(1)
Nursing Homes and Hostels Legislation Amendment Act 1986	115, 1986	24 Nov 1986	s 6, 8–15, 18–20 and 23: 24 Nov 1986 (s 2(5)) s 7: 1 Aug 1991 (s 2(4) and gaz 1991, No S207) s 16, 17 and 21: 1 May 1987 (s 2(4) and gaz 1987, No S68) s 22: repealed before commencing (s 2(4))	s 23
as amended by				
Community Services and Health Legislation Amendment Act 1991	84, 1991	26 June 1991	s 15, 16: 26 June 1991 (s 2(1))	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment Act 1987	22, 1987	26 May 1987	s. 3(1): 1 Nov 1986 (*see* s. 2(2)) s. 4(1): 1 Nov 1986 (*see* s. 2(3)) s. 5: 1 Jan 1988 (*see Gazette* 1987, No. S348) Remainder: Royal Assent	ss. 3(3), 5(2) and 8(2)
as amended by				
Health and Community Services Legislation Amendment Act (No. 2) 1992	192, 1992	21 Dec 1992	(*see* 192, 1992 below)	—
Health Legislation Amendment Act 1987	44, 1987	5 June 1987	1 Aug 1987	s. 6(2)
Nursing Homes and Hostels Legislation Amendment Act 1987	72, 1987	5 June 1987	ss. 1 and 2: Royal Assent s. 30: 1 May 1993 (*see Gazette* 1993, No. GN16) Remainder: 1 July 1987	ss. 13(2), 30, 32 and 33 s. 31 (am. by 79, 1988, s. 33)
as amended by				
Community Services and Health Legislation Amendment Act 1988	79, 1988	24 June 1988	(*see* 79, 1988 below)	—
National Health Amendment Act (No. 2) 1987	118, 1987	16 Dec 1987	ss. 1 and 2: Royal Assent Remainder: 1 Mar 1988 (*see Gazette* 1988, No. S54)	s. 8(2)
Health Legislation Amendment Act (No. 2) 1987	131, 1987	16 Dec 1987	s. 4: 13 Dec 1987 ss. 5, 6, 8(a) and 9: 1 Jan 1988 Remainder: Royal Assent	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Community Services and Health Legislation Amendment Act 1987	132, 1987	16 Dec 1987	ss. 1–3, 4(d), (g), 5–7, 21, 22 and 31: 16 Dec 1987 ss. 23–30 and 32: 1 Mar 1988 (*see Gazette* 1988, No. S58) Part V (s. 33): 1 May 1988 (*see Gazette* 1988, No. S118) Remainder: 11 Jan 1989 (*see Gazette* 1988, No. S411)	—
National Health Amendment Act 1988	46, 1988	15 June 1988	1 July 1988	s. 4
Community Services and Health Legislation Amendment Act 1988	79, 1988	24 June 1988	Part II (ss. 3–6): 28 June 1989 (*see* s. 2(3) and *Gazette* 1989, No. S206) ss. 11, 14, 16, 18, 19, 20(a), (c)–(o), 21–26 and 31: 1 July 1988 ss. 12, 29, 30, 32 and 34: 1 Oct 1988 (*see Gazette* 1988, No. S303) ss. 27 and 28: 1 July 1989 (*see Gazette* 1989, No. S206) s. 33: 1 July 1987 Remainder: Royal Assent	ss. 15(2) and 17(2)
as amended by				
Community Services and Health Legislation Amendment Act (No. 2) 1988	155, 1988	26 Dec 1988	(*see* 155, 1988 below)	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Industrial Relations (Consequential Provisions) Act 1988	87, 1988	8 Nov 1988	ss. 1 and 2: Royal Assent Remainder: 1 Mar 1989 (*see* s. 2(2) and *Gazette* 1989, No. S53)	s. 90
Statutory Instruments (Tabling and Disallowance) Legislation Amendment Act 1988	99, 1988	2 Dec 1988	2 Dec 1988	—
Community Services and Health Legislation Amendment Act (No. 2) 1988	155, 1988	26 Dec 1988	s. 10: 1 Jan 1989 ss. 12 and 13: 1 July 1989 (*see Gazette* 1989, No. S228) ss. 14 and 17: 1 July 1988 ss. 19–26 and 28–34: 24 Jan 1990 (*see Gazette* 1990, No. S13) ss. 27 and 36: 15 Mar 1989 (*see Gazette* 1989, No. S91) Part V (ss. 38–40): 24 June 1988 s. 41(2): 16 Dec 1987 s. 41(3): 6 Nov 1987 s. 41(4): 1 Mar 1989 (*see* s. 2(8) and *Gazette* 1989, No. S54) Remainder: Royal Assent	ss. 27(3)–(7) and 37

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Community Services and Health Legislation Amendment Act 1989	95, 1989	28 June 1989	s. 10: 10 Oct 1989 (*see Gazette* 1989, No. S323) ss. 11–16 and 18: 1 Aug 1989 ss. 20(2), 21, 22, 53(2) and 54: 28 Dec 1989 s. 23: 15 Mar 1989 ss. 28–33, 43 and 44: 15 Nov 1989 (*see Gazette* 1989, No. S355) s. 37(a)–(k) and (s): 1 June 1989 Part 5 (ss. 55–62): 1 July 1989 Part 7 (ss. 65–68): 1 Jan 1989 Remainder: Royal Assent	ss. 2(10), 28(2), 36(2) and 54
Social Security and Veterans' Affairs Legislation Amendment Act (No. 4) 1989	164, 1989	19 Dec 1989	s 11, 12(a): 19 Dec 1989 (s 2) s 12(b): 1 Jan 1990 (s 2) s 12(c), (d): 1 June 1990 (s 2)	—
National Health Amendment Act 1989	175, 1989	24 Dec 1989	24 Dec 1989	s. 6

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Community Services and Health Legislation Amendment Act (No. 2) 1989	3, 1990	17 Jan 1990	ss. 4, 26(b), (c), 28 and 31: 1 July 1990 ss. 5 and 26(d), (e): 1 July 1990 (*see Gazette* 1990, No. S164) s. 14(e): 1 June 1990 s. 16: 1 July 1988 ss. 33, 34 and 36: 1 Apr 1990 (*see Gazette* 1990, No. S83) Remainder: Royal Assent	s. 25(2)
Social Welfare Legislation (Pharmaceutical Benefits) Amendment Act 1990	84, 1990	30 Oct 1990	s 3 and 9: 30 Oct 1990 s 4, 5(a), 5(c)–(e), 6, 7, 8(a), 8(c)–(e) and 10: 1 Nov 1990 s 5(b) and 8(b): 1 Jan 1991 s 11: 1 Feb 1991 (s 2)	—
Community Services and Health Legislation Amendment Act 1990	106, 1990	18 Dec 1990	s 19–21, 23, 25, 26 and 29–31: 18 Dec 1990 s 22(a): 1 Nov 1990 s 22(b)–(e), 24 and 27: 1 Jan 1991 s 28: 1 Feb 1991 (s 2)	—
Community Services and Health Legislation Amendment Act (No. 2) 1990	141, 1990	28 Dec 1990	s 49: 1 Mar 1990 (s 2(2)) s 50, 51(a), 52–55 and 72–74: 28 Dec 1990 (s 2(1)) s 51(b) and 56–71: 1 Jan 1991 (s 2(3))	s 72(2)
Social Security Legislation Amendment Act 1990	6, 1991	8 Jan 1991	s 92 and 93: 1 June 1990 (s 2)	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security (Job Search and Newstart) Amendment Act 1991	68, 1991	25 June 1991	s 33: 1 July 1991 (s 2)	—
Social Security (Rewrite) Transition Act 1991	70, 1991	25 June 1991	Sch 3: 1 July 1991 (s 2)	—
Veterans' Entitlements (Rewrite) Transition Act 1991	73, 1991	25 June 1991	Sch 4: 1 July 1991 (s 2(1))	—
National Health Amendment Act 1991	83, 1991	26 June 1991	ss. 4, 5 (in part), 7(1), 11, 12, 16 and 23: 1 Jan 1991 Remainder: Royal Assent	ss. 3 and 24
Community Services and Health Legislation Amendment Act 1991	84, 1991	26 June 1991	s 7–13: 26 June 1991 (s 2(1)) s 14: 1 Aug 1991 (s 2(2) and gaz 1991, No S207)	—
Social Security Legislation Amendment Act (No. 2) 1991	115, 1991	27 June 1991	s 42: 1 Mar 1991 (s 2(5))	—
Social Security (Rewrite) Amendment Act 1991	116, 1991	27 June 1991	Sch 6: 1 July 1991 (s 2)	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation (Pharmaceutical Benefits) Amendment Act 1991	119, 1991	27 June 1991	ss. 4 (in part), 5, 7(c), 8 and 9: 1 July 1991 ss. 4 (in part), 7(b), (d), 13, 14, 15(a), (b), (d)–(h), 16 and 17: 1 Aug 1991 (*see Gazette* 1991, No. S209) s. 10(1): 1 Jan 1991 Remainder: Royal Assent	s. 2 (am. by 136, 1992, s. 26)
as amended by				
Health and Community Services Legislation Amendment Act 1992	136, 1992	11 Nov 1992	(*see* 136, 1992 below)	—
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 2 (item 16): 1 Aug 1991 (s 2(7))	—
Industrial Relations Legislation Amendment Act 1991	122, 1991	27 June 1991	ss. 4(1), 10(b) and 15–20: 1 Dec 1988 ss. 28(b)–(e), 30 and 31: 10 Dec 1991 (*see Gazette* 1991, No. S332) Remainder: Royal Assent	s. 31(2)
Social Security (Disability and Sickness Support) Amendment Act 1991	141, 1991	9 Oct 1991	Part 1 (ss. 1, 2): Royal Assent Remainder: 12 Nov 1991	—
Hearing Services Act 1991	169, 1991	20 Nov 1991	1 July 1992	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security Legislation Amendment Act (No. 3) 1991	175, 1991	25 Nov 1991	ss. 4–12 and Schedule (Part 2): 17 Aug 1991 ss. 13, 14, 21–24, 36–40, 42, 43(b), 44(a), 45–57, 97, 98(a), 99, 100–105 and Schedule (Part 3): 1 Jan 1992 ss. 25–28: 20 Mar 1992 ss. 41, 43(a) and 44(b): 1 Apr 1992 ss. 58–73 and 75–96: 1 July 1992 s. 74: 26 Mar 1992 Part 5 (s. 106) and Schedule (Part 1): 12 Nov 1991 Schedule (Part 4): 12 Nov 1991 (*see* s. 2(4)) Schedule (Part 5): 1 Dec 1991 (*see* s. 2(5)) Remainder: Royal Assent	—
Veterans' Affairs Legislation Amendment Act (No. 2) 1991	208, 1991	24 Dec 1991	s 4–8 and 9(b): 1 Jan 1992 (s 2) s 9(a): 2 Jan 1992 (s 2)	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health and Community Services Legislation Amendment Act 1991	211, 1991	24 Dec 1991	ss. 10 and 11: 29 Apr 1992 Part 5 (ss. 30, 31): 19 Aug 1991 ss. 35, 37 and 39: 1 Apr 1992 Remainder: Royal Assent	—
as amended by				
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 2 (item 4): 24 Dec 1991 (s 2(4))	—
Veterans' Affairs Legislation Amendment Act 1992	70, 1992	26 June 1992	s 87: 1 Mar 1991 (s 2(5))	—
Social Security Legislation Amendment Act 1992	81, 1992	30 June 1992	s 117: 30 June 1992 (s 2(1)(f)) Sch 2 (Pt 2): 1 July 1991 (s 2(4))	—
Health, Housing and Community Services Legislation Amendment Act 1992	88, 1992	30 June 1992	s 50–59, 65 and 67: 1 Jan 1992 (s 2(6)) s 60–64, 66, 69–80 and Sch 3: 30 June 1992 (s 2(1))	s 61(2) and 71(2)
as amended by				
Health and Community Services Legislation Amendment Act 1993	12, 1994	18 Jan 1994	s 9: 30 June 1992 (s 2(3))	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health and Community Services Legislation Amendment Act 1992	136, 1992	11 Nov 1992	ss. 38, 39(a), 41, 43, 44(d) and 49: 12 May 1954 (*see* s. 2(2) and *Gazette* 1954, p. 1179) s. 40: 1 July 1992 ss. 46 and 47: 18 Dec 1990 Remainder: Royal Assent	s. 41(2)
Health and Community Services Legislation Amendment Act (No. 2) 1992	192, 1992	21 Dec 1992	s 13–18, 21–23 and 28–33: 21 Dec 1992 (s 2(1)) s 20: 1 Nov 1992 (s 2(5)) s 24–27: 6 Jan 1993 (s 2(6))	—
as amended by				
Health and Community Services Legislation Amendment Act 1993	12, 1994	18 Jan 1994	s 6: 21 Dec 1992 (s 2(2)) s 7: 18 Jan 1994 (s 2(1))	—
National Health Amendment Act 1992	200, 1992	21 Dec 1992	s 19 (amdt to s 65, 65A, 65B National Health Act 1953): 21 Dec 1992 (s 2(2)) Remainder: 1 July 1993 (s 2(1))	—
Health and Community Services Legislation Amendment Act (No. 3) 1992	204, 1992	21 Dec 1992	21 Dec 1992	—
Social Security Legislation Amendment Act (No. 3) 1992	230, 1992	24 Dec 1992	s 32: 20 Mar 1993 (s 2(8)(a)) Sch 3 (items 12, 13): 1 Apr 1993 (s 2(10))	—
National Health Amendment Act 1993	28, 1993	9 June 1993	9 June 1993	s. 4(2)

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security Legislation Amendment Act (No. 2) 1993	61, 1993	3 Nov 1993	s 17: 1 July 1994 (s 2(5))	—
Health and Community Services Legislation Amendment Act (No. 2) 1993	76, 1993	25 Nov 1993	s 19–21: 25 Nov 1993 (s 2(1))	s 20(2)
as amended by				
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 2 (item 5): 25 Nov 1993 (s 2(5))	—
National Health Amendment Act (No. 2) 1993	106, 1993	22 Dec 1993	1 Jan 1994 (s 2)	s 3
as amended by				
Human Services and Health Legislation Amendment Act (No. 2) 1994	116, 1994	16 Sept 1994	Sch: 1 Jan 1994 (s 2(6))	—
Health and Community Services Legislation Amendment Act 1993	12, 1994	18 Jan 1994	s 19–31: 1 July 1993 (s 2(4))	—
as amended by				
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 2 (item 6): 1 July 1993 (s 2(6))	—
Health Legislation (Professional Services Review) Amendment Act 1994	22, 1994	16 Feb 1994	1 July 1994	s. 15

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment Act 1994	23, 1994	16 Feb 1994	ss. 8–10 and 15: 1 July 1993 Remainder: Royal Assent	—
Social Security Legislation Amendment Act 1994	63, 1994	19 May 1994	s 33: 20 Mar 1993 (s 2(6))	—
Veterans' Affairs Legislation Amendment Act 1994	78, 1994	21 June 1994	Sch 1 (items 8, 9): 1 July 1994 (s 2(3))	—
Human Services and Health Legislation Amendment Act 1994	80, 1994	23 June 1994	Sch: 23 June 1994 (s 2(1))	—
Health Legislation (Powers of Investigation) Amendment Act 1994	85, 1994	23 June 1994	21 July 1994	s. 2 (rep. by 19, 1996, Sch. 1 [item 1])
as amended by				
Health Legislation (Powers of Investigation) Amendment Act 1996	19, 1996	28 June 1996	28 June 1996	—
Human Services and Health Legislation Amendment Act (No. 2) 1994	116, 1994	16 Sept 1994	Sch: 16 Sept 1994 (s 2(1)) Sch: 1 Dec 1994 (s 2(4)) Sch: 1 Jan 1995 (s 2(5))	—
Veterans' Affairs (1994–95 Budget Measures) Legislation Amendment Act (No. 2) 1994	164, 1994	16 Dec 1994	Sch 4 (items 2–5): 20 Mar 1995 (s 2(3))	—
Social Security (Parenting Allowance and Other Measures) Legislation Amendment Act 1994	174, 1994	16 Dec 1994	Sch 3 (item 39): 1 Jan 1995 (s 2(3)) Sch 3 (item 40): 1 July 1995 (s 2(1))	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Student Assistance (Youth Training Allowance—Transitional Provisions and Consequential Amendments) Act 1994	184, 1994	23 Dec 1994	Sch 3 (items 63, 64): 1 Jan 1995 (s 2)	—
Evidence (Transitional Provisions and Consequential Amendments) Act 1995	3, 1995	23 Feb 1995	s 14 and 25: 23 Feb 1995 (s 2(1), (12)) Sch: 18 Apr 1995 (s 2(13))	s 14
National Health Amendment Act 1995	24, 1995	31 Mar 1995	s. 3 (items 1–25, 27–44): 1 Apr 1995 s. 3 (item 26): 1 July 1995 Remainder: Royal Assent	s. 3 (item 45)
Health Legislation (Private Health Insurance Reform) Amendment Act 1995	41, 1995	29 May 1995	s 7(2) and Sch 4 (items 1–25): 1 July 1997 (s 2(5)) Sch 1 (items 1–70): 29 May 1995 (s 2(2)) Sch 2 (items 1–108): 1 Oct 1995 (s 2(3)) Sch 3 (items 1–4): 1 July 1996 (s 2(4))	s 7(2) and Sch 3 (item 4)
as amended by				
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 2 (item 17): 16 Dec 1995 (s 2(1))	—
Statute Law Revision Act 1996	43, 1996	25 Oct 1996	Sch 3 (item 28): 29 May 1995 (s 2(3))	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security (Non-Budget Measures) Legislation Amendment Act 1995	105, 1995	29 Sept 1995	s 51–53: 29 Sept 1995 (s 2(1))	—
Health and Other Services (Compensation) (Consequential Amendments) Act 1995	132, 1995	14 Nov 1995	1 Feb 1996 (*see* s. 2 and *Gazette* 1996, No. GN2)	—
Human Services and Health Legislation Amendment Act (No. 3) 1995	149, 1995	16 Dec 1995	Sch 1 (items 69–78) and Sch 2 (items 19, 21, 22): 16 Dec 1995 (s 2(1)) Sch 2 (item 20): 1 Oct 1995 (s 2(9))	Sch 1 (item 78)
Human Services and Health Legislation Amendment Act (No. 2) 1995	164, 1995	16 Dec 1995	Schedule (items 1–4, 14–17, 19–25): 1 Jan 1996 Remainder: Royal Assent	—
Social Security and Veterans' Affairs Legislation Amendment Act 1995	1, 1996	9 Jan 1996	Sch 10 (items 1–3): 20 Mar 1996 (s 2(3)(b)) Sch 10 (items 4–7): 1 July 1996 (s 2(4)(c)) Sch 10 (items 8–11): 20 Sept 1996 (s 2(5)(c))	—
Statute Law Revision Act 1996	43, 1996	25 Oct 1996	Sch 2 (items 76, 77): 6 Nov 1995 (s 2(2)) Sch 4 (item 102): 25 Oct 1996 (s 2(1))	—
National Health (Budget Measures) Amendment Act 1996	79, 1996	19 Dec 1996	Schedule 2 (item 1): 2 Jan 1997 Remainder: 1 Jan 1997	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security Legislation Amendment (Budget and Other Measures) Act 1996	84, 1996	23 Dec 1996	Sch 14 (items 4, 5) and Sch 16 (item 3): 1 July 1997 (s 2(4))	—
Commonwealth Services Delivery Agency (Consequential Amendments) Act 1997	29, 1997	17 Apr 1997	1 July 1997 (*see* s. 2)	—
Health Legislation Amendment (Private Health Insurance Incentives) Act 1997	45, 1997	22 Apr 1997	22 Apr 1997	—
Aged Care (Consequential Provisions) Act 1997	114, 1997	7 July 1997	Sch 1: 1 Oct 1997 (s 2(1)) Sch 6: 1 July 1998 (s 2(5))	Sch 1 (items 45A, 49A)
as amended by				
Aged Care Amendment (Omnibus) Act 1999	132, 1999	13 Oct 1999	Sch 5: (items 3, 4): 1 Oct 1997 (s 2(4))	—
Audit (Transitional and Miscellaneous) Amendment Act 1997	152, 1997	24 Oct 1997	Sch 2 (items 963–972): 1 Jan 1998 (s 2(2))	—
Veterans' Affairs Legislation Amendment (Budget and Compensation Measures) Act 1997	157, 1997	3 Nov 1997	Sch 7: 1 Dec 1997 (s 2(8))	—
Social Security Legislation Amendment (Parenting and Other Measures) Act 1997	197, 1997	11 Dec 1997	Sch 1 (items 345, 346): 20 Mar 1998 (s 2(2))	Sch 1 (item 346)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act 1998	19, 1998	17 Apr 1998	Sch 3 (items 2, 3): 1 May 1998 (s 2(4)) Sch 3 (items 1, 4–16): 17 Apr 1998 (s 2(1))	—
Health Legislation Amendment Act (No. 2) 1998	37, 1998	24 Apr 1998	Sch 1–3, Sch 4 (items 1–14), Sch 5, 6, 9 and Sch 10 (items 5, 8, 11): 24 Apr 1998 (s 2(1)) Sch 4 (items 15–22): 1 July 1998 (s 2(2)) Sch 10 (items 4, 9): 16 Dec 1995 (s 2(5), (7)) Sch 10 (items 6, 7): 29 May 1995 (s 2(6)) Sch 10 (item 10): 1 Jan 1997 (s 2(8))	Sch 2 (items 8–11), Sch 4 (item 14), Sch 5 (items 47–49) and Sch 6 (item 13)
Social Security Legislation Amendment (Youth Allowance Consequential and Related Measures) Act 1998	45, 1998	17 June 1998	Sch 13 (items 43–47): 1 July 1998 (s 2(1))	Sch 13 (item 46)
Financial Sector Reform (Consequential Amendments) Act 1998	48, 1998	29 June 1998	Sch 1 (item 121): 1 July 1998 (s 2(2))	—
1998 Budget Measures Legislation Amendment (Social Security and Veterans' Entitlements) Act 1998	116, 1998	11 Dec 1998	Sch 3 (item 4): 1 July 1999 (s 2(4))	—
Assistance for Carers Legislation Amendment Act 1999	13, 1999	9 Apr 1999	Sch 2 (items 43–49) and Sch 3 (items 3, 4): 1 July 1999 (s 2(2))	Sch 3 (items 3, 4)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act (No. 2) 1999	21, 1999	19 Apr 1999	Schedules 1 and 2: 20 Oct 1999 Remainder: Royal Assent	Sch. 1 (items 3, 15)
National Health Amendment Act (No. 1) 1999	35, 1999	31 May 1999	Schedule 1: 1 Dec 1999 Remainder: Royal Assent	—
Financial Sector Reform (Amendments and Transitional Provisions) Act (No. 1) 1999	44, 1999	17 July 1999	Sch 6 (item 26) and Sch 7 (item 122): 1 July 1999 (s 3(2)(d), (e), (16) and gaz 1999, No S283)	—
as amended by				
Financial Sector Legislation Amendment Act (No. 1) 2000	160, 2000	21 Dec 2000	Sch 4 (item 4): 18 Jan 2001 (s 2(1))	—
A New Tax System (Compensation Measures Legislation Amendment) Act 1999	68, 1999	8 July 1999	Sch 3: 1 July 2000 (s 2(2), (3))	—
Statute Stocktake Act 1999	118, 1999	22 Sept 1999	22 Sept 1999	Sch. 2 (item 44)
National Health Amendment (Lifetime Health Cover) Act 1999	130, 1999	13 Oct 1999	1 July 2000	s. 4
Public Employment (Consequential and Transitional) Amendment Act 1999	146, 1999	11 Nov 1999	Sch 1 (items 628–637): 5 Dec 1999 (s 2(1), (2))	—
Corporate Law Economic Reform Program Act 1999	156, 1999	24 Nov 1999	Sch 10 (items 96–98): 13 Mar 2000 (s 2(2)(c) and gaz 2000, No S114)	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment Act (No. 3) 1999	159, 1999	8 Dec 1999	Sch 1 and Sch 2: 1 Jan 2000 (s 2(2), (4) and gaz 1999, No S635) Sch 3 (items 71–80): 1 Jan 1999 (s 2(5))	Sch 1 (items 13, 21, 51, 52) and Sch 2 (items 43, 45, 49–51, 64)
Health Legislation Amendment (Gap Cover Schemes) Act 2000	72, 2000	27 June 2000	11 Aug 2000 (*see Gazette* 2000, No. S435)	s. 4
National Health Amendment Act (No. 1) 2000	75, 2000	28 June 2000	Sch 1 (items 1, 3–9, 11–15): 1 July 2000 (s 2(3)) Sch 1 (items 2, 10): 30 June 2000 (s 2(2))	Sch 1 (items 9, 12)
Criminal Code Amendment (Theft, Fraud, Bribery and Related Offences) Act 2000	137, 2000	24 Nov 2000	Sch 2 (items 286, 418, 419): 24 May 2001 (s 2(3))	Sch 2 (items 418, 419)
National Health Amendment (Improved Monitoring of Entitlements to Pharmaceutical Benefits) Act 2000	146, 2000	11 Dec 2000	Schedule 2: 1 Jan 2001 Remainder: Royal Assent	—
Health Legislation Amendment Act (No. 1) 2001	6, 2001	21 Mar 2001	s 4, 5, Sch 2 and Sch 4: 21 Mar 2001 (s 2(1)) Schedule 1 (items 2–6): 8 June 2001 (s 2(2) and gaz 2001, No S193) Schedule 3: 1 July 2000 (s 2(4))	s 4 and 5
Corporations (Repeals, Consequentials and Transitionals) Act 2001	55, 2001	28 June 2001	s 4–14 and Schedule 3 (items 340–389): 15 July 2001 (s 2(1), (3) and gaz 2001, No S285)	s 4–14

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Social Security Legislation Amendment (Concession Cards) Act 2001	80, 2001	30 June 2001	1 July 2001	—
Health and Aged Care Legislation Amendment (Application of Criminal Code) Act 2001	111, 2001	17 Sept 2001	17 Sept 2001	s. 4
Abolition of Compulsory Age Retirement (Statutory Officeholders) Act 2001	159, 2001	1 Oct 2001	29 Oct 2001	Sch. 1 (item 97)
Statute Law Revision Act 2002	63, 2002	3 July 2002	Sch 1 (item 22): 21 July 1994 (s 2(1) item 17) Sch 1 (item 23): 3 July 2002 (s 2(1) item 18)	—
Health Legislation Amendment (Private Health Industry Measures) Act 2002	76, 2002	8 Oct 2002	Schedule 1 (items 1–7): Royal Assent Schedule 1 (items 8, 9): 5 Nov 2002	—
Medical Indemnity (Consequential Amendments) Act 2002	133, 2002	19 Dec 2002	1 Jan 2003	—
National Health Amendment (Private Health Insurance Levies) Act 2003	69, 2003	15 July 2003	1 July 2004	Sch. 1 (item 29)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment (Private Health Insurance Reform) Act 2004	1, 2004	27 Feb 2004	Schedule 1 (items 1–27): 1 July 2004 (*see Gazette* 2004, S125) Schedule 1 (items 28–39): 1 July 2004 Schedule 1 (items 58, 65–69, 71, 73): 23 Apr 2004 (*see Gazette* 2004, No. S125) Remainder: Royal Assent	Sch. 1 (items 17, 28A, 54, 59, 64, 73)
as amended by				
National Health Amendment (Prostheses) Act 2005	31, 2005	21 Mar 2005	Schedule 2: (*see* 31, 2005 below)	—
Medical Indemnity Amendment Act 2004	17, 2004	23 Mar 2004	Schedule 3 (item 82): 24 Mar 2004	—
Health and Ageing Legislation Amendment Act 2004	50, 2004	21 Apr 2004	Schedule 1 (items 1–4, 7–22, 24–35): Royal Assent Schedule 2: 19 May 2004	Sch. 1 (items 10, 35)
Military Rehabilitation and Compensation (Consequential and Transitional Provisions) Act 2004	52, 2004	27 Apr 2004	Schedule 3 (items 30–32): 1 July 2004 (*see* s. 2(1))	—
Medical Indemnity Legislation Amendment (Run-off Cover Indemnity and Other Measures) Act 2004	77, 2004	23 June 2004	Schedule 2 (item 16): 1 July 2004	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment (Podiatric Surgery and Other Matters) Act 2004	117, 2004	13 July 2004	Schedule 1 (item 6): Royal Assent Schedule 1 (items 7–14): 13 Jan 2005	—
as amended by				
Health Legislation Amendment (Australian Community Pharmacy Authority) Act 2005	60, 2005	26 June 2005	Schedule 1 (item 1): (*see* 60, 2005 below)	—
National Health Amendment (Pharmaceutical Benefits—Budget Measures) Act 2004	119, 2004	13 July 2004	Schedule 1: 1 Jan 2005 Remainder: Royal Assent	Sch. 1 (item 24)
Private Health Insurance Incentives Amendment Act 2005	9, 2005	22 Feb 2005	Schedule 2: 22 Feb 2005	Sch. 2 (item 3)
National Health Amendment (Prostheses) Act 2005	31, 2005	21 Mar 2005	Schedule 1: 31 Oct 2005 (*see* F2005L02548) Schedule 2: 1 July 2004 (*see* s. 2(1)) Remainder: Royal Assent	Sch. 1 (items 8, 12)
Health Legislation Amendment (Australian Community Pharmacy Authority) Act 2005	60, 2005	26 June 2005	Sch 1 (items 2, 3): 26 June 2005 (s 2(1) item 3)	—
Human Services Legislation Amendment Act 2005	111, 2005	6 Sept 2005	Schedule 2 (items 551–605): 1 Oct 2005	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Medical Indemnity Legislation Amendment (Competitive Neutrality) Act 2005	126, 2005	19 Oct 2005	Schedule 1 (item 14): 1 July 2005	—
National Health Amendment (Immunisation Program) Act 2005	140, 2005	18 Nov 2005	Schedule 1: 1 Jan 2006 (*see* F2005L04086) Remainder: Royal Assent	Sch. 1 (item 9)
National Health Amendment (Budget Measures—Pharmaceutical Benefits Safety Net) Act 2005	151, 2005	14 Dec 2005	Schedule 1 (items 3–11, 13) and Schedule 2 (items 8, 9): 1 Jan 2006 Schedule 2 (items 10, 11): 1 Jan 2007 Schedule 2 (items 12, 13): 1 Jan 2008 Schedule 2 (items 14, 15): 1 Jan 2009 Schedule 2 (items 16–18): 31 Dec 2009 Remainder: Royal Assent	Sch. 1 (item 13)
Health Legislation Amendment Act 2005	155, 2005	19 Dec 2005	Schedule 2: 20 Dec 2005 Schedule 4: 1 Oct 2005 Remainder: Royal Assent	—
Health Legislation Amendment (Pharmacy Location Arrangements) Act 2006	37, 2006	3 May 2006	Sch 1 (items 3, 4) and Sch 2: 1 July 2006 (s 2(1) items 3, 5) Sch 1 (items 5, 6): 1 July 2000 (s 2(1) item 4) Remainder: 3 May 2006 (s 2(1) items 1, 2)	Sch 2 (item 13)
National Health and Medical Research Council Amendment Act 2006	50, 2006	9 June 2006	Schedule 1 (item 114): 1 July 2006	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment (Private Health Insurance) Act 2006	83, 2006	30 June 2006	1 July 2006	—
Privacy Legislation Amendment Act 2006	99, 2006	14 Sept 2006	14 Sept 2006	—
National Health Amendment (Immunisation) Act 2006	105, 2006	27 Sept 2006	27 Sept 2006	—
Australian Participants in British Nuclear Tests (Treatment) (Consequential Amendments and Transitional Provisions) Act 2006	136, 2006	30 Nov 2006	Schedules 1 and 2: 1 Dec 2006 (*see* s. 2(1)) Remainder: Royal Assent	Sch. 2 (items 1, 2)
Medibank Private Sale Act 2006	160, 2006	11 Dec 2006	Schedule 1 (items 4–7): 12 Dec 2006	—
Statute Law Revision Act 2007	8, 2007	15 Mar 2007	Schedule 4 (item 21): Royal Assent	—
Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007	32, 2007	30 Mar 2007	s 4–54, Sch 1 (items 4–59) and Sch 2 (items 81–103): 1 Apr 2007 (s 2(1) items 2, 3, 7)	s 4–54
National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007	111, 2007	28 June 2007	1 Aug 2007	Sch. 1 (items 94–100)
National Health Amendment (National HPV Vaccination Program Register) Act 2007	135, 2007	20 Aug 2007	20 Aug 2007	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment (Pharmaceutical Benefits) Act 2007	169, 2007	28 Sept 2007	Schedule 1 (items 12, 13, 36, 43): 1 Jan 2008 Schedule 2: 29 Sept 2007 Remainder: Royal Assent	Sch. 2 (item 21)
Health Legislation Amendment Act 2007	180, 2007	28 Sept 2007	Sch 2 (items 1–6, 8–11): 1 Aug 2007 (s 2(1) items 6, 8) Sch 2 (item 7): 28 Sept 2007 (s 2(1) item 7)	—
National Health Amendment (Pharmaceutical Benefits Scheme) Act 2008	49, 2008	25 June 2008	Schedule 2: 26 June 2008 Remainder: Royal Assent	Sch. 1 (item 6), Sch. 3 (item 3) and Sch. 4 (item 6)
Same-Sex Relationships (Equal Treatment in Commonwealth Laws—General Law Reform) Act 2008	144, 2008	9 Dec 2008	Schedule 9 (items 15–29): 1 Jan 2009	—
Customs Legislation Amendment (Name Change) Act 2009	33, 2009	22 May 2009	Schedule 2 (items 43–45): 23 May 2009	—
Fair Work (State Referral and Consequential and Other Amendments) Act 2009	54, 2009	25 June 2009	Sch 11 (items 5–9): 1 July 2009 (s 2(1) item 33)	—
National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Act 2009	71, 2009	22 July 2009	Schedule 1: 1 July 2008 Remainder: Royal Assent	—
Statute Stocktake (Regulatory and Other Laws) Act 2009	111, 2009	16 Nov 2009	Schedule 2 (item 13): 17 Nov 2009	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010	29, 2010	12 Apr 2010	Schedule 1 (items 67–112): 13 Apr 2010 Schedule 2 (items 19–21): 1 July 2010 (*see* s. 2(1))	—
as amended by				
Statute Law Revision Act 2012	136, 2012	22 Sept 2012	Sch 2 (items 19, 20): 13 Apr 2010 (s 2(1) item 18)	—
Freedom of Information Amendment (Reform) Act 2010	51, 2010	31 May 2010	Sch 5 (items 39–46) and Sch 7: 1 Nov 2010 (s 2(1) item 7)	Sch 7
Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act 2010	63, 2010	28 June 2010	Schedule 1: Royal Assent	—
National Health Amendment (Continence Aids Payment Scheme) Act 2010	68, 2010	28 June 2010	Schedule 1: 1 July 2010 Remainder: Royal Assent	Sch. 1 (item 3)
National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010	126, 2010	23 Nov 2010	Schedule 1: 1 Feb 2011 Schedules 2–4, Schedule 6 (items 1–27, 30–33) and Schedule 7: 1 Dec 2010 Schedule 5: 1 Apr 2012	Sch. 4 (item 20) and Sch. 6 (items 30–33)
Statute Law Revision Act 2011	5, 2011	22 Mar 2011	Schedule 5 (items 145–154), Schedule 6 (items 70–78) and Schedule 7 (items 99, 100): 19 Apr 2011	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Human Services Legislation Amendment Act 2011	32, 2011	25 May 2011	Sch 4 (items 419–467): 1 July 2011 (s 2(1) item 3) Sch 4 (item 654): 1 Apr 2012 (s 2(1) item 7)	—
Acts Interpretation Amendment Act 2011	46, 2011	27 June 2011	Schedule 2 (items 798–806) and Schedule 3 (items 10, 11): 27 Dec 2011	Sch. 3 (items 10, 11)
Aged Care Amendment Act 2011	86, 2011	26 July 2011	Schedule 3 (items 20–55): 27 July 2011	—
National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012	8, 2012	20 Mar 2012	Schedules 1–3: 1 July 2012	Sch. 1 (item 3) and Sch. 3 (item 4)
Personally Controlled Electronic Health Records (Consequential Amendments) Act 2012	64, 2012	26 June 2012	Schedule 1 (items 31–34): 29 June 2012 (*see* F2012L01398)	—
National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012	87, 2012	28 June 2012	1 Oct 2012 (s 2)	Sch 1 (items 66–81), Sch 2 (item 6) and Sch 3 (items 16–18)
Statute Law Revision Act 2012	136, 2012	22 Sept 2012	Sch 1 (items 90–92): 22 Sept 2012 (s 2(1) item 2) Sch 5 (items 6–9): 20 Oct 2012 (s 2(1) item 36)	—
Fair Work Amendment Act 2012	174, 2012	4 Dec 2012	Sch 9 (items 1282–1287): 1 Jan 2013 (s 2(1) item 5)	—

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
Privacy Amendment (Enhancing Privacy Protection) Act 2012 (C2012A00197)	197, 2012	12 Dec 2012	sch 5 (items 58-62, 165-177), sch 6 (items 15-19): 12 Mar 2014 (s 2(1) items 3, 13, 19) sch 6 (item 1): 12 Dec 2012 (s 2(1) item 16)	sch 6 (items 1, 15-19)
National Health Amendment (Simplified Price Disclosure) Act 2014 (C2014A00006)	6, 2014	13 Mar 2014	13 Mar 2014 (s 2)	sch 1 (item 3)
Public Governance, Performance and Accountability (Consequential and Transitional Provisions) Act 2014 (C2014A00062)	62, 2014	30 June 2014	sch 10 (item 85), sch 14: 1 July 2014 (s 2(1) items 6, 14)	sch 14

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
as amended by				
Public Governance and Resources Legislation Amendment Act (No. 1) 2015 (C2015A00036)	36, 2015	13 Apr 2015	sch 2 (items 7-9), sch 7: 14 Apr 2015 (s 2)	sch 7
as amended by				
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015 (C2015A00126)	126, 2015	10 Sept 2015	sch 1 (item 486): 5 Mar 2016 (s 2(1) item 2)	—
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015 (C2015A00126)	126, 2015	10 Sept 2015	sch 1 (item 495): 5 Mar 2016 (s 2(1) item 2)	—
Statute Law Revision Act (No. 1) 2015 (C2015A00005)	5, 2015	25 Feb 2015	sch 1 (item 32), sch 3 (items 127-131): 25 Mar 2015 (s 2(1) items 2, 10)	—
Acts and Instruments (Framework Reform) Act 2015 (C2015A00010)	10, 2015	5 Mar 2015	sch 3 (items 274-299, 348, 349): 5 Mar 2016 (s 2(1) item 2)	sch 3 (items 348, 349)
Customs and Other Legislation Amendment (Australian Border Force) Act 2015 (C2015A00041)	41, 2015	20 May 2015	sch 5 (items 102-106), sch 6 (items 141-147), sch 9: 1 July 2015 (s 2(1) items 2, 7)	sch 6 (item 147), sch 9

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as amended by				
Australian Border Force Amendment (Protected Information) Act 2017 (C2017A00115)	115, 2017	30 Oct 2017	sch 1 (item 26): 1 July 2015 (s 2(1) item 2)	—
Norfolk Island Legislation Amendment Act 2015 (C2015A00059)	59, 2015	26 May 2015	sch 1 (item 145), sch 2 (items 356-396): 18 June 2015 (s 2(1) items 2, 6) sch 1 (items 184-203): 27 May 2015 (s 2(1) item 3) sch 2 (items 265-271): 1 July 2016 (s 2(1) item 5)	sch 1 (items 184-203), sch 2 (items 356-396)
as amended by				
Territories Legislation Amendment Act 2016 (C2016A00033)	33, 2016	23 Mar 2016	sch 2: 24 Mar 2016 (s 2(1) item 2)	—
Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015 (C2015A00062)	62, 2015	16 June 2015	sch 2 (item 36), sch 4: 16 June 2016 (s 2(1) items 2, 4) sch 3: 16 June 2015 (s 2(1) item 3)	sch 3, sch 4

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
as amended by				
Statute Update (Winter 2017) Act 2017 (C2017A00093)	93, 2017	23 Aug 2017	sch 2 (item 9): 20 Sept 2017 (s 2(1) item 4)	—
National Health Amendment (Pharmaceutical Benefits) Act 2015 (C2015A00089)	89, 2015	26 June 2015	sch 1: 27 June 2015 (s 2(1) item 2) sch 2: 1 Nov 2015 (s 2(1) item 3) sch 3: 1 Jan 2016 (s 2(1) item 4) Remainder: 26 June 2015 (s 2(1) item 1)	sch 1 (item 40)
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015 (C2015A00126)	126, 2015	10 Sept 2015	sch 1 (item 400): 5 Mar 2016 (s 2(1) item 2)	—
Australian Immunisation Register (Consequential and Transitional Provisions) Act 2015 (C2015A00139)	139, 2015	12 Nov 2015	sch 1 (items 12, 13): 1 Jan 2016 (s 2(1) item 2) sch 3 (items 4-6): 1 Jan 2017 (s 2(1) item 4)	—
Statute Law Revision Act (No. 2) 2015 (C2015A00145)	145, 2015	12 Nov 2015	sch 4 (item 32): 10 Dec 2015 (s 2(1) item 7)	—
Health Legislation Amendment (eHealth) Act 2015 (C2015A00157)	157, 2015	26 Nov 2015	sch 2 (items 11–14), sch 3 (item 3): 27 Nov 2015 (s 2(1) item 2)	—
Statute Law Revision Act (No. 1) 2016 (C2016A00004)	4, 2016	11 Feb 2016	sch 4 (items 1, 219): 10 Mar 2016 (s 2(1) item 6)	—

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
Statute Update Act 2016 (C2016A00061)	61, 2016	23 Sept 2016	sch 1 (items 335-345), sch 3 (item 32): 21 Oct 2016 (s 2(1) item 1)	—
Statute Law Revision (Spring 2016) Act 2016 (C2016A00067)	67, 2016	20 Oct 2016	sch 4 (items 2-4): 17 Nov 2016 (s 2(1) item 7)	—
National Health Amendment (Pharmaceutical Benefits) Act 2017 (C2017A00016)	16, 2017	28 Mar 2017	29 Mar 2017 (s 2(1) item 1)	sch 1 (items 7, 12)
Veterans' Affairs Legislation Amendment (Budget Measures) Act 2017 (C2017A00059)	59, 2017	22 June 2017	sch 1 (items 36-39): 1 July 2017 (s 2(1) item 4)	—
Medicare Guarantee (Consequential Amendments) Act 2017 (C2017A00072)	72, 2017	26 June 2017	sch 1 (items 3-6): 3 July 2017 (s 2(1) item 2)	sch 1 (item 6)
Veterans' Affairs Legislation Amendment (Omnibus) Act 2017 (C2017A00128)	128, 2017	30 Nov 2017	sch 5A: 1 Dec 2017 (s 2(1) item 10)	—

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018 (C2018A00001)	1, 2018	20 Feb 2018	sch 1 (items 1-47): 1 Oct 2018 (s 2(1) item 2) sch 1 (items 48-87), sch 2 (items 19, 20), sch 3 (items 8-12), sch 4 (items 9-15): repealed before commencing (s 2(1) items 3, 5, 7, 9) sch 2 (items 1-18), sch 3 (items 1-7), sch 4 (items 1-8), sch 5-9: 21 Feb 2018 (s 2(1) items 4, 6, 8, 10)	sch 3 (item 7), sch 7 (item 24)
as amended by				
National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021 (C2021A00139)	139, 2021	13 Dec 2021	sch 1 (items 1-3A): 14 Dec 2021 (s 2(1) item 2)	
Health Legislation Amendment (Improved Medicare Compliance and Other Measures) Act 2018 (C2018A00064)	64, 2018	29 June 2018	sch 5: 1 July 2018 (s 2(1) item 3)	sch 5 (item 7)
Treatment Benefits (Special Access) (Consequential Amendments and Transitional Provisions) Act 2019 (C2019A00042)	42, 2019	5 Apr 2019	sch 2 (items 14-18): 6 Apr 2019 (s 2(1) item 2)	—

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Endnote 3—Legislation history

Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment (Pharmaceutical Benefits) Act 2019 (C2019A00077)	77, 2019	2 Oct 2019	sch 1: 2 Dec 2019 (s 2(1) item 2) sch 2: 5 Dec 2019 (s 2(1) item 3)	sch 1 (item 7), sch 2 (item 8)
Medical and Midwife Indemnity Legislation Amendment Act 2019 (C2019A00105)	105, 2019	28 Nov 2019	sch 1 (items 53, 54): 1 July 2020 (s 2(1) item 2)	sch 1 (item 54)
National Health Amendment (Safety Net Thresholds) Act 2019 (C2019A00106)	106, 2019	28 Nov 2019	1 Jan 2020 (s 2(1) item 1)	—
Health Legislation Amendment (Data-matching and Other Matters) Act 2019 (C2019A00121)	121, 2019	12 Dec 2019	sch 1 (items 1-5): 13 Dec 2019 (s 2(1) item 1)	sch 1 (item 4)
National Emergency Declaration (Consequential Amendments) Act 2020 (C2020A00129)	129, 2020	15 Dec 2020	sch 1 (item 30): 16 Dec 2020 (s 2(1) item 2)	—
Federal Circuit and Family Court of Australia (Consequential Amendments and Transitional Provisions) Act 2021 (C2021A00013)	13, 2021	1 Mar 2021	sch 2 (item 616): 1 Sept 2021 (s 2(1) item 5)	—

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Endnote 3—Legislation history

Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment (Decisions under the Continence Aids Payment Scheme) Act 2021 (C2021A00102)	102, 2021	10 Sept 2021	11 Sept 2021 (s 2(1) item 1)	sch 1 (item 2)
National Health Amendment (COVID-19) Act 2021 (C2021A00108)	108, 2021	13 Sept 2021	13 Sept 2021 (s 2(1) item 1)	—
National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021 (C2021A00139)	139, 2021	13 Dec 2021	sch 1 (items 4-83): 1 July 2022 (s 2(1) item 3) sch 1 (items 84, 85): 1 Oct 2022 (s 2(1) item 4) sch 1 (items 86, 87): 1 July 2023 (s 2(1) item 5) sch 1 (items 87A-126): 1 July 2027 (s 2(1) item 6)	—
Treasury Laws Amendment (Cost of Living Support and Other Measures) Act 2022 (C2022A00014)	14, 2022	31 Mar 2022	sch 7 (items 1, 2): 1 July 2022 (s 2(1) item 8)	—
National Health Amendment (General Co-payment) Act 2022 (C2022A00053)	53, 2022	9 Nov 2022	sch 1: 1 Jan 2023 (s 2(1) item 2) sch 2: 1 July 2023 (s 2(1) item 3)	sch 1 (item 16)
Health Legislation Amendment (Medicare Compliance and Other Measures) Act 2022 (C2022A00077)	77, 2022	5 Dec 2022	sch 1 (items 55-57, 88-97, 103-108): 6 Dec 2022 (s 2(1) item 1)	sch 1 (items 57, 97, 108)

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Endnote 3—Legislation history

Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
National Health Amendment (Effect of Prosecution—Approved Pharmacist Corporations) Act 2023 (C2023A00016)	16, 2023	11 Apr 2023	12 Apr 2023 (s 2(1) item 1)	sch 1 (item 7)
Health Legislation Amendment (Removal of Requirement for a Collaborative Arrangement) Act 2024 (C2024A00033)	33, 2024	31 May 2024	sch 1 (items 5, 6): 1 Nov 2024 (s 2(1) item 2)	—
Administrative Review Tribunal (Consequential and Transitional Provisions No. 2) Act 2024 (C2024A00039)	39, 2024	31 May 2024	sch 9 (items 113-150): 14 Oct 2024 (s 2(1) item 2)	—
National Health Amendment (Supporting Patient Access to Cheaper Medicines and Other Measures) Act 2024 (C2024A00073)	73, 2024	9 July 2024	sch 1, 2: 10 July 2024 (s 2(1) items 2, 3)	sch 1 (items 33, 34)
National Health Amendment (Technical Changes to Averaging Price Disclosure Threshold and Other Matters) Act 2024 (C2024A00088)	88, 2024	26 Sept 2024	sch 1: 1 July 2022 (s 2(1) item 2)	sch 1 (item 6)
Privacy and Other Legislation Amendment Act 2024 (C2024A00128)	128, 2024	10 Dec 2024	sch 1 (items 81, 86): 11 Dec 2024 (s 2(1) item 6)	sch 1 (item 86)

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Endnote 3—Legislation history

Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
Health Legislation Amendment (Modernising My Health Record—Sharing by Default) Act 2025 (C2025A00008)	8, 2025	14 Feb 2025	sch 2 (items 17-21): 15 Feb 2025 (s 2(1) item 7)	—
Veterans' Entitlements, Treatment and Support (Simplification and Harmonisation) Act 2025 (C2025A00017)	17, 2025	20 Feb 2025	sch 8 (item 55): 1 July 2026 (s 2(1) item 6)	—
Health Legislation Amendment (Improved Medicare Integrity and Other Measures) Act 2025 (C2025A00038)	38, 2025	4 Sept 2025	sch 1 (items 14-26): 5 Sept 2025 (s 2(1) item 5)	sch 1 (items 23, 26)
National Health Amendment (Cheaper Medicines) Act 2025 (C2025A00039)	39, 2025	4 Sept 2025	1 Jan 2026 (s 2(1) item 1)	—
Aged Care and Other Legislation Amendment Act 2025 (C2025A00045)	45, 2025	19 Sept 2025	sch 3 (item 245): 1 Nov 2025 (s 2(1) item 6)	—
Regulatory Reform Omnibus Act 2025 (C2025A00073)	73, 2025	4 Dec 2025	sch 2 (items 28-36, 115-158): 5 Dec 2025 (s 2(1) item 9)	sch 2 (items 34-36, 156-158)
National Health Amendment (Passive Immunological Products) Act 2026 (C2026A00034)	34, 2026	8 Apr 2027	9 Apr 2026 (s 2(1) item 1)	—

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Endnote 3—Legislation history

Number and year	Registration or gazettal	Commencement	Application, saving and transitional provisions
310, 1991	16 Oct 1991	r 3: 16 Oct 1991	—
274, 1993	1 Nov 1993	1 Nov 1993 (r 2)	—
50, 2006	17 Mar 2006 (F2006L00820)	Sch 44: 27 Mar 2006 (r 2(b))	—

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Endnote 4—Amendment history

Provision affected	How affected
Long Title	rs. No. 94, 1986
Part I	
s. 1	am. No. 94, 1986
s. 2	am. No. 60, 1976
s. 3	am. No. 68, 1955; No. 68, 1958; No. 82, 1962; No. 100, 1968; No. 102, 1969; No. 41, 1970; No. 114, 1972
	rep. No. 202, 1973
s 4	am No 68, 1955; No 92, 1957; No 82, 1962; No 37, 1964; No 100, 1965; No 44, 1966; No 14, 1967; No 100, 1968; No 41, 1970; No 114, 1972; No 202, 1973; No 1, 1975; No 60, 1976 (as am by No 91, 1976); No 91, 1976; No 99, 1976; No 108, 1976; No 100, 1977; No 132, 1978; No 54, 1979;No 122, 1979; No 131, 1980; No 118, 1981; No 176, 1981; No 49, 1982;No 80, 1982; No 112, 1982; No 54, 1983; No 139, 1983; No 63, 1984; No 135, 1984; No 65, 1985; No 70, 1985; No 127, 1985; No 28, 1986; No 75, 1986; No 94, 1986; No 115, 1986; No 22, 1987; No 44, 1987; No 72, 1987; No 131, 1987; No 79, 1988; No 95, 1989; No 164, 1989; No 3, 1990; No 6, 1991; No 68, 1991; No 70, 1991; No 73, 1991; No 83, 1991; No 116, 1991; No 141, 1991; No 175, 1991; No 211, 1991; No 81, 1992; No 88, 1992; No 136, 1992; No 192, 1992 (as am by No 12, 1994); No 204, 1992; No 230, 1992; No 12, 1994; No 116, 1994; No 164, 1994; No 174, 1994; No 184, 1994; No 41, 1995; No 105, 1995; No 149, 1995; No 1, 1996; No 79, 1996; No 84, 1996; No 114, 1997; No 197, 1997; No 45, 1998; No 44, 1999; No 118, 1999; No 146, 1999; No 130, 1999; No 159, 1999; No 72, 2000; No 6, 2001; No 80, 2001; No 69, 2003; No 52, 2004; No 117, 2004; No 31, 2005; No 111, 2005; No 140, 2005; No 155, 2005; No 136, 2006; Nos 8, 2007; No 32, 2007; No 111, 2007; No 169, 2007; No 144, 2008; No 29, 2010; No 5, 2011; No 32, 2011; No 46, 2011; No 86, 2011; No 136, 2012; No 62, 2014; No 64, 2018; No 17, 2025; No 73, 2025; No 34, 2026
s. 4AAAA	ad. No. 83, 1991
	rep. No. 114, 1997
s. 4AAA	ad. No. 6, 1991

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 81, 1992; No. 1, 1996
	rep. No. 80, 2001
s. 4AAAB	ad. No. 105, 1995
	am. No. 1, 1996
	rep. No. 80, 2001
s. 4AA	ad. No. 135, 1984
	am. Nos. 95 and 127, 1985; Nos. 28 and 94, 1986; No. 72, 1987; No. 155, 1988; No. 141, 1990; No. 88, 1992; No. 12, 1994
	rep. No. 86, 2011
s. 4A	ad. No. 132, 1978
	am. No. 118, 1981; No. 54, 1983; No. 94, 1986; No. 79, 1988; No. 41, 1995
	rep. No. 41, 1995
s. 4B	ad. No. 95, 1989
	rep. No. 41, 1995
s. 4C	ad. No. 95, 1989
	am. No. 211, 1991
	rep. No. 41, 1995
s. 4D	ad. No. 95, 1989
	rep. No. 41, 1995
s. 5	am. No. 202, 1973; No. 91, 1976
	rep. No. 74, 1981
	ad. No. 70, 1985
	am. No. 167, 1985; No. 99, 1988
	rs. No. 95, 1989
	rep. No. 41, 1995
s. 5A	ad. No. 41, 1995
	am. No. 41, 1995
	rep. No. 32, 2007
s. 5AB	ad. No. 21, 1999
	rep. No. 32, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 5B	ad. No. 41, 1995
	am. No. 117, 2004
	rep. No. 32, 2007
ss. 5C–5E	ad. No. 6, 2001
	rep. No. 32, 2007
ss. 5F, 5G	ad. No. 31, 2005
	rep. No. 32, 2007
s 6	am No 68, 1955
	rs No 202, 1973
	am No 91, 1976
	rs No 139, 1983
	am No 63, 1984; No 167, 1985; No 94, 1986; No 6, 2001; No 37, 2006; No 32, 2007; No 68, 2010; No 77, 2019; No 121, 2019; No 38, 2025
s. 6A	ad. No. 46, 1984
	am. No. 120, 1984; No 59, 2015
s. 7	rep. No. 41, 1970
	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 7A	ad. No. 111, 2001
Part II	
s. 8	rep. No. 41, 1970
	ad. No. 202, 1973
	rep. No. 91, 1976
	ad. No. 94, 1986
s. 9	am. No. 98, 1977; No. 94, 1986
s. 9A	ad. No. 37, 1964
	am. No. 100, 1967; Nos. 49 and 202, 1973
	rs. No. 1, 1975
	am. No. 135, 1984; No. 94, 1986; No. 169, 1991

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Endnote 4—Amendment history

Provision affected	How affected
s. 9B	ad. No. 37, 1964
	rs. No. 100, 1968; No. 41, 1970
	am. No. 49, 1982; No. 94, 1986
	rs. No. 140, 2005
	am. No. 105, 2006; No 62, 2015
s. 9BA	ad. No. 135, 2007
	am. No. 144, 2008; No 197, 2012; No 139, 2015
	rep No 139, 2015
s. 9C	ad. No. 135, 1984
	am. No. 94, 1986
ss. 10, 11	am. No. 94, 1986
Part III	
Part III	rep. No. 60, 1976
	ad. No. 88, 1978
	rep. No. 94, 1986
	ad. No. 68, 2010
s. 11A	ad. No. 202, 1973
	rep. No. 91, 1976
s 12	rep No 60, 1976
	ad No 88, 1978
	am No 54, 1979; No 118, 1981; No 54, 1983; No 139, 1983; No 63, 1984; No 167, 1985
	rep No 94, 1986
	ad No 68, 2010
	am No 32, 2011; No 102, 2021; No 39, 2024
s. 13	am. No. 16, 1961; No. 37, 1964; No. 102, 1969; No. 41, 1970; No. 202, 1973; No. 1, 1975; No. 1, 1976
	rep. No. 60, 1976
	ad. No. 88, 1978
	am. No. 54, 1979; No. 118, 1981; No. 139, 1983; No. 63, 1984
	rep. No. 94, 1986

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Endnote 4—Amendment history

Provision affected	How affected
	ad. No. 68, 2010
	am. No. 32, 2011
s. 13AA	ad. No. 1, 1976
	rep. No. 60, 1976
s. 13A	ad. No. 41, 1970
	am. No. 202, 1973; No. 1, 1975
	rep. No. 60, 1976
s 14	rs No 72, 1959
	am No 37, 1964; No 102, 1969; No 41, 1970; No 1, 1976
	rep No 60, 1976
	ad No 88, 1978
	am No 54, 1979; No 118, 1981; No 139, 1983; No 63, 1984
	rep No 94, 1986
	ad No 68, 2010
	am No 32, 2011; No 39, 2024
s 15	am No 68, 1955
	rep No 72, 1959
	ad No 88, 1978
	am No 63, 1984
	rep No 94, 1986
	ad No 68, 2010
	am No 32, 2011; No 39, 2024
s. 15A	ad. No. 55, 1956
	am. No. 72, 1959; No. 37, 1964; No. 44, 1966
	rep. No. 41, 1970
s. 16A	ad. No. 41, 1970
	am. No. 114, 1972
	rep. No. 60, 1976
s. 16	am. No. 72, 1959; No. 16, 1961; No. 37, 1964; No. 44, 1966
	rs. No. 41, 1970
	rep. No. 60, 1976

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Endnote 4—Amendment history

Provision affected	How affected
	ad. No. 88, 1978
	am. No. 63, 1984
	rep. No. 94, 1986
s. 17	am. No. 92, 1957; No. 37, 1964; No. 41, 1970; No. 202, 1973
	rep. No. 60, 1976
	ad. No. 88, 1978
	am. No. 131, 1980; Nos. 54 and 139, 1983
	rep. No. 94, 1986
s. 17A	ad. No. 202, 1973
	rep. No. 60, 1976
s. 18	am. No. 37, 1964; No. 41, 1970; No. 202, 1973
	rep. No. 60, 1976
	ad. No. 88, 1978
	am. No. 131, 1980; No. 139, 1983; No. 63, 1984
	rep. No. 94, 1986
s. 18A	ad. No. 68, 1958
	am. No. 102, 1969
	rs. No. 41, 1970
	rep. No. 60, 1976
	ad. No. 139, 1983
	am. No. 63, 1984
	rep. No. 94, 1986
s. 19	am. No. 55, 1956; No. 92, 1957; No. 82, 1962; No. 37, 1964; No. 100, 1967; No. 41, 1970; No. 114, 1972; No. 202, 1973
	rep. No. 60, 1976
	ad. No. 88, 1978
	rep. No. 94, 1986
s. 20	am. No. 95, 1956; No. 82, 1962
	rep. No. 60, 1976
	ad. No. 88, 1978
	rs. No. 54, 1979; No. 131, 1980

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 118, 1981; No. 112, 1982; No. 63, 1984
	rep. No. 94, 1986
s. 21	rs. No. 82, 1962
	am. No. 41, 1970; No. 202, 1973
	rep. No. 60, 1976
	ad. No. 88, 1978
	rep. No. 94, 1986
s. 22	rs. No. 146, 1965
	am. No. 44, 1966
	rep. No. 60, 1976
	ad. No. 88, 1978
	am. No. 54, 1979
	rep. No. 94, 1986
s. 23	am. No. 37, 1964; No. 102, 1969; No. 41, 1970
	rep. No. 60, 1976
s. 24	am. No. 202, 1973
	rep. No. 60, 1976
s. 25	am. No. 37, 1964; No. 102, 1969
	rep. No. 60, 1976
s. 26	rs. No. 68, 1955
	am. No. 202, 1973
	rep. No. 60, 1976
s. 27	am. No. 202, 1973
	rep. No. 60, 1976
s. 28	rs. No. 41, 1970
	rep. No. 60, 1976
s. 29	am. No. 202, 1973
	rep. No. 60, 1976
ss. 29A–29C	ad. No. 41, 1970
	rep. No. 60, 1976
ss. 29D, 29E	ad. No. 41, 1970

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 202, 1973
	rep. No. 60, 1976
s. 29F	ad. No. 41, 1970
	rep. No. 60, 1976
s. 30	rs. No. 68, 1958
	am. No. 44, 1966; No. 102, 1969
	rep. No. 60, 1976
Part IV	rep. No. 60, 1976
s. 31	rep. No. 82, 1962
	ad. No. 202, 1973
	rep. No. 91, 1976
s. 32	am. No. 82, 1962; No. 41, 1970; No. 202, 1973
	rep. No. 60, 1976
s. 33	am. No. 82, 1962; No. 202, 1973
	rep. No. 60, 1976
s. 34	rs. No. 68, 1955
	am. No. 82, 1962
	rep. No. 60, 1976
s. 35	am. No. 68, 1955
	rep. No. 60, 1976
s. 36	rep. No. 68, 1955
s. 37	am. No. 68, 1955; No. 202, 1973
	rep. No. 60, 1976
s. 37A	ad. No. 68, 1955
	am. No. 44, 1966
	rep. No. 60, 1976
Heading to Part V	am. No. 60, 1976
	rs. No. 100, 1977
	rep. No. 86, 2011
Part V	rs. No. 82, 1962
	rep. No. 86, 2011

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Provision affected	How affected
Div. 1 of Part V	rep. No. 100, 1977
s. 38	am. No. 68, 1955
	rs. No. 82, 1962
	am. No. 44, 1966; No. 102, 1969; No. 41, 1970; No. 202, 1973; Nos. 1, 60, 91 and 99, 1976
	rep. No. 100, 1977
s. 38A	ad. No. 1, 1976
	rep. No. 60, 1976
s. 39	am. No. 92, 1957; No. 68, 1958
	rs. No. 82, 1962
	am. No. 100, 1968; No. 1, 1975; No. 60, 1976
	rs. No. 100, 1977
	am. No. 176, 1981; No. 139, 1983
	rs. No. 115, 1986
	am. No. 72, 1987; No. 155, 1988; Nos. 3 and 141, 1990; Nos. 83 and 211, 1991; No. 200, 1992; No. 114, 1997
	rep. No. 86, 2011
s. 39AAA	ad. No. 155, 1988
	rep. No. 114, 1997
s. 39AA	ad. No. 115, 1986
	am. No. 72, 1987
	rep. No. 114, 1997
s. 39A	ad. No. 139, 1983
	am. Nos. 94 and 115, 1986; No. 72, 1987; No. 79, 1988
	rep. No. 114, 1997
s. 39AB	ad. No. 155, 1988
	am. No. 83, 1991
	rep. No. 114, 1997
ss. 39AC, 39AD	ad. No. 83, 1991
	rep. No. 114, 1997
s. 39B	ad. No. 132, 1987

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 88, 1992
	rep. No. 114, 1997
ss. 39BA, 39BB	ad. No. 3, 1990
	am. No. 88, 1992
	rep. No. 114, 1997
Heading to Div. 2 of Part V	rep. No. 100, 1977
s. 40	rs. No. 82, 1962
	am. No. 114, 1972; No. 202, 1973
	rep. No. 60, 1976
s. 40AA	ad. No. 114, 1972
	am. No. 202, 1973; No. 1, 1975; No. 100, 1977; No. 117, 1980; No. 118, 1981; Nos. 35 and 139, 1983; Nos. 63 and 135, 1984; No. 95, 1985; Nos. 94 and 115, 1986; Nos. 72 and 132, 1987; Nos. 79 and 155, 1988; Nos. 3 and 141, 1990; Nos. 83 and 84, 1991; Nos. 88 and 204, 1992; No. 12, 1994; No. 114, 1997
	rep. No. 86, 2011
s. 40AAA	ad. No. 155, 1988
	rep. No. 114, 1997
s. 40AB	ad. No. 114, 1972
	am. No. 202, 1973; No. 117, 1980; No. 139, 1983; No. 135, 1984; Nos. 94 and 115, 1986; Nos. 72 and 132, 1987; No. 79, 1988; No. 3, 1990; No. 114, 1997
	rep. No. 86, 2011
s. 40ABB	ad. No. 3, 1990
	am. No. 141, 1990
	rep. No. 114, 1997
s. 40ABA	ad. No. 135, 1984
	am. Nos. 94 and 115, 1986; No. 132, 1987
	rep. No. 3, 1990
s. 40AC	ad. No. 114, 1972
	am. No. 202, 1973
	rep. No. 139, 1983

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Provision affected	How affected
	ad. No. 72, 1987
	am. No. 114, 1997
	rep. No. 86, 2011
s. 40AD	ad. No. 114, 1972
	am. No. 202, 1973; No. 139, 1983; Nos. 63 and 135, 1984; No. 65, 1985; Nos. 94 and 115, 1986; Nos. 72 and 132, 1987; Nos. 79 and 155, 1988; No. 211, 1991; No. 149, 1995
	rep. No. 114, 1997
s. 40ADA	ad. No. 79, 1988
	am. No. 95, 1989
	rep. No. 149, 1995
s. 40ADB	ad. No. 155, 1988
	am. Nos. 83 and 211, 1991
	rep. No. 114, 1997
s. 40AE	ad. No. 114, 1972
	am. No. 202, 1973; Nos. 35 and 139, 1983; No. 63, 1984; No. 94, 1986 (as am. by No. 141, 1987); Nos. 72 and 132, 1987
	rs. No. 155, 1988
	am. No. 149, 1995; No. 114, 1997
	rep. No. 86, 2011
ss. 40AEA, 40AEB	ad. No. 155, 1988
	am. No. 114, 1997
	rep. No. 86, 2011
s. 40AEC	ad. No. 155, 1988
	am. No. 141, 1990; No. 114, 1997
	rep. No. 86, 2011
ss. 40AED–40AEF	ad. No. 155, 1988
	rep. No. 86, 2011
ss. 40AEG, 40AEH	ad. No. 155, 1988
	am. No. 114, 1997
	rep. No. 86, 2011

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Endnote 4—Amendment history

Provision affected	How affected
s. 40AF	ad. No. 100, 1977
	am. No. 139, 1983; No. 63, 1984; No. 94, 1986; No. 79, 1988
	rep. No. 86, 2011
s. 40AFA	ad. No. 79, 1988
	am. No. 192, 1992
	rep. No. 114, 1997
ss. 40AFB, 40AFC	ad. No. 79, 1988
	rep. No. 114, 1997
s. 40AFD	ad. No. 79, 1988
	am. No. 95, 1989; No. 211, 1991; No. 88, 1992
	rep. No. 114, 1997
s. 40AFDA	ad. No. 211, 1991
	rep. No. 114, 1997
s. 40AFE	ad. No. 79, 1988
	am. No. 95, 1989; No. 192, 1992
	rep. No. 114, 1997
s. 40AFF	ad. No. 79, 1988
	am. No. 192, 1992
	rep. No. 114, 1997
ss. 40AFG, 40AFH, 40AFJ	ad. No. 95, 1989
	rep. No. 114, 1997
s. 40AFK	ad. No. 95, 1989
	rep. No. 86, 2011
s. 40AG	ad. No. 100, 1977
	rep. No. 118, 1981
	ad. No. 72, 1987
	am. Nos. 79 and 155, 1988; No. 114, 1997
	rep. No. 86, 2011
s. 40AGA	ad. No. 79, 1988
	am. No. 155, 1988; No. 83, 1991; No. 114, 1997
	rep. No. 86, 2011

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Provision affected	How affected
s. 40AH	ad. No. 72, 1987
	am. No. 83, 1991; No. 114, 1997
	rep. No. 86, 2011
s. 40AI	ad. No. 79, 1988
	rep. No. 86, 2011
s. 40A	ad. No. 100, 1968
	am. No. 202, 1973
	rep. No. 1, 1975
s. 41	rs. No. 82, 1962
	am. No. 44, 1966
	rs. No. 100, 1968
	am. No. 114, 1972; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976
	am. No. 139, 1983; No. 65, 1985; No. 115, 1986; Nos. 72 and 132, 1987; No. 211, 1991
	rep. No. 86, 2011
s. 42	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976; No. 139, 1983
	am. No. 135, 1984; No. 65, 1985; No. 94, 1986; No. 132, 1987; No. 211, 1991
	rep. No. 86, 2011
s. 42A	ad. No. 88, 1992
	am. No. 204, 1992
	rep. No. 200, 1992
s. 43	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976
	am. No. 139, 1983; No. 65, 1985; No. 94, 1986; No. 132, 1987; No. 211, 1991; No. 200, 1992
	rep. No. 86, 2011

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Endnote 4—Amendment history

Provision affected	How affected
s. 43A	ad. No. 117, 1980
	am. No. 118, 1981; No. 139, 1983; No. 135, 1984; Nos. 94 and 115, 1986
	rep. No. 86, 2011
s. 44	rs. No. 82, 1962
	am. No. 100, 1968; No. 114, 1972; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976
	am. No. 100, 1977; No. 117, 1980; No. 139, 1983; No. 94, 1986; No. 155, 1988; No. 204, 1992
	rep. No. 86, 2011
s. 44A	ad. No. 155, 1988
	am. No. 83, 1991
	rep. No. 114, 1997
s. 45	am. No. 16, 1961
	rs. No. 82, 1962
	am. No. 100, 1968; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976
	am. No. 100, 1977; No. 117, 1980
	rep. No. 139, 1983
	ad. No. 211, 1991
	rep. No. 86, 2011
s. 45A	ad. No. 117, 1980
	am. No. 139, 1983; No. 94, 1986
	rep. No. 86, 2011
s. 45B	ad. No. 117, 1980
	am. No. 118, 1981; No. 135, 1984; No. 94, 1986
	rep. No. 86, 2011
s. 45C	ad. No. 139, 1983
	am. No. 65, 1985; No. 94, 1986; No. 99, 1988
	rs. No. 155, 1988
	rep. No. 83, 1991

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Endnote 4—Amendment history

Provision affected	How affected
s. 45D	ad. No. 72, 1987
	rep. No. 86, 2011
s. 45DA	ad. No. 3, 1990
	am. No. 84, 1991; No. 114, 1997
	rep. No. 86, 2011
s. 45DB	ad. No. 84, 1991
	rep. No. 86, 2011
s. 45DC	ad. No. 84, 1991
	am. No. 114, 1997
	rep. No. 86, 2011
s. 45E	ad. No. 72, 1987
	am. No. 132, 1987; No. 83, 1991; No. 149, 1995
	rep. No. 114, 1997
s. 45EA	ad. No. 84, 1991
	rep. No. 114, 1997
s. 45EB	ad. No. 204, 1992
	rep. No. 114, 1997
s. 45F	ad. No. 3, 1990
	rs. No. 141, 1990
	rep. No. 114, 1997
Heading to Div. 3 of Part V	am. No. 41, 1970
	rep. No. 60, 1976
Div. 3 of Part V	rep. No. 60, 1976
Heading to Div. 4 of Part V	rs. No. 41, 1970
	rep. No. 60, 1976
Div. 4 of Part V	rep. No. 60, 1976
Div. 4A of Part V	ad. No. 41, 1970
	rep. No. 60, 1976
Div. 5 of Part V	rep. No. 100, 1977
Div. 5A of Part V	ad. No. 100, 1968
	rep. No. 1, 1975

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Endnote 4—Amendment history

Provision affected	How affected
Heading to Div. 5B of Part V	rep. No. 100, 1977
Div. 5B of Part V	ad. No. 114, 1972
Heading to Div. 6 of Part V	rep. No. 100, 1977
Part VA	ad. No. 100, 1977
	rep. No. 86, 2011
Heading to Div. 1 of Part VA	ad. No. 200, 1992
	rep. No. 86, 2011
s. 46	am. No. 68, 1955
	rs. No. 82, 1962
	am. No. 44, 1966; No. 102, 1969; No. 1, 1976
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. Nos. 118 and 176, 1981; No. 63, 1984; No. 200, 1992
	rep. No. 86, 2011
s. 46A	ad. No. 72, 1987
	am. No. 88, 1992; No. 12, 1994; No. 37, 1998
	rep. No. 86, 2011
s. 46B	ad. No. 88, 1992
Renumbered s. 46AB	No. 12, 1994 (as am. by No. 149, 1995)
s. 46AB	rep. No. 86, 2011
s. 46B	ad. No. 200, 1992
	rep. No. 86, 2011
s. 46C	ad. No. 200, 1992
	am. No. 12, 1994; No. 114, 1997
	rep. No. 86, 2011
ss. 46D, 46E	ad. No. 200, 1992
	rep. No. 86, 2011
Heading to Div. 2 of Part VA	ad. No. 200, 1992
	rep. No. 86, 2011
s. 47	am. No. 68, 1955
	rs. No. 82, 1962

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Provision affected	How affected
	am. No. 102, 1969; No. 41, 1970
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. Nos. 118 and 176, 1981; No. 127, 1985; No. 115, 1986; No. 72, 1987; No. 79, 1988
	rep. No. 86, 2011
s. 47A	ad. No. 79, 1988
	am. No. 155, 1988; No. 200, 1992; No. 114, 1997
	rep. No. 86, 2011
s. 48	am. No. 68, 1955
	rs. No. 82, 1962
	am. No. 44, 1966; No. 102, 1969
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. No. 63, 1984; No. 94, 1986
	rep. No. 200, 1992
s. 48A	ad. No. 72, 1987
	am. Nos. 79 and 155, 1988; No. 83, 1991; No. 200, 1992; No. 114, 1997
	rep. No. 86, 2011
s. 48AB	ad. No. 200, 1992
	am. No. 114, 1997
	rep. No. 86, 2011
s. 48B	ad. No. 83, 1991
	am. No. 114, 1997; No. 13, 1999
	rep. No. 86, 2011
ss. 48C–48E	ad. No. 211, 1991
	am. No. 114, 1997
	rep. No. 86, 2011
s. 49	am. No. 68, 1955
	rs. No. 82, 1962

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 41, 1970
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. Nos. 118 and 176, 1981; No. 115, 1986
	rs. No. 72, 1987
	am. No. 79, 1988
	rep. No. 86, 2011
s. 49AA	ad. No. 79, 1988 (as am. by No. 155, 1988)
	am. No. 114, 1997
	rep. No. 86, 2011
Heading to Div. 3 of Part VA	ad. No. 200, 1992
	rep. No. 86, 2011
s. 49A	ad. No. 37, 1964
	am. No. 202, 1973
	rep. No. 60, 1976
	ad. No. 117, 1980
	rep. No. 86, 2011
s. 49B	ad. No. 200, 1992
	rep. No. 86, 2011
s. 50	rs. No. 82, 1962; No. 41, 1970
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. No. 118, 1981; No. 63, 1984; No. 65, 1985; No. 132, 1987; No. 211, 1991; No. 32, 2007
	rep. No. 86, 2011
s. 51	rs. No. 82, 1962
	am. No. 202, 1973
	rep. No. 60, 1976
	ad. No. 100, 1977
	am. No. 63, 1984; No. 72, 1987; No. 200, 1992
	rep. No. 86, 2011

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Endnote 4—Amendment history

Provision affected	How affected
s. 51A	ad. No. 72, 1987
	rs. No. 200, 1992
	am. No. 149, 1995
	rep. No. 86, 2011
s. 51B	ad. No. 83, 1991
	rs. No. 200, 1992
	rep. No. 86, 2011
s. 51C	ad. No. 200, 1992
	rep. No. 86, 2011
Part VAB	ad. No. 211, 1991
	rep. No. 86, 2011
Division 1 heading	ad. No. 192, 1992
	rep. No. 86, 2011
s. 52	rs. No. 82, 1962
	am. No. 202, 1973
	rep. No. 60, 1976
	ad. No. 211, 1991
	am. No. 192, 1992; No. 114, 1997
	rep. No. 86, 2011
Div. 2 of Part VAB	ad. No. 192, 1992
	rep. No. 86, 2011
ss. 52A–52C	ad. No. 192, 1992
	rep. No. 114, 1997
s. 52D	ad. No. 192, 1992
	rep. No. 86, 2011
Division 3 heading	ad. No. 192, 1992
	rep. No. 86, 2011
s. 53	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 41, 1970; No. 202, 1973
	rep. No. 60, 1976
	ad. No. 211, 1991

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 86, 2011
s. 54	rs. No. 82, 1962
	am. No. 44, 1966
	rep. No. 60, 1976
	ad. No. 211, 1991
	rep. No. 86, 2011
s. 55	am. No. 92, 1957
	rs. No. 82, 1962
	am. No. 202, 1973
	rep. No. 60, 1976
	ad. No. 211, 1991
	am. No. 192, 1992
	rep. No. 86, 2011
ss. 55A, 55B	ad. No. 41, 1970
	rep. No. 60, 1976
s. 55C	ad. No. 1, 1975
	rep. No. 100, 1977
s. 56	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 85, 1971; No. 114, 1972
	rep. No. 100, 1977
	ad. No. 211, 1991
	am. No. 114, 1997
	rep. No. 86, 2011
s. 56A	ad. No. 92, 1957
	rep. No. 82, 1962
	ad. No. 114, 1972
	am. No. 202, 1973; No. 60, 1976
	rep. No. 100, 1977
s. 57	rs. No. 92, 1957; No. 82, 1962
	am. No. 100, 1968; No. 202, 1973
	rep. No. 100, 1977

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Provision affected	How affected
	ad. No. 211, 1991
	am. No. 114, 1997
	rep. No. 86, 2011
s. 57A	ad. No. 100, 1968
	am. No. 202, 1973; No. 60, 1976
	rep. No. 100, 1977
s. 57B	ad. No. 114, 1972
	am. No. 1, 1975; Nos. 60 and 99, 1976
	rep. No. 100, 1977
s. 57C	ad. No. 114, 1972
	am. No. 202, 1973; Nos. 60 and 99, 1976
	rep. No. 100, 1977
Part VAC	ad. No. 204, 1992
	rep. No. 86, 2011
s. 58	rs. No. 82, 1962
	am. No. 100, 1968; No. 202, 1973; No. 60, 1976
	rep. No. 100, 1977
	ad. No. 204, 1992
	am. No. 114, 1997
	rep. No. 86, 2011
s. 58A	ad. No. 100, 1968
	am. No. 202, 1973
	rep. No. 1, 1975
	ad. No. 204, 1992
	rep. No. 86, 2011
s. 58B	ad. No. 100, 1968
	rep. No. 1, 1975
	ad. No. 204, 1992
	rep. No. 114, 1997
s. 58C	ad. No. 100, 1968
	am. No. 202, 1973

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 1, 1975
	ad. No. 204, 1992
	rep. No. 114, 1997
s. 58CA	ad. No. 204, 1992
	rep. No. 114, 1997
s. 58CB	ad. No. 204, 1992
	rep. No. 86, 2011
ss. 58CC, 58CD	ad. No. 204, 1992
	rep. No. 86, 2011
ss. 58CE–58CG	ad. No. 204, 1992
	am. No. 114, 1997
	rep. No. 86, 2011
Heading to Part VB	ad. No. 100, 1977
	rep. No. 13, 1999
Part VB	rep. No. 13, 1999
s. 58D	ad. No. 114, 1972
	am. No. 100, 1977; No. 131, 1980; Nos. 46 and 120, 1984; Nos. 94 and 115, 1986; No. 192, 1992
	rep. No. 13, 1999
s. 58E	ad. No. 114, 1972
	am. No. 202, 1973; No. 60, 1976; No. 100, 1977; No. 54, 1979; No. 63, 1984; No. 94, 1986; No. 3, 1990; No. 83, 1991; No. 114, 1997
	rep. No. 13, 1999
s. 58F	ad. No. 114, 1972
	am. No. 202, 1973; No. 63, 1984; No. 94, 1986
	rep. No. 13, 1999
s. 58G	ad. No. 114, 1972
	am. No. 131, 1980
	rs. No. 192, 1992
	am. No. 114, 1997

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Provision affected	How affected
	rep. No. 13, 1999
s. 58GA	ad. No. 131, 1980
	am. No. 63, 1984; No. 192, 1992
	rep. No. 13, 1999
s. 58H	ad. No. 114, 1972
	am. No. 202, 1973; No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 211, 1991; No. 192, 1992
	rep. No. 13, 1999
s. 58J	ad. No. 114, 1972
	am. No. 202, 1973; No. 131, 1980; No. 35, 1983; No. 63, 1984; No. 94, 1986
	rep. No. 13, 1999
Heading to Part VC	ad. No. 100, 1977
	am. No. 211, 1991; No. 200, 1992
	rs. No. 13, 1999
	rep. No. 86, 2011
Part VC	rep. No. 86, 2011
s. 58K	ad. No. 100, 1977
	rs. No. 132, 1987
	am. No. 211, 1991 (as am. by No. 149, 1995); No. 13, 1999
	rep. No. 86, 2011
s. 59	rs. No. 82, 1962
	am. No. 100, 1968; No. 202, 1973; No. 1, 1975
	rs. No. 60, 1976
	am. No. 100, 1977; Nos. 118 and 176, 1981; No. 94, 1986; No. 132, 1995
	rep. No. 86, 2011
s. 60	rs. No. 68, 1955; No. 82, 1962
	am. No. 44, 1966; No. 202, 1973
	rep. No. 60, 1976
s. 60A	ad. No. 114, 1972

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 202, 1973
	rs. No. 100, 1977; No. 118, 1981
	am. No. 63, 1984; No. 94, 1986; No. 72, 1987
	rep. No. 114, 1997
s. 60B	ad. No. 100, 1977
	am. No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 72, 1987; No. 211, 1991
	rep. No. 86, 2011
s. 61	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 114, 1972; No. 1, 1975
	rs. No. 60, 1976; No. 117, 1980
	am. No. 139, 1983; No. 63, 1984; No. 94, 1986; No. 132, 1987; No. 211, 1991; No. 12, 1994
	rep. No. 86, 2011
s. 61AA	ad. No. 88, 1992
	rep. No. 86, 2011
s. 61A	ad. No. 132, 1987
	am. No. 211, 1991
	rep. No. 86, 2011
s. 61B	ad. No. 132, 1987
	am. No. 211, 1991; No. 111, 2001
	rep. No. 86, 2011
ss. 61C, 61D	ad. No. 132, 1987
	rep. No. 86, 2011
s. 61E	ad. No. 132, 1987
	am. No. 211, 1991; No. 111, 2001
	rep. No. 86, 2011
s. 62	rs. No. 82, 1962
	am. No. 44, 1966; No. 100, 1968; No. 102, 1969; No. 114, 1972; No. 1, 1975; No. 60, 1976
	rs. No. 100, 1977; No. 117, 1980

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Provision affected	How affected
	am. No. 139, 1983; No. 63, 1984; No. 65, 1985; No. 94, 1986; Nos. 72 and 132, 1987; No. 79, 1988; Nos. 83 and 211, 1991; No. 111, 2001
	rep. No. 86, 2011
Part VD	ad. No. 200, 1992
	rep. No. 86, 2011
s. 63	rs. No. 82, 1962
	am. No. 202, 1973
	rep. No. 60, 1976
	ad. No. 117, 1980
	rep. No. 139, 1983
	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
s. 64	rs. No. 68, 1958; No. 82, 1962
	rep. No. 60, 1976
	ad. No. 200, 1992
	am. No. 23, 1994; No. 114, 1997
	rep. No. 86, 2011
s. 65	rs. No. 82, 1962
	am. No. 60, 1976
	rep. No. 99, 1976
	ad. No. 200, 1992
	am. Nos. 12 and 23, 1994; No. 114, 1997
	rep. No. 86, 2011
ss. 65A, 65B	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
s. 65C	ad. No. 200, 1992
	am. Nos. 12 and 23, 1994; No. 114, 1997
	rep. No. 86, 2011

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Endnote 4—Amendment history

Provision affected	How affected
s. 65D	ad. No. 200, 1992
	rep. No. 86, 2011
s. 65E	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
ss. 65F, 65G	ad. No. 200, 1992
	am. No. 23, 1994; No. 114, 1997
	rep. No. 86, 2011
s. 65GAA	ad. No. 114, 1997
	rep. No. 86, 2011
Div. 2A of Part VD	ad. No. 23, 1994
	rep. No. 86, 2011
ss. 65GA–65GK	ad. No. 23, 1994
	rep. No. 86, 2011
ss. 65GL–65GQ	ad. No. 23, 1994
	rep. No. 86, 2011
ss. 65GR–65GW	ad. No. 23, 1994
	rep. No. 86, 2011
ss. 65H, 65J	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
ss. 65K–65M	ad. No. 200, 1992
	rep. No. 86, 2011
s. 65N	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
ss. 65P–65R	ad. No. 200, 1992
	rep. No. 86, 2011
s. 65S	ad. No. 200, 1992
	am. No. 12, 1994
	rep. No. 86, 2011

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Endnote 4—Amendment history

Provision affected	How affected
Heading to Div. 4 of Part VD	ad. No. 23, 1994
	rep. No. 86, 2011
ss. 65SA, 65SB	ad. No. 23, 1994
	rep. No. 86, 2011
s. 65T	ad. No. 200, 1992
	am. No. 12, 1994
	rep. No. 86, 2011
s. 65U	ad. No. 200, 1992
	am. No. 23, 1994
	rep. No. 86, 2011
Heading to Part VI	rs. No. 54, 1983
	rep. No. 32, 2007
Part VI	rep. No. 32, 2007
Heading to Div. 1 of Part VI	ad. No. 68, 1958
	rep. No. 32, 2007
s. 66	rs. No. 68, 1958
	am. No. 72, 1959; No. 16, 1961; No. 82, 1962; No. 77, 1963; No. 37, 1964; No. 44, 1966; No. 100, 1968; No. 41, 1970; No. 114, 1972; No. 202, 1973; Nos. 1 and 13, 1975; Nos. 60, 91 and 99, 1976; No. 100, 1977; Nos. 132 and 189, 1978; No. 118, 1981; No. 54, 1983; Nos. 46 and 120, 1984; No. 41, 1995; No. 1, 2004
	rep. No. 32, 2007
s. 67	am. No. 68, 1958
	rs. No. 37, 1964; No. 41, 1970
	am. No. 202, 1973; Nos. 60 and 99, 1976; No. 132, 1978
	rep. No. 54, 1983
	ad. No. 70, 1985
	am. No. 155, 1988; No. 136, 1992; No. 41, 1995; No. 37, 1998; No. 76, 2002; No. 31, 2005
	rep. No. 32, 2007
s. 67A	ad. No. 95, 1989
	am. No. 1, 2004

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
s. 67B	ad. No. 1, 2004
	rep. No. 32, 2007
Div. 1A of Part VI	ad. No. 99, 1976
	rep. No. 132, 1978
Division 2 heading	ad. No. 41, 1995
	rep. No. 32, 2007
Division 2	ad. No. 68, 1958
	rep. No. 132, 1978
s. 68	am. No. 68, 1958; No. 82, 1962; No. 37, 1964; No. 44, 1966
	rs. No. 41, 1970
	am. No. 202, 1973; Nos. 60 and 99, 1976; No. 132, 1978; No. 118, 1981; No. 54, 1983; Nos. 63 and 135, 1984; No. 70, 1985; No. 95, 1989; No. 41, 1995 (as am. by No. 43, 1996); No. 37, 1998
	rs. No. 159, 1999
	am. No. 160, 2006
	rep. No. 32, 2007
s. 68A	ad. No. 54, 1983
	am. No. 94, 1986
	rep. No. 88, 1992
s. 69	am. No. 41, 1970; No. 202, 1973; No. 63, 1984; No. 95, 1989; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 70	am. No. 202, 1973; No. 91, 1976; No. 63, 1984; No. 94, 1986; No. 37, 1998; No. 159, 1999
	rep. No. 32, 2007
s. 71	am. No. 202, 1973; No. 63, 1984; No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 72	am. No. 68, 1958
	rs. No. 41, 1970; No. 95, 1989
	am. No. 41, 1995; No. 159, 1999

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Provision affected	How affected
	rep. No. 32, 2007
s. 72A	ad. No. 41, 1970
	am. No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 73	am. No. 41, 1970; No. 202, 1973; Nos. 60 and 99, 1976; No. 54, 1983; No. 63, 1984; No. 94, 1986; No. 95, 1989; No. 88, 1992; No. 41, 1995; No. 159, 1999; No. 1, 2004
	rep. No. 32, 2007
s. 73AA	ad. No. 54, 1983
	rep. No. 88, 1992
	ad. No. 159, 1999
	rep. No. 32, 2007
s. 73AAB	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 32, 2007
s. 73AAC	ad. No. 159, 1999
	rep. No. 32, 2007
s. 73AAD	ad. No. 159, 1999
	am. No. 160, 2006
	rep. No. 32, 2007
s. 73AADA	ad. No. 160, 2006
	rep. No. 32, 2007
s. 73AAE	ad. No. 159, 1999
	am. No. 1, 2004
	rep. No. 32, 2007
Heading to Div. 3 of Part VI	ad. No. 41, 1995
	rep. No. 32, 2007
Div. 3 of Part VI	ad. No. 102, 1969
	rep. No. 1, 1976
s. 73AAF	ad. No. 1, 2004
	rep. No. 32, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 73AAG	ad. No. 1, 2004
	am. No. 31, 2005
	rep. No. 32, 2007
s. 73AAH	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73AAI	ad. No. 1, 2004
	am. No. 155, 2005
	rep. No. 32, 2007
ss. 73AAJ–73AAL	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73A	ad. No. 37, 1964
	am. No. 202, 1973; No. 60, 1976; No. 100, 1977; No. 63, 1984; Nos. 21 and 159, 1999; No. 1, 2004
	rep. No. 32, 2007
s. 73AB	ad. No. 41, 1995
	am. No. 37, 1998; No. 1, 2004
	rep. No. 32, 2007
s. 73ABA	ad. No. 41, 1995
	rep. No. 1, 2004
s. 73ABB	ad. No. 45, 1997
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 73ABBA	ad. No. 69, 2003
	rep. No. 32, 2007
s. 73ABC	ad. No. 37, 1998
	am. No. 76, 2002
	rep. No. 32, 2007
s. 73ABD	ad. No. 159, 1999
	rep. No. 32, 2007
s. 73B	ad. No. 41, 1970
	am. No. 37, 1974; No. 1, 1975; No. 1, 1976

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Provision affected	How affected
	rs. No. 60, 1976
	am. No. 112, 1982; No. 94, 1986; No. 159, 1999; No. 1, 2004
	rep. No. 32, 2007
s. 73BA	ad. No. 60, 1976
	am. No. 99, 1976; No. 100, 1977
	rs. No. 132, 1978
	am. No. 54, 1983; No. 141, 1990; Nos. 41 and 149, 1995; No. 21, 1999
	rep. No. 1, 2004
s. 73BAAA	ad. No. 130, 1999
	rep. No. 32, 2007
s. 73BAA	ad. No. 54, 1983
	rep. No. 95, 1989
	ad. No. 21, 1999
	rep. No. 32, 2007
s. 73BAB	ad. No. 54, 1983
	am. No. 95, 1989; No. 88, 1992; No. 41, 1995
	rep. No. 159, 1999
s. 73BAC	ad. No. 54, 1983
	am. No. 94, 1986; No. 95, 1989
	rep. No. 159, 1999
Division 3AA heading	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73BB	ad. No. 60, 1976
	rs. No. 99, 1976
	am. No. 100, 1977; No. 132, 1978; No. 118, 1981; No. 54, 1983; Nos. 46, 63 and 120, 1984; Nos. 70 and 167, 1985; No. 95, 1989; No. 88, 1992; No. 41, 1995
	rs. No. 37, 1998
	am. No. 1, 2004
	rep. No. 32, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 73BC	ad. No. 60, 1976
	am. No. 54, 1983; No. 135, 1984; No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 37, 1998; No. 69, 2003
	rep. No. 32, 2007
Div. 3A of Part VI	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 73BCA–73BCE	ad. No. 159, 1999
	rep. No. 32, 2007
Div. 3B of Part VI	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 73BCF–73BCJ	ad. No. 159, 1999
	rep. No. 32, 2007
Div. 4 of Part VI	ad. No. 41, 1995
	rep. No. 32, 2007
s. 73BD	ad. No. 60, 1976
	am. No. 54, 1983; No. 135, 1984; No. 94, 1986
	rep. No. 95, 1989
	ad. No. 41, 1995
	am. No. 41, 1995; No. 6, 2001; Nos. 31 and 155, 2005
	rep. No. 32, 2007
s. 73BDAAA	ad. No. 31, 2005
	am. No. 155, 2005
	rep. No. 32, 2007
s. 73BDAA	ad. No. 41, 1995
	am. No. 41, 1995; No. 37, 1998; No. 6, 2001; No. 155, 2005
	rep. No. 32, 2007
s. 73BDA	ad. No. 41, 1995
	am. No. 41, 1995; No. 37, 1998; No. 50, 2004; No. 155, 2005
	rep. No. 32, 2007
s. 73BDB	ad. No. 41, 1995
	am. No. 76, 2002; No. 155, 2005

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Provision affected	How affected
	rep. No. 32, 2007
s. 73BDC	ad. No. 41, 1995
	rep. No. 32, 2007
Div. 4A of Part VI	ad. No. 72, 2000
	rep. No. 32, 2007
s. 73BDDA	ad. No. 72, 2000
	rep. No. 32, 2007
s. 73BDD	ad. No. 41, 1995
	rep. No. 37, 1998
	ad. No. 72, 2000
	rep. No. 32, 2007
s. 73BDE	ad. No. 72, 2000
	rep. No. 32, 2007
s. 73BDEA	ad. No. 72, 2000
	rep. No. 32, 2007
Heading to Div. 5 of Part VI	ad. No. 37, 1998
	rs. No. 1, 2004
	rep. No. 32, 2007
Div. 5 of Part VI	rs. No. 1, 2004
	rep. No. 32, 2007
s. 73BE	ad. No. 60, 1976
	am. No. 189, 1978; No. 54, 1979; No. 112, 1982; No. 54, 1983; No. 70, 1985; No. 94, 1986; No. 41, 1995
	rep. No. 1, 2004
s. 73BEA	ad. No. 49, 1982
	am. No. 112, 1982
	rep. No. 54, 1983
	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73BEB	ad. No. 112, 1982
	am. No. 54, 1983; No. 159, 1999

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Endnote 4—Amendment history

Provision affected	How affected
	rs. No. 1, 2004
	rep. No. 32, 2007
s. 73BEC	ad. No. 1, 2004
	rep. No. 32, 2007
ss. 73BED–73BEG	ad. No. 1, 2004
	rep. No. 32, 2007
ss. 73BEH, 73BEI	ad. No. 1, 2004
	rep. No. 32, 2007
ss. 73BEJ, 73BEK	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73BEL	ad. No. 1, 2004
	rep. No. 32, 2007
ss. 73BEM–73BEO	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73BEP	ad. No. 1, 2004
	rep. No. 32, 2007
s. 73BF	ad. No. 60, 1976
	rs. No. 99, 1976
	am. No. 132, 1978; No. 112, 1982; No. 54, 1983; No. 94, 1986; No. 88, 1992; No. 41, 1995
	rep. No. 1, 2004
s. 73BFA	ad. No. 132, 1978
	am. No. 112, 1982; No. 54, 1983; No. 94, 1986; No. 88, 1992; No. 41, 1995
	rep. No. 1, 2004
s. 73BFB	ad. No. 189, 1978
	am. No. 112, 1982; No. 54, 1983; No. 94, 1986; No. 88, 1992; No. 80, 1994; No. 41, 1995
	rep. No. 1, 2004
s. 73BG	ad. No. 60, 1976
	am. No. 99, 1976; No. 100, 1977; No. 132, 1978

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Provision affected	How affected
	rep. No. 54, 1983
s. 73BH	ad. No. 60, 1976
	am. No. 54, 1983; No. 94, 1986; No. 88, 1992
	rep. No. 1, 2004
s. 73C	ad. No. 114, 1972
	am. No. 1, 1975; Nos. 60 and 99, 1976
	rs. No. 100, 1977
	am. No. 132, 1978; No. 117, 1980
	rep. No. 118, 1981
s. 73D	ad. No. 60, 1976
	rs. No. 99, 1976
	am. No. 88, 1978; No. 94, 1986; No. 41, 1995
	rep. No. 1, 2004
Div. 5A of Part VI	ad. No. 41, 1995
	rep. No. 32, 2007
s. 73E	ad. No. 88, 1978
	rs. No. 132, 1978
	am. No. 189, 1978; No. 54, 1979
	rep. No. 118, 1981
	ad. No. 41, 1995
	rep. No. 32, 2007
s. 73EA	ad. No. 41, 1995
	am. No. 50, 2006
	rep. No. 32, 2007
ss. 73EB–73EE	ad. No. 41, 1995
	rep. No. 32, 2007
Heading to Div. 6 of Part VI	ad. No. 41, 1995
	rep. No. 32, 2007
s. 73F	ad. No. 132, 1978
	am. No. 118, 1981; No. 54, 1983; No. 63, 1984; No. 70, 1985; No. 94, 1986; No. 88, 1992

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Endnote 4—Amendment history

Provision affected	How affected
	rs. No. 41, 1995
	rep. No. 32, 2007
s. 73G	ad. No. 118, 1981
	am. No. 54, 1983; No. 63, 1984; No. 70, 1985; No. 94, 1986; No. 88, 1992
	rs. No. 41, 1995
	am. No. 6, 2001
	rep. No. 32, 2007
s. 74	am. No. 44, 1966; No. 202, 1973; No. 60, 1976; No. 118, 1981; No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 79, 1988; No. 159, 1999; No. 111, 2001; No. 1, 2004
	rep. No. 32, 2007
s. 74A	ad. No. 60, 1976
	am. No. 92, 1981
	rs. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 1, 2004
s. 74B	ad. No. 60, 1976
	am. No. 189, 1978; No. 54, 1979; No. 54, 1983; No. 95, 1989; No. 88, 1992; No. 41, 1995
	rep. No. 1, 2004
s. 74BA	ad. No. 79, 1988
	am. No. 41, 1995; No. 111, 2001
	rep. No. 32, 2007
s. 74C	ad. No. 60, 1976
	rs. No. 132, 1978
	am. No. 54, 1983; No. 88, 1992; No. 41, 1995
	rep. No. 32, 2007
s. 74D	ad. No. 132, 1978
	am. No. 63, 1984
	rep. No. 32, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 75	am. No. 68, 1955; No. 44, 1966; No. 202, 1973; Nos. 60 and 91, 1976; No. 54, 1983; No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 41, 1995; No. 111, 2001
	rs. No. 1, 2004
	rep. No. 32, 2007
s. 76	rs. No. 68, 1958
	am. No. 44, 1966
	rs. No. 41, 1970
	am. No. 202, 1973; No. 60, 1976; No. 63, 1984; No. 65, 1985; No. 94, 1986
	rep. No. 95, 1989
s. 76A	ad. No. 41, 1970
	am. No. 202, 1973; No. 60, 1976; No. 132, 1978; No. 54, 1983; No. 63, 1984; No. 94, 1986 (as am. by No. 141, 1987)
	rep. No. 95, 1989
s. 77	am. No. 202, 1973; No. 60, 1976; No. 63, 1984
	rep. No. 95, 1989
s. 78	rs. No. 68, 1955
	am. No. 44, 1966; No. 41, 1970; No. 114, 1972; No. 202, 1973; No. 37, 1974; Nos. 60 and 99, 1976; Nos. 88, 132 and 189, 1978; Nos. 118 and 176, 1981; No. 49, 1982; No. 54, 1983; No. 63, 1984; No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 37, 1998; No. 159, 1999; No. 6, 2001; No. 1, 2004
	rep. No. 32, 2007
s. 79	am. No. 41, 1970
	rs. No. 60, 1976
	am. No. 54, 1983; No. 94, 1986; No. 95, 1989; No. 192, 1992; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 80	rep. No. 60, 1976
s. 80A	ad. No. 41, 1970
	rep. No. 60, 1976

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Endnote 4—Amendment history

Provision affected	How affected
s. 81	am. No. 41, 1970; No. 202, 1973; No. 60, 1976; No. 63, 1984; No. 159, 1999
	rep. No. 32, 2007
s. 81A	ad. No. 100, 1968
	am. No. 114, 1972; Nos. 60 and 99, 1976; No. 118, 1981; No. 94, 1986
	rep. No. 88, 1992
s. 82	am. No. 68, 1955; No. 68, 1958; No. 82, 1962; No. 44, 1966; No. 114, 1972; No. 60, 1976; No. 100, 1977; No. 112, 1982; No. 54, 1983; No. 65, 1985; No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 111, 2001
	rep. No. 32, 2007
ss. 82AA–82AC	ad. No. 99, 1976
	rep. No. 132, 1978
Part VIAA	ad. No. 95, 1989
	rep. No. 32, 2007
s. 82A	ad. No. 68, 1958
	rs. No. 41, 1970; No. 60, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 37, 1998; No. 159, 1999
	rep. No. 32, 2007
s. 82B	ad. No. 68, 1958
	am. No. 72, 1959
	rep. No. 77, 1963
	ad. No. 95, 1989
	am. No. 152, 1997; No. 37, 1998
	rep. No. 32, 2007
s. 82BA	ad. No. 152, 1997
	rep. No. 37, 1998
	ad. No. 159, 1999
	rep. No. 32, 2007

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Provision affected	How affected
s. 82C	ad. No. 68, 1958
	am. No. 72, 1959; No. 100, 1968; No. 41, 1970; No. 114, 1972; No. 202, 1973; No. 60, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	rs. No. 37, 1998
	rep. No. 32, 2007
s. 82CA	ad. No. 77, 1963
	am. No. 41, 1970; No. 60, 1976
	rep. No. 132, 1978
	ad. No. 152, 1997
	rep. No. 37, 1998
s. 82D	ad. No. 68, 1958
	am. No. 82, 1962; No. 77, 1963; No. 100, 1968; No. 41, 1970; No. 114, 1972; No. 202, 1973; No. 1, 1975; Nos. 60 and 99, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	rs. No. 37, 1998
	am. No. 159, 1999
	rep. No. 32, 2007
s. 82E	ad. No. 68, 1958
	am. No. 72, 1959; No. 16, 1961; No. 82, 1962; No. 77, 1963; No. 100, 1968; No. 41, 1970; No. 114, 1972; No. 202, 1973; No. 13, 1975; No. 60, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	rep. No. 37, 1998
s. 82F	ad. No. 68, 1958
	am. No. 41, 1970; No. 1, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 37, 1998; No. 159, 1999

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
s. 82G	ad. No. 68, 1958
	am. No. 72, 1959; No. 77, 1963; No. 41, 1970
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 41, 1995; No. 45, 1997; No. 37, 1998; No. 159, 1999; No. 72, 2000; No. 69, 2003; No. 1, 2004
	rep. No. 32, 2007
s. 82H	ad. No. 68, 1958
	am. No. 202, 1973
	rep. No. 132, 1978
	ad. No. 95, 1989
	rep. No. 32, 2007
s. 82J	ad. No. 68, 1958
	am. No. 41, 1970
	rep. No. 132, 1978
	ad. No. 95, 1989
	rep. No. 32, 2007
s. 82K	ad. No. 68, 1958
	am. No. 60, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 37, 1998; No. 111, 2001
	rep. No. 32, 2007
s. 82L	ad. No. 68, 1958
	am. No. 41, 1970; No. 202, 1973; No. 60, 1976
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 45, 1997; No. 159, 1999; No. 111, 2001; No. 111, 2005
	rep. No. 32, 2007
s. 82M	ad. No. 68, 1958

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Provision affected	How affected
	am. No. 202, 1973
	rep. No. 132, 1978
	ad. No. 95, 1989
	rep. No. 32, 2007
s. 82N	ad. No. 68, 1958
	am. No. 202, 1973
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82P	ad. No. 68, 1958
	am. No. 44, 1966; No. 202, 1973
	rep. No. 132, 1978
	ad. No. 95, 1989
	am. No. 152, 1997; No. 37, 1998
	rep. No. 32, 2007
s. 82PA	ad. No. 95, 1989
	am. No. 41, 1995; No. 45, 1997; No. 152, 1997; No. 159, 1999
	rep. No. 32, 2007
s. 82PAA	ad. No. 37, 1998
	rep. No. 32, 2007
ss. 82PB, 82PC	ad. No. 95, 1989
	rep. No. 32, 2007
ss. 82PCA, 82PCB	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82PD	ad. No. 95, 1989
	rep. No. 159, 1999
s. 82PE	ad. No. 95, 1989
	rep. No. 32, 2007
s. 82PEA	ad. No. 122, 1991
	am. No. 146, 1999

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
ss. 82PF, 82PG	ad. No. 95, 1989
	am. No. 159, 1999
	rep. No. 32, 2007
Division 7 heading	rs. No. 37, 1998
	rep. No. 32, 2007
s. 82PH	ad. No. 95, 1989
	am. No. 37, 1998; No. 159, 2001
	rep. No. 32, 2007
ss. 82PJ, 82PK	ad. No. 95, 1989
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82PL	ad. No. 95, 1989
	am. No. 146, 1999
	rep. No. 32, 2007
s. 82PM	ad. No. 95, 1989
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82PN	ad. No. 122, 1991
	am. No. 37, 1998; No. 146, 1999
	rep. No. 32, 2007
Div. 8 of Part VIAA	ad. No. 69, 2003
	rep. No. 32, 2007
s. 82PO	ad. No. 69, 2003
	rep. No. 32, 2007
Part VIA	ad. No. 60, 1976
	rep. No. 32, 2007
Heading to Div. 1 of Part VIA	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82QA–82QC	ad. No. 159, 1999
	rep. No. 32, 2007

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Provision affected	How affected
s. 82Q	ad. No. 102, 1969
	am. No. 41, 1970; No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 157, 1976; No. 54, 1983; No. 88, 1992; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 82QAA	ad. No. 44, 1999
	rep. No. 32, 2007
Heading to Div. 2 of Part VIA	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82R	ad. No. 102, 1969
	rs. No. 41, 1970
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 54, 1983; No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 45, 1997; Nos. 146 and 159, 1999
	rep. No. 32, 2007
s. 82S	ad. No. 102, 1969
	rs. No. 41, 1970
	am. No. 114, 1972; Nos. 1 and 13, 1975
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 94, 1986
	rep. No. 32, 2007
s. 82T	ad. No. 102, 1969
	rs. No. 41, 1970
	am. No. 114, 1972; No. 1, 1975
	rep. No. 1, 1976
	ad. No. 60, 1976
	rep. No. 32, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 82U	ad. No. 102, 1969
	am. No. 41, 1970; No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 65, 1985; No. 94, 1986; No. 111, 2001
	rep. No. 32, 2007
s. 82V	ad. No. 102, 1969
	rs. No. 41, 1970
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 65, 1985; No. 94, 1986; No. 111, 2001
	rep. No. 32, 2007
s. 82W	ad. No. 102, 1969
	am. No. 41, 1970; No. 114, 1972; No. 1, 1975
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 54, 1983; No. 94, 1986; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
s. 82WA	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82WB (prev s. 82X)	rep. No. 32, 2007
s. 82WC (prev s. 82Y)	am. No. 111, 2001
	rep. No. 32, 2007
s. 82X	ad. No. 102, 1969
	am. No. 102, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 94, 1986; No. 146, 1999
Renumbered s. 82WB	No. 159, 1999
Div. 3 of Part VIA	ad. No. 159, 1999
	rep. No. 32, 2007

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Provision affected	How affected
s. 82XA	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XB	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 32, 2007
s. 82XC	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XD	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XE	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XF	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001; No. 1, 2004
	rep. No. 32, 2007
ss. 82XG–82XK	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XL–82XP	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XQ	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XR	ad. No. 159, 1999
	am. No. 159, 1999; No. 111, 2001
	rep. No. 32, 2007
ss. 82XS–82XV	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82XW, 82XX	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
ss. 82XY, 82XZ	ad. No. 159, 1999

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
ss. 82XZA, 82XZB	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82XZC–82XZE	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XZF	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XZG	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XZH	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XZI	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
ss. 82XZJ, 82XZK	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XZL	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82XZM	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82XZN	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82Y	ad. No. 102, 1969
	am. No. 102, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976

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Provision affected	How affected
	am. No. 65, 1985; No. 94, 1986
	renum No 159, 1999
Division 4	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YA	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YB	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 32, 2007
s. 82YC	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YD	ad. No. 159, 1999
	am. No. 159, 1999
	rep. No. 32, 2007
s. 82YE	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YF	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
ss. 82YG–82YJ	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YK	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82YL	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 32, 2007
s. 82YM	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YN	ad. No. 159, 1999
	am. No. 55, 2001

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
s. 82YO	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001; No. 1, 2004
	rep. No. 32, 2007
ss. 82YP–82YS	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82YT	ad. No. 159, 1999
	am. No. 159, 1999; No. 55, 2001
	rep. No. 32, 2007
ss. 82YU–82YX	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82YY, 82YZ	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82YZA, 82YZB	ad. No. 159, 1999
	am. No. 55, 2001
	rep. No. 32, 2007
s. 82YZC	ad. No. 159, 1999
	rep. No. 32, 2007
ss. 82YZD–82YZF	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82Z	ad. No. 102, 1969
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 54, 1983; No. 94, 1986; No. 95, 1989; No. 88, 1992; No. 41, 1995
	rep. No. 159, 1999
Division 5	ad. No. 159, 1999
	rep. No. 32, 2007
s. 82ZA	ad. No. 102, 1969
	am. No. 202, 1973
	rep. No. 1, 1976

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Provision affected	How affected
	ad. No. 60, 1976
	am. No. 94, 1986; No. 41, 1995
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZB	ad. No. 102, 1969
	rep. No. 202, 1973
	ad. No. 60, 1976
	am. No. 94, 1986
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZC	ad. No. 102, 1969
	rs. No. 41, 1970
	am. No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZD	ad. No. 102, 1969
	am. No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 41, 1995
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZE	ad. No. 102, 1969
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 94, 1986; No. 41, 1995
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZF	ad. No. 102, 1969

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 41, 1995
	rs. No. 159, 1999
	rep. No. 32, 2007
s. 82ZG	ad. No. 102, 1969
	am. No. 202, 1973
	rep. No. 1, 1976
	ad. No. 60, 1976
	am. No. 41, 1995
	rep. No. 159, 1999
s. 82ZGA	ad. No. 54, 1983
	am. No. 94, 1986
	rep. No. 88, 1992
s. 82ZH	ad. No. 102, 1969
	rep. No. 1, 1976
	ad. No. 60, 1976
	rep. No. 159, 1999
s. 82ZJ	ad. No. 60, 1976
	rep. No. 159, 1999
s. 82ZK	ad. No. 60, 1976
	am. No. 94, 1986; No. 41, 1995
	rep. No. 159, 1999
s. 82ZL	ad. No. 60, 1976
	am. No. 132, 1978; No. 54, 1983; No. 94, 1986; No. 48, 1998
	rep. No. 159, 1999
s. 82ZM	ad. No. 60, 1976
	am. No. 157, 1976
	rep. No. 159, 1999
Part VIB	ad. No. 54, 1983

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Provision affected	How affected
	rep. No. 32, 2007
s. 82ZN	ad. No. 54, 1983
	am. No. 88, 1992; No. 41, 1995
	rep. No. 32, 2007
s. 82ZP	ad. No. 54, 1983
	am. No. 94, 1986; No. 95, 1989; No. 41, 1995; No. 159, 1999
	rep. No. 32, 2007
Part VIC heading	rs. No. 37, 1998
	rep. No. 32, 2007
Part VIC	ad. No. 41, 1995
	rep. No. 32, 2007
s. 82ZPA	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZQ	ad. No. 41, 1995
	am. No. 41, 1995; No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
Division 2 heading	rs. No. 37, 1998
	rep. No. 32, 2007
s. 82ZR	ad. No. 41, 1995
	am. No. 152, 1997; No. 37, 1998
	rep. No. 32, 2007
s. 82ZRAA	ad. No. 152, 1997
	am. No. 37, 1998; No. 156, 1999
	rep. No. 32, 2007
s 82ZRA	ad No 41, 1995
	am No 37, 1998
	rep No 32, 2007
s 82ZRB	ad No 41, 1995
	am No 37, 1998
	rep No 32, 2007
s. 82ZRC	ad. No. 41, 1995

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
s. 82ZS	ad. No. 41, 1995
	am. No. 37, 1998; No. 31, 2005; No. 83, 2006
	rep. No. 32, 2007
s. 82ZSAAA	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZSA	ad. No. 41, 1995
	rs. No. 45, 1997
	am. No. 159, 1999; No. 31, 2005; No. 83, 2006
	rep. No. 32, 2007
s. 82ZSAA	ad. No. 1, 2004
	am. No. 83, 2006
	rep. No. 32, 2007
s. 82ZSAB	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZSB	ad. No. 41, 1995
	rs. No. 37, 1998
	am. No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
ss. 82ZSBAA–82ZSBAD	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZSBA	ad. No. 41, 1995
	am. No. 43, 1996; No. 37, 1998
	rep. No. 32, 2007
s. 82ZSC	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZSD	ad. No. 41, 1995
	am. No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007

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Provision affected	How affected
s. 82ZSDA	ad. No. 1, 2004
	am. No. 83, 2006
	rep. No. 32, 2007
s. 82ZSE	ad. No. 41, 1995
	am. No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
s. 82ZSF	ad. No. 41, 1995
	rep. No. 37, 1998
s. 82ZSG	ad. No. 41, 1995
	am. No. 37, 1998; No. 83, 2006
	rep. No. 32, 2007
s. 82ZSH	ad. No. 37, 1998
	rep. No. 32, 2007
s. 82ZSI	ad. No. 83, 2006
	rep. No. 32, 2007
Division 4 heading	rs. No. 37, 1998
	rep. No. 32, 2007
s. 82ZT	ad. No. 41, 1995
	am. No. 37, 1998; No. 83, 2006
	rep. No. 32, 2007
s. 82ZTA	ad. No. 41, 1995
	am. No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
s. 82ZTB	ad. No. 41, 1995
	am. No. 37, 1998
	rs. No. 1, 2004
	am. No. 83, 2006
	rep. No. 32, 2007
ss. 82ZTBAA–82ZTBAF	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZTBA	ad. No. 41, 1995

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 37, 1998
s. 82ZTBB	ad. No. 41, 1995
	am. No. 43, 1996; No. 37, 1998
	rep. No. 32, 2007
s. 82ZTC	ad. No. 41, 1995
	am. No. 37, 1998; No. 1, 2004; No. 83, 2006
	rep. No. 32, 2007
s. 82ZTCA	ad. No. 1, 2004
	am. No. 83, 2006
	rep. No. 32, 2007
s. 82ZTD	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
Division 5 heading	rs. No. 37, 1998
	rep. No. 32, 2007
s. 82ZU	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUA	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUB	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUBA	ad. No. 152, 1997
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUC	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUD	ad. No. 41, 1995

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Provision affected	How affected
	am. No. 37, 1998; No. 146, 1999
	rep. No. 32, 2007
s 82ZUE	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s 82ZUF	ad. No. 41, 1995
	am. No. 37, 1998
	rep. No. 32, 2007
s. 82ZUG	ad. No. 41, 1995
	am. No. 37, 1998; No. 146, 1999
	rep. No. 32, 2007
s. 82ZUH	ad. No. 83, 2006
	rep. No. 32, 2007
s. 82ZV	ad. No. 41, 1995
	am. No. 37, 1998; No. 83, 2006
	rep. No. 32, 2007
s. 82ZVA	ad. No. 41, 1995
	am. No. 152, 1997; No. 37, 1998
	rep. No. 32, 2007
s 82ZVB	ad No 41, 1995
	rep No 32, 2007
s 82ZVC	ad No 41, 1995
	rep No 32, 2007
s. 82ZVD	ad. No. 37, 1998
	rep. No. 32, 2007
s. 82ZVE	ad. No. 37, 1998
	am. No. 83, 2006
	rep. No. 32, 2007
s. 82ZVF	ad. No. 83, 2006
	rep. No. 32, 2007
Part VID	ad. No. 69, 2003

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 32, 2007
s. 83A	ad. No. 69, 2003
	rep. No. 32, 2007
ss. 83B–83G	ad. No. 69, 2003
	rep. No. 32, 2007
ss. 83H–83J	ad. No. 69, 2003
	rep. No. 32, 2007
ss. 83K–83P	ad. No. 69, 2003
	rep. No. 32, 2007
Part VII	
Division 1	
Division 1 heading	ad No 177, 1976
s 83	am No 60, 1976; No 136, 1992
	renum No 69, 2003
s 83Z (prev s 83)	
s 84	am No 68, 1955; No 72, 1959; No 82, 1962; No 37, 1964; No 85, 1971; No 202, 1973; No 1, 1975; No 93, 1975; No 1, 1976; No 60, 1976; No 91, 1976; No 177, 1976; No 88, 1978; No 132, 1978; No 91, 1979; No 40, 1981; No 163, 1981; No 112, 1982; No 139, 1983; No 120, 1984; No 127, 1985; No 28, 1986; No 75, 1986; No 94, 1986; No 118, 1987; No 131, 1987; No 84, 1990; No 106, 1990; No 141, 1990; No 70, 1991; No 73, 1991; No 115, 1991; No 119, 1991; No 175, 1991; No 208, 1991; No 70, 1992; No 88, 1992; No 136, 1992; No 192, 1992; No 230, 1992; No 61, 1993; No 63, 1994; No 78, 1994; No 164, 1994; No 184, 1994; No 24, 1995; No 105, 1995; No 149, 1995; No 1, 1996; No 79, 1996; No 84,1996; No 157, 1997; No 45, 1998; No 116, 1998; No 75, 2000; No 146, 2000; No 80, 2001; No 50, 2004; No 52, 2004; No 117, 2004; No 111, 2005; No 151, 2005; No 136, 2006; No 32, 2007; No 111, 2007; No 169, 2007; No 180, 2007; No 49, 2008; No 144, 2008; No 29, 2010; No 126, 2010; No 32, 2011; No 87, 2012; No 10, 2015; No 59, 2015; No 89, 2015; No 67, 2016; No 16, 2017; No 59, 2017; No 128, 2017; No 1, 2018; No 42, 2019; No 77, 2019; No 139, 2021; No 53, 2022; No 33, 2024; No 73, 2024; No 39, 2025

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Provision affected	How affected
s 84AAA	ad No 151, 2005
	am No 32, 2007; No 111, 2007; No 180, 2007; No 89, 2015; No 1, 2018
	ed C126
s. 84AA	ad. No. 112, 1982
	rs. No. 35, 1983
	am. No. 94, 1986; Nos. 106 and 141, 1990; No. 80, 2001; No. 169, 2007
s. 84A	ad. No. 132, 1978
	am. No. 63, 1984; No. 94, 1986
s 84AAB	ad No 169, 2007
	am No 29, 2010; No 39, 2024
s 84AAC	ad No 169, 2007
	am No 29, 2010; No 39, 2024
s 84AAD	ad No 169, 2007
	am No 29, 2010 (as am by No 136, 2012); No 39, 2024
s 84AAE	ad No 29, 2010
s 84AAF	ad No 29, 2010
	am No 39, 2024
s 84AAG	ad No 29, 2010
	am No 39, 2024
s 84AAH	ad No 29, 2010
	am No 39, 2024
s 84AAI	ad No 29, 2010
s 84AAJ	ad No 29, 2010
	am No 39, 2024
s 84AAK	ad No 29, 2010
	am No 39, 2024
s 84AAL	ad No 29, 2010
	am No 39, 2024
s. 84AB	ad. No. 111, 2007

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Endnote 4—Amendment history

Provision affected	How affected
s. 84ABA	ad. No. 49, 2008
	am. No. 126, 2010
s. 84AC	ad. No. 111, 2007
s. 84AD	ad. No. 111, 2007
	am. No. 126, 2010
	rep No 67, 2016
s. 84AE	ad. No. 111, 2007
	am. No. 49, 2008
s 84AF	ad. No. 111, 2007
s 84AG	ad No 111, 2007
	am No 89, 2015
s 84AH	ad No 111, 2007
s 84AI	ad No 111, 2007
s. 84AJ	ad. No. 180, 2007
s. 84AK	ad. No. 87, 2012
Division 1A	
Division 1A heading	am No 141, 1990
Division 1A	ad No 94, 1986
s. 84B	ad. No. 94, 1986
	am. Nos. 49 and 144, 2008
s. 84BA	ad. No. 88, 1992
	am. No. 80, 2001
s 84C	ad No 94, 1986
	am No 22, 1987; No 46, 1988; No 84, 1990; No 106, 1990; No 141, 1990; No 119, 1991; No 208, 1991; No 88, 1992; No 192, 1992; No 106, 1993 (as am by No 116, 1994); No 116, 1994; No 149, 1995; No 164, 1995; No 79, 1996; No 37, 1998; No 50, 2004; No 52, 2004; No 119, 2004; No 151, 2005; No 136, 2006; No 111, 2007; No 169, 2007; No 180, 2007; No 87, 2012; No 89, 2015; No 16, 2017; No 59, 2017; No 1, 2018; No 42, 2019; No 53, 2022; No 73, 2024
s 84CA	ad No 84, 1990
	am No 88, 1992; No 106, 1993; No 79, 1996; No 119, 2004

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Provision affected	How affected
	rs No 1, 2018
s. 84D	ad. No. 94, 1986
	am. Nos. 84, 1990; No. 208, 1991; No. 88, 1992
s. 84DA	ad. No. 141, 1990
	am. No. 88, 1992; No. 50, 2004
s. 84E	ad. No. 94, 1986
	am. No. 22, 1987; No. 106, 1990; No. 88, 1992; No. 50, 2004
s. 84F	ad. No. 94, 1986
	am. No. 141, 1990; No. 192, 1992
s 84G	ad No 94, 1986
	am No 141, 1990
s 84H	ad No 94, 1986
	am No 141, 1990; No 39, 2024
s. 84HA	ad. No. 22, 1987
	am. No. 141, 1990
ss. 84J, 84K	ad. No. 94, 1986
	am. No. 141, 1990
s. 84L	ad. No. 94, 1986
	am. No. 22, 1987; No. 141, 1990; No. 88, 1992; No. 111, 2001; No 61, 2016
Division 2	
Division 2 heading	ad No 177, 1976
s 85	rs No 68, 1955; No 72, 1959
	am No 60, 1976; No 132, 1978; No 94, 1986; No 118, 1987; No 99, 1988; No 3, 1995; No 19, 1998; No 50, 2004; No 111, 2007; No 126, 2010; No 87, 2012; No 89, 2015; No 1, 2018
s. 85AAA	ad. No. 87, 2012
s. 85AA	ad. No. 126, 2010
s. 85A	ad. No. 132, 1978
	am. No. 131, 1980; No. 94, 1986; No. 111, 2007; No. 8, 2012
s 85AB	ad No 111, 2007

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Endnote 4—Amendment history

Provision affected	How affected
	am No 1, 2018; No 139, 2021
s. 85AC	ad. No. 111, 2007
	am. No. 126, 2010
	rep No 67, 2016
s. 85AD	ad. No. 111, 2007
	am. No. 87, 2012
s. 85B	ad. No. 53, 1985
	am. No. 94, 1986; No. 22, 1987; No. 3, 1990; No. 119, 1991
	rs. No. 111, 2007; No. 87, 2012
s 85BA	ad No 139, 2021
s. 85C	ad. No. 87, 2012
s. 85D	ad. No. 87, 2012
s 85E	ad No 89, 2015
	am No 59, 2017; No 42, 2019
s 86	am No 68, 1955
	rs No 72, 1959
	am No 132, 1978; No 94, 1986
	rs No 146, 2000
	am No 169, 2007; No 49, 2008; No 29, 2010; No 1, 2018
s. 86A	ad. No. 146, 2000
	am. No. 49, 2008
s. 86B	ad. No. 146, 2000
	am. No. 111, 2005; No. 32, 2011
s. 86C	ad. No. 146, 2000
	am. No. 111, 2005; No. 32, 2011; No 73, 2024
s. 86D	ad. No. 146, 2000
	am. No. 169, 2007; No 10, 2015
s 86E	ad No 146, 2000
	am No 10, 2015; No 129, 2020
s 87	rs No. 72, 1959

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Provision affected	How affected
	am No 44, 1966; No 85, 1971; No 1, 1976; No 60, 1976; No 132, 1978; No 112, 1982; No 53, 1985; No 75, 1986; No 94, 1986; No 22, 1987; No 46, 1988; No 3, 1990; No 84, 1990; No 106, 1990; No 141, 1990; No 119, 1991; No 208, 1991; No 88, 1992; No 106, 1993; No 164, 1995; No 79, 1996; No 37, 1998; No 80, 2001; No 119, 2004; No 151, 2005; No 111, 2007; No 49, 2008; No 29, 2010; No 87, 2012; No 89, 2015; No 1, 2018; No 53, 2022; No 73, 2024; No 39, 2025
s 87AA	ad No 53, 2022
s 87A	ad No 3, 1990
	am No 141, 1990; No 88, 1992; No 136, 1992; No 79, 1996; No 80, 2001; No 1, 2018; No 73, 2024
s 88	am No 68, 1955; No 72, 1959; No 44, 1966; No 60, 1976
	rs No 132, 1978
	am No 131, 1980; No 94, 1986; No 146, 2000; No 111, 2007; No 169, 2007; No 180, 2007; No 49, 2008; No 29, 2010; No 1, 2018
s. 88AA	ad. No. 146, 2000
	am. No. 169, 2007; No 10, 2015
s. 88A	ad. No. 131, 1980
	rs. No. 94, 1986
	am. No. 111, 2007; No. 126, 2010
s 89	rs No 68, 1955
	am No 72, 1959; No 60, 1976; No 132, 1978; No 94, 1986; No 19, 1998; No 50, 2004; No 169, 2007; No 29, 2010; No 8, 2012; No 87, 2012; No 16, 2017
s. 89A	ad. No. 8, 2012
s 90	am No 60, 1976; No 91, 1976; No 112, 1982; No 63, 1984; No 94, 1986; No 106, 1990; No 136, 1992; No 76, 1993; No 24, 1995; No 75, 2000; No 117, 2004 (as am by No 60, 2005); No 60, 2005; No 155, 2005; No 37, 2006; No 169, 2007; No 63, 2010; No 89, 2015; No 1, 2018; No 77, 2019
s 90A	ad No 37, 2006
	am No 169, 2007; No 39, 2024; No 38, 2025
s 90B	ad No 37, 2006

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Endnote 4—Amendment history

Provision affected	How affected
	am No 39, 2024; No 38, 2025
	ed C150
s 90C	ad No 37, 2006
	am No 39, 2024; No 38, 2025
s 90D	ad No 37, 2006
	am No 38, 2025
s. 90E	ad. No. 37, 2006
	am. No. 169, 2007; No 10, 2015
s. 91	rs. No. 37, 1964
	am. No. 1, 1975; No. 60, 1976
	rep. No. 139, 1983
	ad. No. 117, 2004
	am. No. 169, 2007; No 10, 2015
s 91A	ad No 16, 2017
s 91B	ad No 77, 2019
	am No 73, 2024
s. 92	am. No. 91, 1976; No. 112, 1982; No. 63, 1984; No. 94, 1986
s 92A	ad No 72, 1959
	rs No 37, 1964
	am No 1, 1975; No 60, 1976; No 91, 1976; No 112, 1982; No 35, 1983; No 63, 1984; No 94, 1986; No 106, 1990; No 141, 1990; No 136, 1992; No 24, 1995; No 69, 2003; No 37, 2006; No 10, 2015; No 1, 2018
s. 92B	ad. No. 37, 1964
	am. No. 44, 1966; No. 65, 1985; No. 94, 1986
	rs. No. 21, 1999
	am. No. 32, 2007
s. 93	am. No. 68, 1955; No. 87, 2012
s. 93AA	ad. No. 29, 2010
	rs. No. 87, 2012
s. 93AB	ad. No. 87, 2012

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Provision affected	How affected
s 93A	ad No 19, 1998
	am No 8, 2012; No 1, 2018; No 45, 2025
s. 94	am. No. 68, 1955; No. 72, 1959; Nos. 60 and 91, 1976; No. 132, 1978; No. 163, 1981; No. 112, 1982; No. 94, 1986; No. 50, 2004
s 94A	ad No 73, 2025
s 94B	ad No 73, 2025
s 95	am No 68, 1955; No 60, 1976; No 91, 1976; No 132, 1978; No 163, 1981; No 63, 1984; No 94, 1986; No 136, 1992; No 22, 1994; No 73, 2025
s. 96	rep. No. 68, 1955
s. 97	am. No. 60, 1976
	rep. No. 60, 1976
s 98	am No 44, 1966; No 60, 1976; No 91, 1976; No 132, 1978; No 163, 1981; No 63, 1984; No 53, 1985; No 65, 1985; No 94, 1986; No 136, 1992; No 76, 1993; No 50, 2004; No 169, 2007; No 29, 2010; No 77, 2019; No 73, 2025
s. 98AA	ad. No. 163, 1981
	am. No. 65, 1985; No. 94, 1986; No. 136, 1992; No. 50, 2004
s. 98AB	ad. No. 111, 2007
s 98AC	ad No 126, 2010
	am No 1, 2018; No 73, 2024
Division 3	
Division 3	ad No 177, 1976
Subdivision A	
Subdivision A	ad No 73, 2024
s 98AD	ad No 73, 2024
Subdivision B	
Subdivision B heading	ad No 73, 2024
s. 98A	ad. No. 177, 1976
	rs. No. 40, 1981
	am. Nos. 75 and 94, 1986; No. 87, 1988; No. 175, 1989; No. 88, 1992; No. 54, 2009; No. 174, 2012

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Endnote 4—Amendment history

Provision affected	How affected
s 98B	ad No 177, 1976
	rs No 40, 1981
	am No 53, 1985; No 94, 1986; No 87, 1988; No 24, 1995; No 75, 2000; SLI 2006 No 50; No 111, 2007; No 54, 2009; No 87, 2012; No 174, 2012; No 73, 2024
s 98BA	ad No 40, 1981
	am No 88, 1992; No 73, 2024
s 98BAA	ad No 84, 1990
	am No 88, 1992; No 73, 2024
ss. 98BB, 98BC	ad. No. 40, 1981
	am. No. 75, 1986; No. 175, 1989
ss. 98BD, 98BE	ad. No. 40, 1981
	am. No. 94, 1986
s. 98C	ad. No. 177, 1976
	am. No. 40, 1981; No. 94, 1986; No. 87, 2012; No 10, 2015
s. 98D	ad. No. 177, 1976
	am. No. 40, 1981
	rep No 10, 2015
s 98E	ad No 177, 1976
	rs No 40, 1981
	am No 75, 1986; No 94, 1986; No 73, 2025
Subdivision C	
Subdivision C heading	ad No 73, 2024
s 99	am No 72, 1959; No 44, 1966; No 85, 1971; No 202, 1973; No 1, 1976; No 60, 1976; No 177, 1976; No 132, 1978; No 112, 1982; No 35, 1983; No 53, 1985; No 94, 1986; No 22, 1987; No 118, 1987; No 46, 1988; No 3, 1990; No 84, 1990; No 106, 1990; No 119, 1991 (as am by No 149, 1995); No 106, 1993; No 79, 1996; No 19, 1998; No 146, 2000; No 50, 2004; No 119, 2004; No 111, 2005; No 151, 2005; No 111, 2007; No 169, 2007; No 29, 2010; No 32, 2011; No 87, 2012; No 10, 2015; No 89, 2015; No 16, 2017; No 1, 2018; No 53, 2022; No 73, 2024; No 39, 2025
s 99AAAA	ad No 73, 2024

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Provision affected	How affected
s 99AAAB	ad No 73, 2024
s. 99AAA	ad. No. 118, 1987
	rs. No. 119, 1991
	am. No. 126, 2010
s. 99AAB	ad. No. 118, 1987
	rs. No. 119, 1991
	am. No. 24, 1995; No. 19, 1998; No. 75, 2000
s. 99AAC	ad. No. 118, 1987
	rs. No. 119, 1991
	am No 10, 2015
Division 3AA	
Division 3AA heading	ad No 64, 2018
s 99AA	ad No 94, 1986
	am No 118, 1987; No 119, 1991; No 80, 2001; No 64, 2018
s 99AB	ad No 22, 1987 (as am by No 192, 1992)
	am No 73, 2024
s 99ABA	ad No 64, 2018
	am No 77, 2022
s 99ABB	ad No 64, 2018
s 99ABC	ad No 64, 2018
s 99ABD	ad No 64, 2018
	am No 77, 2022; No 39, 2024
s 99ABE	ad No 64, 2018
s 99ABF	ad No 64, 2018
s 99ABG	ad No 64, 2018
	am No 77, 2022; No 39, 2024
s 99ABH	ad No 64, 2018
	am No 77, 2022
s 99ABI	ad No 64, 2018
s 99ABJ	ad No 64, 2018
	am No 39, 2024

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Endnote 4—Amendment history

Provision affected	How affected
s 99ABK	ad No 64, 2018
s 99ABL	ad No 64, 2018
	am No 77, 2022
Division 3A	
Division 3A	ad No 111, 2007
Subdivision A	
s 99AC	ad No 111, 2007
	rs No 126, 2010
	am No 126, 2010; No 89, 2015; No 1, 2018; No 139, 2021
s 99ACA	ad No 111, 2007
	am No 126, 2010; No 89, 2015; No 1, 2018; No 139, 2021
Subdivision B	
Subdivision B heading	rs No 126, 2010; No 1, 2018
	am No 139, 2021
s 99ACB	ad No 111, 2007
	am No 126, 2010; No 87, 2012; No 1, 2018; No 139, 2021 (sch 1 items 88-100)
s 99ACBA	ad No 1, 2018
	rep No 139, 2021
Subdivision C	
s 99ACC	ad No. 111, 2007
	am No. 126, 2010; No. 87, 2012; No 89, 2015; No 1, 2018; No 139, 2021 (sch 1 items 101-103)
s 99ACD	ad No. 111, 2007
	am No 126, 2010; No 87, 2012; No 1, 2018; No 139, 2021 (sch 1 items 104-116)
s 99ACE	ad No. 111, 2007
	am No 126, 2010; No 87, 2012; No 1, 2018
	rep No 139, 2021
Subdivision CA	ad No 126, 2010
	rep No 89, 2015

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Provision affected	How affected
s 99ACEA	ad No. 126, 2010
	am No. 87, 2012
	rep No 89, 2015
	ad No 1, 2018
	rep No 139, 2021
s. 99ACEB	ad. No. 126, 2010
	am. No. 136, 2012
	rep No 89, 2015
Subdivision D	
s 99ACF	ad No 111, 2007
	am No 126, 2010; No 87, 2012; No 89, 2015; No 1, 2018; No 139, 2021 (sch 1 items 117-119)
s 99ACG	ad No 111, 2007
	am No 126, 2010; No 89, 2015; No 1, 2018; No 139, 2021
s 99ACH	ad No 111, 2007
	am No 126, 2010; No 1, 2018
	rep No 139, 2021
s 99ACHA	ad No 89, 2015
	rep No 89, 2015
	am No 1, 2018; No 139, 2021
s 99ACHB	ad No 139, 2021
s. 99ACI	ad. No. 111, 2007
	am No. 126, 2010
	rep No 89, 2015
s. 99ACIA	ad. No. 126, 2010
	rep No 89, 2015
s 99ACJ	ad No 111, 2007
	rep No 89, 2015
	ad No 1, 2018
s 99ACJA	ad No 139, 2021
s 99ACK	ad No 111, 2007

Endnote 4—Amendment history

Provision affected	How affected
	am No 126, 2010; No 87, 2012
	rep No 89, 2015
	ad No 1, 2018
s 99ACKA	ad No 139, 2021
s 99ACKB	ad No 139, 2021
s 99ACL	ad No 126, 2010
	rep No 89, 2015
	ad No 1, 2018
s 99ACM	ad No 126, 2010
	rep No 89, 2015
	ad No 139, 2021
s 99ACN	ad No 126, 2010
	rep No 89, 2015
	ad No 139, 2021
s 99ACNA	ad No 139, 2021
s 99ACO	ad No 126, 2010
	rep No 89, 2015
s 99ACP	ad No 126, 2010
	rep No 89, 2015
	ad No 139, 2021
	rep No 139, 2021
Subdivision E	
Subdivision E	ad No 139, 2021
s 99ACQ	ad No 126, 2010
	rep No 89, 2015
	ad No 139, 2021
	am No 139, 2021
s 99ACR	ad No 139, 2021
	am No 139, 2021
Division 3B	
Division 3B	ad No 111, 2007

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Provision affected	How affected
Subdivision A	
s. 99AD	ad. No. 111, 2007
	am. No. 126, 2010; No. 87, 2012
s. 99ADA	ad. No. 111, 2007
	rs. No. 126, 2010
s 99ADB	ad No 111, 2007
	am No 126, 2010; No 87, 2012; No 6, 2014; No 89, 2015; No 1, 2018
s 99ADBA	ad No 1, 2018
Subdivision B	
s. 99ADC	ad. No. 111, 2007
Subdivision C heading	rep. No. 126, 2010
s. 99ADD	ad. No. 111, 2007
	rs. No. 126, 2010
s. 99ADE	ad. No. 111, 2007
	rep. No. 126, 2010
Subdivision D	
ss. 99ADF, 99ADG	ad. No. 111, 2007
Subdivision E	
s 99ADH	ad No 111, 2007
	am No 126, 2010; No 87, 2012; No 6, 2014; No 1, 2018; No 139, 2021; No 88, 2024
s. 99ADHA	ad. No. 87, 2012
s 99ADHB	ad No 89, 2015
	am No 139, 2021
s. 99ADJ	ad. No. 126, 2010
	rep. No. 87, 2012
Division 3BA	
Division 3BA	ad No 139, 2021
s 99ADHC	ad No 139, 2021
	am No 88, 2024

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Endnote 4—Amendment history

Provision affected	How affected
s 99ADHD	ad No 88, 2024
Division 3C	
Division 3C	ad No 111, 2007
Subdivision A	
s. 99AE	ad. No. 111, 2007
s. 99AEA	ad. No. 111, 2007
Subdivision B	
s. 99AEB	ad. No. 111, 2007
Subdivision C	
s. 99AEC	ad. No. 111, 2007
s. 99AED	ad. No. 111, 2007
	am. No. 87, 2012
Subdivision D	
ss. 99AEE, 99AEF	ad. No. 111, 2007
Subdivision E	
s. 99AEG	ad. No. 111, 2007
Subdivision F	
s. 99AEH	ad. No. 111, 2007
Subdivision G	
s 99AEI	ad No 111, 2007
	am No 126, 2010; No 87, 2012; No 89, 2015; No 139, 2021 (sch 1 items 123-125)
ss. 99AEJ, 99AEK	ad. No. 111, 2007
Division 3CAA	
Division 3CAA	ad No 139, 2021
s 99AEKA	ad No 139, 2021
s 99AEKB	ad No 139, 2021
s 99AEKC	ad No 139, 2021
s 99AEKD	ad No 139, 2021
s 99AEKE	ad No 139, 2021
s 99AEKF	ad No 139, 2021

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Provision affected	How affected
Division 3CA	
Division 3CA	ad No 139, 2021
s 99AEL	ad No 111, 2007
	rep No 126, 2010
	ad No 139, 2021
	am No 139, 2021
Division 4	
Division 4	ad. No. 177, 1976
	rs. No. 40, 1981
s. 99A	ad. No. 177, 1976
	rs. No. 40, 1981
	am. Nos. 75 and 94, 1986; No. 87, 1988; No. 106, 1990; No. 88, 1992; No. 54, 2009; No. 174, 2012
s. 99B	ad. No. 177, 1976
	rs. No. 40, 1981
	am. Nos. 75 and 94, 1986; No. 87, 1988; No. 88, 1992 (as am. by No. 12, 1994); No. 43, 1996; No. 54, 2009; No. 174, 2012
s. 99C	ad. No. 177, 1976
	rs. No. 40, 1981
	am. Nos. 75 and 94, 1986
s. 99D	ad. No. 177, 1976
	rs. No. 40, 1981
	am. Nos. 75 and 94, 1986; No. 87, 1988; No. 88, 1992; No. 54, 2009; No. 46, 2011; No. 174, 2012
s. 99E	ad. No. 177, 1976
	rs. No. 40, 1981
	am. No. 94, 1986; No. 46, 2011
Division 4A	
Division 4A heading	am No 73, 2024
Division 4A	ad No 84, 1990

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Endnote 4—Amendment history

Provision affected	How affected
Subdivision A	
Subdivision A heading	ad No 73, 2024
s 99F	ad No 177, 1976
	rep No 40, 1981
	ad No 84, 1990
	am No 106, 1990; No 141, 1990; No 208, 1991; No 88, 1992; No 106, 1993; No 164, 1995; No 79, 1996; No 119, 2004; No 151, 2005; No 1, 2018; No 106, 2019; No 14, 2022; No 53, 2022
Subdivision B	
Subdivision B heading	ad No 73, 2024
s 99G	ad No 177, 1976
	rep No 40, 1981
	ad No 84, 1990
	am No 208, 1991; No 106, 1993; No 164, 1995; No 79, 1996; No 119, 2004; No 151, 2005; No 145, 2015; No 106, 2019; No 53, 2022; No 73, 2024; No 39, 2025
Subdivision C	
Subdivision C	ad No 73, 2024
s 99GA	ad No 73, 2024
s 99GB	ad No 73, 2024
s 99GC	ad No 73, 2024
	rep No 39, 2025
s 99GD	ad No 73, 2024
	exp (s 99GD(4))
s 99GE	ad No 73, 2024
	am No 39, 2025
Division 4B	
Division 4B heading	am No 24, 1995
Division 4B	ad No 106, 1990
s. 99H	ad. No. 177, 1976
	rep. No. 40, 1981
	ad. No. 106, 1990

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Provision affected	How affected
s. 99J	ad. No. 106, 1990
	am. No. 24, 1995
s. 99K	ad. No. 106, 1990
	am. No. 136, 1992; No. 24, 1995; No. 75, 2000
	ed C135
s. 99L	ad. No. 106, 1990
	am. No. 24, 1995; No. 75, 2000; No 10, 2015
s. 99M	ad. No. 106, 1990
s 99N	ad No 106, 1990
	rs No 24, 1995
	am No 37, 2006; No 38, 2025
s 99P	ad. No. 106, 1990
s 99Q	ad No 106, 1990
s 99R	ad. No. 106, 1990
	am. No. 24, 1995
s 99S	ad No 106, 1990
	am No 24, 1995
s. 99T	ad. No. 106, 1990
s. 99U	ad. No. 106, 1990
	rs. No. 24, 1995
s 99V	ad. No. 106, 1990
	am. No. 24, 1995
s 99W	ad No 106, 1990
	am No 24, 1995
s. 99X	ad. No. 106, 1990
s 99Y	ad No 106, 1990
	am No 24, 1995; No 75, 2000; No 60, 2005; No 155, 2005; No 37, 2006; No 63, 2010; No 89, 2015
	rep No 1, 2018
Division 4C	
Division 4C	ad. No. 106, 1990

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 75, 2000
	ad. No. 71, 2009
Subdivision A	
s. 99YB	ad. No. 71, 2009
Subdivision B	
s. 99YBA	ad. No. 71, 2009
Subdivision C	
s. 99YBB	ad. No. 71, 2009
Subdivision D	
s. 99YBC	ad. No. 71, 2009
	am. No. 5, 2011; No. 136, 2012
s. 99Z	ad. No. 106, 1990
	am. No. 136, 1992
	rep. No. 19, 1998
s. 99ZA	ad. No. 106, 1990
	am. No. 24, 1995
	rep. No. 75, 2000
s. 99ZAA	ad. No. 24, 1995
	rep. No. 75, 2000
s. 99ZB	ad. No. 106, 1990
	rep. No. 19, 1998
s. 99ZC	ad. No. 106, 1990
	am. No. 88, 1992; No. 24, 1995
	rep. No. 19, 1998
s. 99ZD	ad. No. 106, 1990
	am. No. 24, 1995
	rep. No. 19, 1998
s. 99ZDA	ad. No. 24, 1995
	rep. No. 75, 2000
s. 99ZE	ad. No. 106, 1990
	rs. No. 24, 1995

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Provision affected	How affected
	rep. No. 19, 1998
s. 99ZF	ad. No. 106, 1990
	rep. No. 24, 1995
s. 99ZG	ad. No. 106, 1990
	am. No. 24, 1995
	rep. No. 75, 2000
Division 4D	
Division 4D	ad No 35, 1999
s. 99ZH	ad. No. 35, 1999
	am. No. 111, 2005; No. 33, 2009; No. 32, 2011; No 41, 2015
s. 99ZI	ad. No. 35, 1999
	am. No. 49, 2008
ss. 99ZJ, 99ZK	ad. No. 35, 1999
	am. No. 111, 2005; No. 169, 2007; No. 49, 2008; No. 29, 2010; No. 32, 2011
s. 99ZL	ad. No. 35, 1999
s. 99ZM	ad. No. 35, 1999
	am No 41, 2015
s. 99ZN	ad. No. 35, 1999
	am. No. 111, 2005; No. 33, 2009; No. 32, 2011; No 41, 2015
s. 99ZO	ad. No. 35, 1999
	am. No. 111, 2005; No. 32, 2011
ss. 99ZP, 99ZQ	ad. No. 35, 1999
s 99ZR	ad. No. 35, 1999
	am. No. 111, 2005; No. 32, 2011
s. 99ZS	ad. No. 35, 1999
	am. No. 111, 2005; No. 32, 2011; No 10, 2015; No 41, 2015
s. 99ZT	ad. No. 35, 1999
	am. No. 111, 2005; No. 49, 2008; No. 32, 2011
Division 5	
Division 5 heading	ad No 177, 1976

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Endnote 4—Amendment history

Provision affected	How affected
s. 100	am. No. 94, 1986
	rs. No. 50, 2004
	am. No. 126, 2010; No 53, 2022
s. 100AA	ad. No. 50, 2004
	rep. No. 126, 2010
s. 100A	ad. No. 146, 2000
	am. No. 50, 2004; No. 140, 2005; No 89, 2015
s. 100B	ad. No. 146, 2000
	am. No. 50, 2004; No 89, 2015
ss. 100C, 100D	ad. No. 146, 2000
s 101	am No 68, 1955; No 72, 1959; No 16, 1961; No 82, 1962; No 41, 1970; No 202, 1973; No 60, 1976; No 91, 1976; No 63, 1984; No 94, 1986; No 118, 1987; No 19, 1998; No 146, 2000; No 50, 2004; No 140, 2005; No 151, 2005; No 111, 2007; No 126, 2010; No 87, 2012; No 89, 2015; No 1, 2018; No 139, 2021
s. 101A	ad. No. 118, 1987
	am. No. 140, 2005
s 101B	ad No 16, 2017
s. 102	am. No. 91, 1976; No. 63, 1984; No. 94, 1986
s. 103	am. No. 68, 1955; No. 72, 1959; No. 44, 1966; No. 91, 1976; No. 132, 1978; No. 112, 1982; No. 35, 1983; No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 88, 1992; Nos. 80 and 116, 1994; No. 35, 1999; No. 137, 2000; No. 111, 2001; No. 63, 2002; No. 111, 2005; Nos. 111, 169 and 180, 2007; No. 49, 2008; No. 29, 2010; No. 32, 2011; No 61, 2016
s. 104	am. No. 68, 1955; No. 37, 1964; No. 44, 1966; Nos. 60 and 91, 1976; No. 132, 1978; Nos. 63 and 135, 1984; No. 65, 1985; No. 94, 1986
	rep. No. 85, 1994
s. 104A	ad. No. 72, 1959
	am. No. 91, 1976; No. 112, 1982; No. 63, 1984; No. 94, 1986
s 104B	ad No 111, 2007
	rep No 16, 2017
	ad No 139, 2021

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Provision affected	How affected
Part VIIA	
Part VIIA heading	am No 39, 2024
Part VIIA	ad No 60, 1976
s 105AA	ad No 60, 1976
	rs No 112, 1982
	am No 39, 2024
s. 105AAA	ad. No. 88, 1978
	am. No. 131, 1980; No. 63, 1984
	rs. No. 72, 1984
	am. No. 165, 1984
	rep. No. 94, 1986
s. 105AAB	ad. No. 139, 1983
	am. No. 139, 1983; No. 135, 1984; Nos. 94 and 115, 1986; No. 72, 1987; No. 3, 1990; Nos. 83 and 84, 1991; No. 12, 1994; No. 149, 1995; No. 114, 1997; No. 111, 2009
	rep. No. 86, 2011
s 105AB	ad No 60, 1976
	am No 99, 1976; No 132, 1978; No 189, 1978; No 112, 1982; No 54, 1983; No 63, 1984; No 70, 1985; No 94, 1986; No 95, 1989; No 106, 1990; No 119, 1991; No 136, 1992; No 192, 1992; No 200, 1992; No 23, 1994; No 24, 1995; No 41, 1995; No 19, 1998; No 37, 1998; No 130, 1999; No 159, 1999; No 75, 2000; No 69, 2003; No 1, 2004; No 117, 2004; No 37, 2006; No 83, 2006; No 32, 2007; No 169, 2007; No 29, 2010; No 86, 2011; No 5, 2015; No 16, 2017; No 1, 2018; No 77, 2019; No 39, 2024; No 73, 2025
s 105AC	ad No 112, 1982
	am No 139, 1983; No 63, 1984; No 72, 1984; No 165, 1984; No 94, 1986; No 115, 1986; No 84, 1991; No 86, 2011; No 39, 2024
s 105AD	ad No 211, 1991
	am No 24, 1995; No 19, 1998; No 75, 2000; No 37, 2006; No 39, 2024
s 105AE	ad No 37, 2006
	am No 39, 2024; No 38, 2025

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Endnote 4—Amendment history

Provision affected	How affected
s. 105A	ad. No. 202, 1973
	rep. No. 91, 1976
s. 106	rep. No. 88, 1978
Part VIII	
Division 1	
s. 107	am. No. 68, 1955; No. 37, 1964; Nos. 60 and 91, 1976; No. 132, 1978; No. 63, 1984; Nos. 75 and 94, 1986; No. 169, 2007; No 59, 2015
Division 2 heading	rs. No. 75, 1986
	rep. No. 22, 1994
Division 2	rep. No. 22, 1994
s. 108	am. No. 82, 1962; No. 91, 1976; No. 63, 1984; Nos. 75 and 94, 1986
	rep. No. 22, 1994
s. 109	am. No. 68, 1955; Nos. 60 and 91, 1976; No. 63, 1984; No. 75, 1986
	rep. No. 22, 1994
s. 110	rs. No. 68, 1955
	am. No. 82, 1962; No. 202, 1973; No. 72, 1984; Nos. 75 and 94, 1986
	rep. No. 22, 1994
s. 111	am. No. 68, 1955; Nos. 60 and 91, 1976; No. 63, 1984; Nos. 75 and 94, 1986
	rep. No. 22, 1994
s. 111A	ad. No. 68, 1955
	am. No. 68, 1958; No. 60, 1976; Nos. 75 and 94, 1986
	rep. No. 22, 1994
s. 112	am. No. 132, 1978; No. 94, 1986
	rep. No. 22, 1994
Division 2AA	ad. No. 132, 1978
	rep. No. 22, 1994
ss. 112AA, 112AB	ad. No. 132, 1978
	am. No. 63, 1984
	rep. No. 22, 1994

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Provision affected	How affected
s. 112AC	ad. No. 132, 1978
	am. No. 72, 1984
	rep. No. 22, 1994
s. 112AD	ad. No. 132, 1978
	am. No. 63, 1984
	rep. No. 22, 1994
s. 112AE	ad. No. 132, 1978
	am. No. 94, 1986
	rep. No. 22, 1994
Division 2A	ad. No. 68, 1955
	rep. No. 211, 1991
s. 112A	ad. No. 68, 1955
	am. No. 82, 1962; No. 94, 1986
	rep. No. 211, 1991
s. 112B	ad. No. 68, 1955
	am. Nos. 60 and 91, 1976; No. 100, 1977; No. 63, 1984; No. 94, 1986
	rep. No. 211, 1991
Division 3	
s. 113	am. No. 91, 1976; No. 63, 1984; No. 94, 1986
s. 114	am. No. 91, 1976; No. 63, 1984; Nos. 75 and 94, 1986; No. 50, 2004; No. 126, 2010
s. 115	am. No. 68, 1955; No. 91, 1976; No. 72, 1984; No. 94, 1986
s. 116	am. Nos. 60 and 91, 1976; No. 63, 1984; Nos. 75 and 94, 1986; No. 50, 2004; No. 126, 2010
s. 117	am. No. 132, 1978; No. 94, 1986; No. 169, 2007
Division 3A	ad. No. 114, 1972
	rep. No. 86, 2011
s. 117A	ad. No. 114, 1972
	am. No. 94, 1986
	rs. No. 141, 1990

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Endnote 4—Amendment history

Provision affected	How affected
	rep. No. 86, 2011
s. 117B	ad. No. 114, 1972
	am. No. 60, 1976; No. 94, 1986; No. 155, 1988
	rep. No. 86, 2011
Division 4	
s. 118	am. No. 75, 1986
s. 119A	ad. No. 55, 1956
	am. No. 94, 1986
s. 120	am. No. 75, 1986
s. 120A	ad. No. 16, 1961
s. 124	am. Nos. 75 and 94, 1986
s. 125	am. Nos. 60 and 91, 1976
	rs. No. 132, 1978
	am. No. 63, 1984; No. 75, 1986; No. 94, 1986 (as am. by No. 141, 1987); No. 169, 2007
s. 126	am. Nos. 75 and 94, 1986
s. 127	am. No. 82, 1962; No. 94, 1986
s. 128	am. No. 44, 1966; No. 65, 1985; No. 94, 1986; No. 111, 2001; No 61, 2016
s. 129	am. No. 44, 1966; No. 65, 1985; No. 94, 1986; No 61, 2016
Division 5	ad. No. 41, 1995
	rep. No. 37, 1998
Part VIIIA	
Part VIIIA	ad No 121, 2019
s 132A	ad No 202, 1973
	rep No 91, 1976
	ad No 41, 1995
	rep No 37, 1998
	ad No 121, 2019
	am No 8, 2025
s 132AB	ad No 8, 2025

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Provision affected	How affected
s 132B	ad No 121, 2019
	am No 8, 2025
s 132C	ad No 121, 2019
s 132D	ad No 121, 2019
s 132E	ad No 121, 2019
s 132F	ad No 121, 2019
Part VIIIB	
Part VIIIB	ad No 108, 2021
	exp 1 July 2022 (s 132G(3))
s 132G	ad No 108, 2021
	exp 1 July 2022 (s 132G(3))
Part IX	
s 133	am No 68, 1955; No 6, 1976, No 91, 1976
	rs No 132, 1978
	am No 63, 1984; No 120, 1984; No 94, 1986; No 136, 1992; No 50, 2004; No 169, 2007; No 29, 2010; No 126, 2010; No 87, 2012; No 59, 2015; No 16, 2023
s. 133A	ad. No. 60, 1976
	am. No. 36, 1978; No. 5, 2011
s. 134	am. No. 44, 1966; Nos. 60 and 91, 1976; No. 132, 1978; No. 63, 1984; No. 65, 1985; No. 94, 1986; No. 72, 1987; No. 50, 2004; No. 169, 2007; Nos. 29 and 126, 2010; No. 87, 2012; No 61, 2016
s. 134A	ad. No. 68, 1955
	am. No. 55, 1956
	rs. No. 82, 1962
	am. Nos. 60 and 91, 1976; No. 63, 1984; No. 94, 1986
s. 134AA	ad. No. 82, 1962
	am. No. 60, 1976
	rep. No. 167, 1985
s. 134B	ad. No. 68, 1955
	am. No. 94, 1986; Nos. 72 and 132, 1987; No. 86, 2011
s. 134C	ad. No. 68, 1955

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 112, 1982; No. 94, 1986; No. 111, 2001
s 134D	ad No 68, 1955
	rep No 32, 2007
	ad No 64, 2018
	am No 13, 2021
s 134E	ad No 64, 2018
s 134E (second occurring)	ad. No. 94, 1986
	am No 5, 2015
	renum
	ed C128
s 134F (prev 134E second occurring)	
s. 135	am. No. 120, 1984; No. 94, 1986; No 59, 2015
s 135A	ad No 1, 1975
	rs No 139, 1983
	am No 63, 1984; No 165, 1984; No 65, 1985; No 94, 1986; No 132, 1987; No 95, 1989; No 3, 1990; No 106, 1990; No 88, 1992; No 204, 1992; No 29, 1997; No 19, 1998; No 111, 2001; No 133, 2002; No 17, 2004; No 50, 2004; No 77, 2004; No 111, 2005; No 126, 2005; No 83, 2006; No 32, 2007; No 169, 2007; No 29, 2010; No 126, 2010; No 5, 2011; No 32, 2011; No 86, 2011; No 64, 2012; No 136, 2012; No 139, 2015; No 157, 2015; No 4, 2016; No 61, 2016; No 72, 2017; No 105, 2019; No 121, 2019; No 8, 2025; No 73, 2025
s 135AAA	ad No 146, 2000
	am No 111, 2005; No 169, 2007; No 32, 2011; No 4, 2016; No 73, 2025
s 135AA	ad No 119, 1991
	rs No 28, 1993
	am No 146, 2000; No 50, 2004; No 111, 2005; No 51, 2010; No 126, 2010; No 32, 2011; No 64, 2012; No 197, 2012; No 126, 2015; No 157, 2015; No 121, 2019
	rep No 73, 2025
s 135AB	ad No 119, 1991

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Provision affected	How affected
	am No. 28, 1993; No 51, 2010; No 197, 2012; No 128, 2024
	rep No 73, 2025
s 135ABA	ad No 73, 2025
s 135ABB	ad No 73, 2025
s 135ABC	ad No 73, 2025
s 135AC	ad No 99, 2006
	am No 32, 2011; No 197, 2012; No 73, 2025
s 135ACA	ad No 73, 2025
s 135ACB	ad No 73, 2025
s 135ACC	ad No 73, 2025
s 135ACD	ad No 73, 2025
s. 135B	ad. No. 139, 1983
	am. No. 65, 1985; No. 94, 1986; No. 132, 1987; No. 211, 1991; No. 86, 2011
s. 136	am. No. 54, 1979; No. 94, 1986
s. 136A	ad. No. 82, 1962
s. 137	am. No. 82, 1962; No. 102, 1969; Nos. 1 and 60, 1976; No. 88, 1978; No. 24, 1985; No. 94, 1986; No. 211, 1991; No. 86, 2011; No 72, 2017
s. 138	am. No. 91, 1976; No. 139, 1983; No. 63, 1984
s. 138A	ad. No. 95, 1989
s. 139	am. No. 91, 1976; No. 63, 1984; No. 94, 1986; No. 3, 1995
s 139A	ad No 68, 1955
	am No 72, 1959; No 82, 1962; No 100, 1968; No 41, 1970; No 114, 1972; No 1, 1975; No 60, 1976; No 91, 1976; No 100, 1977; No 132, 1978; No 112, 1982; No 54, 1983; No 63, 1984; No 94, 1986; No 72, 1987; No 136, 1992; No 13, 1999; No 32, 2007; No 169, 2007; No 29, 2010; No 86, 2011; No 87, 2012; No 61, 2016; No 1, 2018
s. 139B	ad. No. 115, 1986
	am. Nos. 72, 118 and 132, 1987
	rs. No. 79, 1988

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Endnote 4—Amendment history

Provision affected	How affected
	am. Nos. 83, 84, 119 and 211, 1991; Nos. 88, 192 and 204, 1992; No. 13, 1999; No. 86, 2011
	rep No 10, 2015
s. 139C	ad. No. 80, 2001
	am. No. 5, 2011; No. 136, 2012
s. 140	am. No. 44, 1966; No. 41, 1970; No. 60, 1976; No. 65, 1985; No. 95, 1989; No. 41, 1995; No. 69, 2003; No, 32, 2007; No 61, 2016
Heading to The Schedules	rep. No. 37, 1964
	ad. No. 41, 1970
	rep. No. 60, 1976
First, Second Schedules	rs. No. 68, 1955; No. 92, 1957
	am. No. 72, 1959
	rep. No. 37, 1964
The Schedule	ad. No. 37, 1964
	rs. No. 44, 1966; No. 100, 1967
	rep. No. 41, 1970
First–Seventh Schedules	ad. No. 41, 1970
	am. No. 85, 1971; No. 114, 1972; No. 202, 1973
	rep. No. 60, 1976
Eighth Schedule	ad. No. 114, 1972
	am. No. 1, 1975; No. 99, 1976
	rep. No. 100, 1977
Heading to Schedule	rep. No. 141, 1990
Heading to Schedule 1	ad. No. 141, 1990
	rep. No. 32, 2007
Schedule 1	ad. No. 132, 1978
	am. No. 54, 1979; No. 118, 1981; No. 49, 1982
	rs. No. 54, 1983

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 63, 1984; Nos. 70 and 167, 1985; No. 94, 1986; No. 79, 1988; No. 95, 1989; Nos. 88 and 136, 1992; No. 80, 1994; No. 41, 1995 (as am. by No. 149, 1995); No. 37, 1998; Nos. 21 and 130, 1999; No. 72, 2000; Nos. 63 and 76, 2002; No. 1, 2004 (as am. by No. 31, 2005); Nos. 31, 111 and 155, 2005
	rep. No. 32, 2007
Schedule 2.....	ad. No. 141, 1990
	rep. No. 114, 1997
	ad. No. 130, 1999
	am. No. 6, 2001; No. 1, 2004; Nos. 9 and 111, 2005
	rep. No. 32, 2007
Schedule 3.....	ad. No. 83, 1991
	am. Statutory Rules 1991 No. 310; 1993 No. 274
	rep. No. 114, 1997
Schedule 4.....	ad. No. 211, 1991
	rep. No. 86, 2011

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