

EXPLANATORY STATEMENT

Select Legislative Instrument 2017 No.

Issued by the authority of the Minister for Health

Subject - *National Health Act 1953*

National Health (Pharmaceutical Benefits) Regulations 2017

The *National Health Act 1953* (the Act) provides in Part VII for the provision of pharmaceutical benefits by the Commonwealth. Provisions in Part VII include eligibility to receive pharmaceutical benefits, requirements for the listing and pricing of drugs and medicinal preparations as pharmaceutical benefits, and arrangements for prescribing, supply, payment, subsidy, and safety nets.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

The National Health (Pharmaceutical Benefits) Regulations 2017 (the new Regulations) replace and repeal the *National Health (Pharmaceutical Benefits) Regulations 1960* (the 1960 regulations), which are due to sunset on 1 April 2017 in accordance with subsection 50(2) of the *Legislation Act 2003*.

The provisions in the new Regulations retain substantially similar content to that of the 1960 regulations, with redrafting where necessary to ensure provisions are clear, consistent and ordered in a logical manner. A number of minor changes clarify the policy intent of existing provisions and reflect current practice. The changes also include updating obsolete references and providing definitions for terms used, but not defined in the 1960 regulations. The provisions have been rewritten, reordered and renumbered using modern drafting style and language.

The new Regulations change the validity period of hospital medication chart (HMC) prescriptions, allowing the period to operate in the same way as for standard prescriptions. The validity period of HMC prescriptions have been extended by one day.

Under the current legislation, a standard (non-medication chart) Pharmaceutical Benefits Scheme (PBS) prescription is valid for supply from the date of prescribing until the 12-month anniversary of that date. HMC prescriptions are currently valid for 1, 4 or 12 months. The proposed amendment sees HMC prescriptions remaining valid for supply under the PBS from the date of prescribing until the 1, 4 or 12-month anniversary of that date.

The 1960 regulations define the terms “maximum value of a pharmaceutical benefit for safety net purposes” and “maximum value of a repatriation pharmaceutical benefit for safety net purposes”. The 1960 regulations also use but do not define the terms “value” and “maximum value” of a pharmaceutical benefit, repatriation pharmaceutical benefit and out-patient medication when referring to the applicable amount to be counted towards a person’s safety net threshold. The terms “value” and “maximum value” are both intended to mean the “maximum value for safety net purposes” in relation to the prescription type.

The new Regulations include a new section setting out the meaning of the term “maximum value for safety net purposes” for pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medications. The new section clarifies that where payment is made by a person to a public hospital authority for supply of out-patient medication, the “maximum value for safety net purposes” is the amount that is taken to have been paid for the supply as determined by the Minister under subsection 84BA(3) of the Act. This amount is described in subsection 84BA(4) as being the “applicable amount” for the purposes of Part VII of the Act. The new section further clarifies that the “maximum value for safety net purposes” for out-patient medication is the lesser of the applicable amount or the amount charged for the supply of the medication.

The new Regulations extend the provisions in the 1960 regulations regarding supply of pharmaceutical benefits before surrender of a written prescription (that is, supply in cases of urgency), to require that where a prescription would be an authority prescription and the pharmaceutical benefit has a relevant streamlined authority code, the PBS prescriber must inform the supplier of that code before the pharmaceutical benefit is supplied.

The new Regulations also contain a number of changes in order to meet modern drafting standards.

In September 2016, pharmacy, pharmaceutical industry, and consumer representative peak bodies were sent a letter advising of the need for the 1960 regulations to be replaced and summarising the proposed changes. The stakeholders involved were the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, Medicines Australia, the Generic and Biological Medicines Association, and the Consumers Health Forum of Australia. As a result of stakeholder comments, the instrument was revised to include a note regarding retention of scanned documents as records for record keeping purposes. In January 2017, a confidential draft of the new Regulations was offered to the same stakeholders and also to the Medical Software Industry Association. Representatives of three stakeholder groups elected to participate in that process and no further comments were received as a result of that process.

Details of the new Regulations are set out in the [Attachment](#).

The Act specifies no conditions that need to be met before the power to make the new Regulations may be exercised.

The new Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The new Regulations commence on 1 April 2017.

The Minute recommends that the Regulations be made in the form proposed.

Authority: Section 140 of the *National Health Act 1953*

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceutical Benefits) Regulations 2017

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

Overview of the Legislative Instrument

The proposed National Health (Pharmaceutical Benefits) Regulations 2017 (the new Regulations) revoke and replace in their entirety, the *National Health (Pharmaceutical Benefits) Regulations 1960* (the 1960 regulations), which sunset on 1 April 2017.

The new Regulations preserve existing arrangements in the 1960 regulations. Some minor and technical changes have been introduced into the new Regulations in order to better articulate existing policy and to comply with modern drafting standards. These changes include extending the validity period of hospital medication chart (HMC) prescriptions by a single day to align with the validity period of other PBS prescriptions; adding a new section which defines the term “maximum value for safety net purposes”; clarifying that certain paper documents required to be kept for record-keeping purposes may be scanned and kept as electronic copies; and extending current requirements for urgent supply of authority prescriptions to include that where a streamlined authority code is associated with the prescription, the PBS prescriber must inform an approved supplier of the code.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

It does not engage or interfere with the right of individuals to the enjoyment of the highest attainable standard of physical and mental health (Articles 2 or 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)).

This is because the new Regulations maintain provisions to ensure ongoing and unchanged access for eligible individuals to the Pharmaceutical Benefits Scheme (PBS). Any additional provisions or changes made from the 1960 regulations clarify and reinforce current arrangements and policy intent. The new Regulations do not alter the operation of the PBS; do not result in any change to PBS entitlements, PBS eligibility or cost to consumers.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

The Hon. Greg Hunt MP, Minister for Health

Details of the *National Health (Pharmaceutical Benefits) Regulation 2017*

**Part 1—Preliminary
Division 1—General**

Section 1 – Name

Section 1 provides that the name of the instrument is the National Health (Pharmaceutical Benefits) Regulations 2017.

Section 2 – Commencement

Section 2 provides that the whole of the instrument commences on 1 April 2017.

The note to subsection 2(1) provides that the commencement information contained in the table relates only to the provisions of the instrument as originally made and that it will not be amended to address any later amendments.

Section 3 – Authority

Section 3 provides that the instrument is made under the *National Health Act 1953*.

Section 4 – Schedules

Section 4 provides that each instrument specified in a Schedule to the instrument is amended or repealed as set out in the applicable items of the relevant Schedule. Any other item in a Schedule to the instrument has effect according to its terms.

Section 5 – Interpretation

Section 5 retains most of the same defined terms and definitions as regulation 5 of the 1960 regulations. Definitions described in the 1960 regulations as having the same meaning as in Part VII of the Act have that meaning retained; those described as having the meaning given by subsection 84(1) of the Act are now defined as having the same meaning as in Part VII of the Act. Subsection 84(1) of the Act is the interpretation section where all definitions are provided for the purposes of Part VII, so a meaning given by subsection 84(1) is the same as a meaning as in Part VII. Amending the definitions in this way ensures all such definitions are written consistently without changing the meaning.

Section 5 removes definitions for terms included in the 1960 regulations that are also defined in Part I of the Act for the purposes of the whole Act. These terms do not need to be redefined in the new Regulations.

Section 5 includes new definitions for terms used in the 1960 regulations but not defined.

A note inserted before subsection 5(1) provides that a number of expressions used in the new Regulations, including Chief Executive Medicare, public hospital and public hospital authority, are defined in the Act.

Subsection 5(1) defines the following terms:

The term “Act” means the *National Health Act 1953*.

The term “applicable amount” has the same meaning as in Part VII of the Act.

The term “approved electronic communication” means an electronic communication of a kind approved in writing by the Secretary under section 11 for the purposes of the provision in which the expression is used.

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

The term “approved hospital authority” has the same meaning as in Part VII of the Act.

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

The term “approved medical practitioner” has the same meaning as in Part VII of the Act. This definition has the same meaning as in the 1960 regulations but has been reworded to be consistent with other references also defined in Part VII of the Act.

The term “approved pharmacist” has the same meaning as in Part VII of the Act. This definition refers to Part VII instead of referencing subsection 84(1) of Act as in the 1960 regulations. The 1960 regulations also contained a note stating that “in Part VII of the Act, approved pharmacist is defined in subsection 84(1) to mean a person for the time being approved under section 90 of the Act and includes certain other persons described in that definition. Under paragraph 91(7)(a) of the Act, a person granted permission to supply pharmaceutical benefits under subsection 91(1) of the Act is to be treated as if the person is approved under section 90 of the Act as an approved pharmacist. Under paragraph 91(7)(c) of the Act, references in the Act to an approval granted under section 90 of the Act include references to an approval treated as having been granted under section 90 by paragraph 91(7)(a) of the Act”. This note has been removed from the definition to comply with modern drafting standards, but the information above still applies to the definition of “approved pharmacist” and is important for accurate understanding of the policy intent of the new Regulations.

The term “approved supplier” has the same meaning as in Part VII of the Act.

The term “authorised midwife” has the same meaning as in Part VII of the Act.

The term “authorised nurse practitioner” has the same meaning as in Part VII of the Act.

The term “authorised optometrist” has the same meaning as in Part VII of the Act.

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

The term “authority prescription” means a prescription that prescribes a pharmaceutical benefit and that has been authorised:

- (a) in accordance with subsection 30(4); or
- (b) in accordance with authority required procedures that:
 - (i) are part of the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or
 - (ii) are part of the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit; or
 - (iii) are incorporated by reference into the circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act.

The term “brand” for a pharmaceutical item means a brand of the pharmaceutical item within the meaning of in Part VII of the Act.

The term “Commonwealth price” has the same meaning as in Part VII of the Act.

The term “concessional beneficiary” has the same meaning as in Part VII of the Act.

The term “concession card” has the same meaning as in Part VII of the Act.

The term “CTS claim” has the same meaning as in Part VII of the Act.

The term “data collection period”, for a brand of a pharmaceutical item has the same meaning given by section 67.

The term “deferred supply authorisation” means a deferred supply authorisation prepared under paragraph 53(3)(a).

The term “delisted brand”, of a pharmaceutical item means one for which a determination made under subsection 85(6) of the Act is no longer in force.

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

The term “drug in a pharmaceutical item” has the same meaning as in Part VII of the Act.

The term “drug is on F2” was introduced in the new Regulations and has the same meaning as in Part VII of the Act.

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

The term “electronic order form” means a form that is approved by the Secretary under subparagraph 33(1)(b)(ii) for the purposes of lodging an order under paragraph 33(1)(b). It continues to be the case that an instrument approving a form is not a

legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

The term “electronic prescription” means a prescription that is prepared and submitted:

- (a) in accordance with approved information technology requirements (if any), by means of an approved electronic communication; and
- (b) in accordance with the form approved by the Secretary under:
 - (i) subparagraph 40(2)(c)(ii) (prescriptions other than medication chart prescriptions); or
 - (ii) subsection 41(5) (medication chart prescriptions).

The corresponding definition in the 1960 regulations provides in paragraph (b) that an electronic prescription be prepared and submitted in accordance with an “appropriate form” under the relevant subparagraph or subsection. To clarify what is meant by “appropriate form” the new Regulations would replace the term “appropriate form” with “form approved by the Secretary”. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

The term “entitlement card” has the same meaning as in Part VII of the Act.

The term “exempt item” was introduced in the new Regulations and has the same meaning as in Part VII of the Act.

The term “final day” of a data collection period, means the last day of the data collection period.

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

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

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

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

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

The term “listed brand” was introduced in the new Regulations and has the same meaning as in Part VII of the Act.

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

The term “maximum value for safety net purposes” has the meaning given by section 6.

The term “Medicare/DVA copy” replaces the term “Medicare Australia/DVA copy” as defined and used in the 1960 regulations. The term “Medicare/DVA copy”, for a paper-based prescription, means the part of the prescription on which the words “Medicare /DVA copy” appear.

The term “medicare number” has the same meaning as in Part VII of the Act.

The term “medication chart” has the meaning given by subsection 41(4).

The term “medication chart prescription” has the meaning given by subsection 41(1).

The term “optometrist” has the same meaning as in Part VII of the Act.

The term “originator brand” was introduced in the new Regulations and has the same meaning as in Division 3B of Part VII of the Act. This term was used in the 1960 regulations but was not defined in the interpretation section.

The term “out-patient medication” has the same meaning as in Part VII of the Act.

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

The term “participating dental practitioner” has the same meaning as in Part VII of the Act.

The term “PBS prescriber” has the same meaning as in Part VII of the Act.

The term “pharmaceutical benefit” has the same meaning as in Part VII of the Act.

The term “pharmaceutical item” has the same meaning as in Part VII of the Act.

The term “pharmaceutical item has a drug” is not defined in the new Regulations as the term is no longer used.

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

The term “practitioner” means:

- (a) in Division 1 of Part 4 of the new Regulations—has the meaning given by section 29 of the Act; and
- (b) in Division 2 of Part 4 of the new Regulations —has the meaning given by section 31 of the Act.

The term “price adjustment” means an adjustment under:

- (a) a price agreement; or
- (b) a price determination; or
- (c) Division 3A of Part VII of the Act.

The term “price agreement” was introduced in the new Regulations and has the same meaning as in Part VII of the Act. This term is used in the 1960 regulations in the definition of “price adjustment” but is not itself defined.

The term “price determination” was introduced in the new Regulations and has the same meaning as in Part VII of the Act. This term is used in the 1960 regulations in the definition of “price adjustment” but is not itself defined.

The term “price disclosure requirements” was introduced in the new Regulations and has the same meaning as in Division 3B of Part VII of the Act. This term is used in the 1960 regulations but is not itself defined.

The term “price sampling day” was introduced in the new Regulations and has the meaning given by section 68.

The term “pricing quantity” has the same meaning as in Part VII of the Act.

The terms “public hospital” and “public hospital authority” are defined in the 1960 regulations but are not defined in the new Regulations. Because they are defined in section 4 of the Act for the purposes of the whole of the Act, they have the same meaning as in the Act by virtue of section 13 of the *Legislation Act 2003*.

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

The term “record form” has the same meaning as in Part VII of the Act.

The term “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.

The term “relevant day” is introduced in the new Regulations and has the same meaning as in Division 3B of Part VII of the Act. This term is used in the 1960 regulations but is not itself defined.

The term “relevant entitlement period” has the same meaning as in Part VII of the Act.

The term “relevant streamlined authority code” was introduced in the new Regulations. The term “relevant streamlined authority code”, for a pharmaceutical benefit that is prescribed, means the streamlined authority code that is part of:

- (a) the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or
- (b) the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit.

The term “repatriation pharmaceutical benefit” has the same meaning as in Part VII of the Act.

The term “repeat authorisation” means a repeat authorisation prepared under subparagraph 52(3)(a)(i).

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

The term “residential care” has the same meaning as in the *Aged Care Act 1997*.

The term “residential care service” has the same meaning as in the *Aged Care Act 1997*.

The term “responsible person” has the same meaning as in Part VII of the Act.

The term “Schedule equivalent” was introduced in the new Regulations and has the same meaning as in Part VII of the Act.

The term “special patient contribution” has the same meaning as in Part VII of the Act.

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

The term “WADP brand” has the meaning given by subsection 83(2).

The term “weighted average disclosed price” was introduced in the new Regulations and has the same meaning as in Division 3B of Part VII of the Act. This term is used in the 1960 regulations but is not itself defined.

Subsection 5(2) provides that a reference to prescribing, or to the writing of a prescription, in the new Regulations is a reference to the writing of a prescription for the supply of a pharmaceutical benefit under Part VII of the Act.

Subsection 5(3) provides that in the new Regulations:

- a reference to the holder of a concession card is a reference to a person who is taken to be a holder of the card under section 84G of the Act;
- a reference to the original holder of a concession card is a reference to the person to whom a concession card has been issued under section 84DA of the Act;

- a reference to the original holder of an entitlement card is a reference to the person to whom an entitlement card has been issued under section 84E of the Act; and
- a reference to a member of the family of a person is a reference to a person who is a member of that family within the meaning of section 84B of the Act.

Section 6 – Meaning of “maximum value for safety net purposes”

Subsection 9A(4) of the 1960 regulations prescribes the particulars to be included on a PBS prescription record form. Paragraph 9A(4)(c) prescribes that the “maximum value of the pharmaceutical benefit or repatriation pharmaceutical benefit for safety net purposes” is one of those particulars. Subsections 9A(5) and 9A(6) prescribe how the “maximum value of a pharmaceutical benefit for safety net purposes” and the “maximum value of a repatriation pharmaceutical benefit for safety net purposes” are to be determined. Section 9A of the 1960 regulations currently makes no mention of a maximum value of out-patient medication for safety net purposes.

Paragraphs 9AA(2)(a) and 9B(2)(a) of the 1960 regulations prescribe documents to accompany an application for a safety net concession card or pharmaceutical benefits entitlement card under paragraph 84DA(3)(b) of the Act. Subparagraphs 9AA(2)(a)(i) and 9B(2)(a)(i) prescribe that a prescription record form must record the “value of pharmaceutical benefits, repatriation pharmaceutical benefits or outpatient medication supplied to the applicant, or a member of the applicant’s family during the relevant entitlement period to which the application relates”. Use of the term “value” in this description, without indicating that it is the maximum value “for safety net purposes” creates ambiguity and fails to account for the fact that some charges for PBS medications do not count for safety net purposes.

Section 6 of the new Regulations is a new section that replaces subregulations 9A(5) and 9A(6) of the 1960 regulations and clearly defines a single term, “maximum value for safety net purposes”. The term defines the “maximum value for safety net purposes” for pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medications. This term is used consistently throughout the new Regulations in relation to prescription record forms under section 18, applications for safety net concession cards in section 19 and pharmaceutical benefits entitlement cards in section 21.

Paragraph 6(1)(a) provides that where the supply of a pharmaceutical benefit is deemed, under subsection 99(2A), (2AB) or (2B) of the Act, to be a supply otherwise than under Part VII of the Act and the price charged for the supply is in accordance with the Act— the “maximum value for safety net purposes” of a pharmaceutical benefit is the lesser of:

- the amount of the price of the pharmaceutical benefit worked out in accordance with a determination in force under subsection 84C(7) of the Act at the time of the supply; or
- the amount charged for the supply of the pharmaceutical benefit.

A determination under subsection 84C(7) of the Act is a legislative instrument.

Paragraph 6(1)(b) provides that, where the supply is not deemed, under subsection 99(2A), (2AB) or (2B) of the Act, to be a supply otherwise than under Part VII of the

Act and the price charged for the supply in accordance with the Act— the “maximum value for safety net purposes” of a pharmaceutical benefit is the amount of the price charged for the supply in accordance with whichever of paragraphs 87(2)(a), (b), (c) or (e) of the Act applies to the supply.

Subsection 6(2) provides that the “maximum value for safety net purposes” of a repatriation pharmaceutical benefit is the amount charge in accordance with a scheme referred to in subsection 91(1) of the *Veterans’ Entitlements Act 1986*.

Subsection 6(3) provides that the “maximum value for safety net purposes” of an out-patient medication is the lesser of the applicable amount or the amount charged for the supply of the medication.

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

Section 7 – Preparing electronic prescriptions

Section 7 is the same in content as regulation 5A of the 1960 regulations, but has been redrafted to reflect modern drafting standards. It provides for the writing or preparing of electronic prescriptions, electronic repeat authorisations or electronic deferred supply authorisations.

Section 7(a) provides that a reference anywhere in the new Regulations to writing or preparing a repeat authorisation that relates to an electronic prescription, is taken to include preparing the electronic prescription as defined in section 5 of the new Regulations. Since the definition of electronic prescription in section 5 of the new Regulations includes details of the form to be used to prepare a prescription, these details do not need to be included in this provision as they were in the corresponding provision of the 1960 regulations.

Section 7(b) provides that a reference anywhere in the new Regulations to writing or preparing a repeat authorisation that relates to an electronic prescription, is taken to include writing or preparing the authorisation by means of an electronic form approved by the Secretary under subparagraph 52(3)(a)(i) for the purposes of supplying a pharmaceutical benefit. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Section 7(c) provides that a reference anywhere in the new Regulations to writing or preparing a deferred supply authorisation that relates to an electronic prescription, is taken to include writing or preparing the authorisation by means of an electronic form approved by the Secretary under paragraph 53(3)(a) for the purposes of deferring the supply of a pharmaceutical benefit. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

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

Section 8 is the same in content as regulation 5B of the 1960 regulations, but has been redrafted to reflect modern drafting standards. It provides that a reference in the new Regulations to the day or date on which a prescription is written or the day or date on which a pharmaceutical benefit is prescribed, in relation to an electronic prescription, is the day or date that the practitioner signs the actual prescription.

Section 9 - Requirement to give information in writing

Section 9 is the same in content as regulation 5C of the 1960 regulations, but has been redrafted to reflect modern drafting standards. It extends the interpretation of the requirement to “write information on a prescription” beyond handwriting, in relation to electronic prescriptions and authorisations, so that information that is written by electronic means can qualify as “writing information on a prescription” for the purpose of the new Regulations.

Paragraph 9(1)(a) provides that the requirement to give information in writing, is taken to have been met, in relation to an electronic prescription, if the practitioner gives the information in accordance with approved information technology requirements (if any) and by means of an approved electronic communication.

Paragraph 9(1)(b) defines the requirement to give information in writing in relation to electronic prescriptions, authorisations and orders.

Subsection 9(2) provides that the requirement to write information on a prescription is taken to be met/satisfied whether the expression “write”, “certify”, “endorse”, “indicate”, “mark”, “specify”, “state” or any other expression is used.

Section 10 – Requirement to give a prescription

Section 10 is the same in content as regulation 5D of the 1960 regulations, but has been redrafted to reflect modern drafting standards. It provides the requirements to give or present a prescription to an approved prescriber, in relation to an electronic prescription, for the purposes of supplying a pharmaceutical benefit.

Section 10 provides that the requirement to give or present a prescription is taken to be met, in relation to electronic prescriptions in certain circumstances.

Section 10(a) and (c) respectively provide that the requirement to give or present a prescription is taken to be met when the person who will receive a pharmaceutical benefit requests the approved supplier to supply the benefit, and the electronic prescription is accessible to the approved supplier.

Section 10(b) provides that the approved supplier must consent to sending and receiving electronic prescriptions by means of electronic communication. This consent is defined by subsection 5(1) of the *Electronic Transactions Act 1999* as consent that can reasonably be inferred from the conduct of the person concerned.

Section 11 - Approval of kinds of electronic communications

Section 11 is the largely the same in content as regulation 5E of the 1960 regulations, but has been redrafted to reflect modern drafting standards and contains a minor

amendment to subsection (d). It provides that the Secretary may approve, in writing, a kind of electronic communication for one or more of the purposes listed in paragraphs (a) to (h). It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Subsection 11(a) provides that the Secretary may approve, in writing, a kind of electronic communication for preparing or submitting an electronic prescription.

Subsection 11(b) provides that the Secretary may approve, in writing, a kind of electronic communication for giving information in relation to an electronic prescription or an authorisation that relates to an electronic prescription or an electronic order form.

Subsection 11(c) provides that the Secretary may approve, in writing, a kind of electronic communication for giving or presenting an electronic prescription to an approved PBS supplier.

Subsection 11(d) provides that the Secretary may approve, in writing, a kind of electronic communication for submitting a prescription to the Minister for variation to the maximum number of repeats or maximum number or quantity of units in accordance with paragraph 30(3)(b) of the new Regulations.

Regulation 5E(d) of the 1960 regulations currently provides that the Secretary may approve, in writing, a kind of electronic communication for submitting an “electronic” prescription to the Minister in order to approve a variation to the maximum number of repeats or maximum number or quantity of units. The word “electronic” was removed from this provision because paragraph 30(3)(b) does not specifically relate to electronic prescriptions. The details of a prescription which might be submitted to the Minister by means of an electronic communication could apply equally to a paper-based prescription as well as an electronic prescription.

Subsection 11(e) provides that the Secretary may approve, in writing, a kind of electronic communication for lodging an order with an approved pharmacist under paragraph 33(4)(c).

Subsection 11(f) provides that the Secretary may approve, in writing, a kind of electronic communication for submitting a receipt for a pharmaceutical benefit received under paragraph 33(4)(c) of the new Regulations.

Subsection 11(g) provides that the Secretary may approve, in writing, a kind of electronic communication for giving an acknowledgement under an electronic prescription or an authorisation that relates to an electronic prescription for the supply of a pharmaceutical benefit.

Subsection 11(h) provides that the Secretary may approve, in writing, a kind of electronic communication for doing any other thing that is required or permitted to be done for the purposes of the new Regulations.

Section 12 - Approval of information technology requirements

Section 12 is the same in content as regulation 5F of the 1960 regulations, but has been redrafted to reflect modern drafting standards. It provides that the Secretary may, in writing, approve information technology requirements for one or more of the purposes listed in paragraphs (a) to (g). It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Subsection 12(a) provides that the Secretary may, in writing, approve information technology requirements for preparing and submitting an electronic prescription.

Subsection 12(b) provides that the Secretary may, in writing, approve information technology requirements for giving information in relation to an electronic prescription, authorisation that relates to an electronic prescription or an electronic order form.

Subsection 12(c) provides that the Secretary may, in writing, approve information technology requirements for giving or presenting an electronic prescription to an approved supplier.

Subsection 12(d) provides that the Secretary may, in writing, approve information technology requirements for lodging an order with an approved pharmacist under paragraph 33(1)(b).

Subsection 12(e) provides that the Secretary may, in writing, approve information technology requirements for submitting a receipt for a pharmaceutical under paragraph 33(4)(c).

Subsection 12(f) provides that the Secretary may, in writing, approve information technology requirements for giving an acknowledgement for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription.

Subsection 12(g) provides that the Secretary may, in writing, approve information technology requirements for doing any other thing that is required or permitted to be done for the purposes of the new Regulations.

Part 2—Approvals under Part VII of the Act

Section 13 – Purpose of this Part

Section 13 is a new section that explains that Part 2 is made for the purposes of section 140 of the Act.

Section 14 – Application for approval to be in approved form

Section 14 is the same in content as regulation 8 of the 1960 regulations, but has been redrafted to meet modern drafting standards.

Subsection 14(1) provides that the Secretary may refuse to consider an application for approval of a pharmacist under section 90 of the Act, or an application for approval of

a medical practitioner under section 92 of the Act if the application is not in a form approved, in writing, by the Secretary of the Department of Health.

Subsection 14(2) provides that the Minister may refuse to consider an application for approval of a hospital authority under section 94 of the Act if the application is not in a form approved, in writing, by the Secretary. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

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

Section 15 is the same in content as regulation 8AA of the 1960 regulations, but has been redrafted to meet modern drafting standards. It provides that an application for approval as an authorised optometrist under subsection 84AAB(1), an application for approval as an authorised midwife under subsection 84AAF(1), or an application for approval as an authorised nurse practitioner under subsection 84AAJ(1) of the Act must be made in a form approved, in writing, by the Secretary. The words “in writing” have been added to this provision in accordance with current standard drafting practice. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Section 16 – Numbering of approvals

Section 16 is the same in content as regulation 8A of the 1960 regulations, but has been redrafted to meet modern drafting standards. It provides for numbers to be allotted for approvals to prescribe or supply pharmaceutical benefits under Part VII of the Act.

Subsection 16(1) provides that the Secretary may allot a number to an approval granted to a dental practitioner under section 84A, an optometrist under section 84AAB, an eligible midwife under section 84AAF, an eligible nurse practitioner under section 84AAJ, a pharmacist under section 90, or a medical practitioner under section 92 of the Act.

Subsection 16(2) provides that where the Minister makes a decision under section 90A of the Act, which substitutes for a decision made by the Secretary under Section 90, approving a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises, the Minister may allot a number to that approval.

Subsection 91(1) of the Act allows for the executor of a deceased pharmacist’s will, or another person with administration over a deceased pharmacist’s estate, to seek approval to supply pharmaceutical benefits from a premises from which the deceased pharmacist had been approved to supply pharmaceutical benefits from under section 90 of the Act prior to his or her death. Under paragraph 91(7)(a) of the Act, an approval under subsection 91(1) of the Act is treated as having been granted to the person under section 90 of the Act.

Subsection 16(3) provides that where the Secretary grants permission to a person to supply pharmaceutical benefits under subsection 91(1) of the Act, the Secretary may allot a number to the approval.

Subsection 16(4) provides that where the Minister approves a hospital authority under section 94 of the Act, the Minister may allot a number to that approval.

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

Section 17 is the same in content as regulation 9 of the 1960 regulations, but has been redrafted to meet modern drafting standards.

Subsection 17(1) applies an offence provision to a person whose approval to supply pharmaceutical benefits under section 90 of the Act has been revoked or cancelled, and that person in any way, indicates that he or she has been, or is, approved to supply pharmaceutical benefits.

Subsection 17(2) provides that an offence against subsection 17(1) is an offence of strict liability.

The penalty for the strict liability offence in subsection 17(2) of the new Regulations remains at 1 penalty unit, which is currently \$180 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 17(2) as a strict liability offence is considered appropriate to deter approved pharmacists from supplying pharmaceutical benefits from a premises for which they are not approved, or misleading customers regarding the pharmacist's eligibility to supply medications as PBS items.

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

Division 1— Pharmaceutical benefits prescription record forms etc.

Part 3 of the new Regulations combines Parts 2B—Safety net concession cards, and 2C—Pharmaceutical benefits entitlement cards of the 1960 regulations, since the provisions relating to eligibility, application and review processes for safety net concession cards and pharmaceutical benefits entitlement cards are essentially identical. Additionally, provisions for concession cards and entitlement cards are already handled together under “Division 1A—safety net concession cards and pharmaceutical benefits entitlements cards” in Part VII of the Act.

Section 18 – Pharmaceutical benefits prescription record forms etc.

Section 18 contains largely the same content as regulation 9A of the 1960 regulations, but has been redrafted to meet modern drafting standards. The content of subsections 9A(5) and (6) of the 1960 regulations have moved to the new section 6 so that they can apply for the purposes of other provisions that refer to the “maximum value for safety net purposes”.

A prescription record form is a required document which must accompany an application for a safety net concession card under section 19 or a pharmaceutical benefits entitlement card under section 21. Section 18 provides the particulars to be included in a prescription record form under section 84D of the Act.

Subsection 18(1) provides that for the purposes of paragraph 84D(3)(b) of the Act, the given name, surname and address of the person are prescribed particulars of the person to whom a record form is issued.

Subsection 18(2) provides that for the purposes of subsection 84D(4) of the Act, the particulars prescribed for a family member of a person to whom a record form is issued are: the given name of the family member, the surname of the family member, and the family member's relationship to the person to whom a record form is issued.

Subsection 18(3) provides that for the purposes of paragraph 84D(7)(c) of the Act, the item code which identifies the item as a pharmaceutical benefit or repatriation pharmaceutical benefit, the number allotted to the person supplying the pharmaceutical benefit or repatriation pharmaceutical benefit under section 16 of the new Regulations and the maximum value for safety net purposes of the pharmaceutical benefit or repatriation pharmaceutical benefit are prescribed particulars in relation to supply of a pharmaceutical benefit or repatriation pharmaceutical benefit.

Subsection 18(4) provides that for the purposes of paragraph 84D(11)(c) of the Act, the particulars that identify the medication, the particulars that identify the public hospital at which the medication was supplied and the maximum value for safety net are prescribed particulars in relation to an out-patient medication.

Division 2— Issue of safety net concession cards

Section 19 – Application for safety net concession card

Section 19 is the same in content as regulation 9AA of the 1960 regulations, but has been redrafted to meet modern drafting standards. It sets out the particulars and documents which paragraph 84DA(3)(b) of the Act provides should be prescribed as particulars to be included in an application, or documents which are to accompany an application, for a safety net concession card.

Section 20 – Prescribed offices

Section 20 is the same in content as regulation 9AF of the 1960 regulations, but has been redrafted to meet modern drafting standards. It provides that for the purposes of subsection 85DA(5) of the Act, the offices in the table in Schedule 1 are a prescribed offices for lodgement of safety net concession card applications and accompanying documents.

Division 3— Issue of pharmaceutical benefits entitlement cards

Section 21 – Application for pharmaceutical benefits entitlement card

Section 21 is the same in content as regulation 9B of the 1960 regulations, but has been redrafted to meet modern drafting standards. It sets out the particulars and documents which paragraph 84E(3)(b) of the Act provides should be prescribed as

particulars to be included in an application, or documents which are to accompany an application, for a safety net concession card.

Section 22 – Prescribed offices

Section 22 is the same in content as regulation 9BA of the 1960 regulations, but has been redrafted to meet modern drafting standards. It provides that for the purposes of subsection 85E(5) of the Act, the offices in the table in Schedule 1 are a prescribed offices for lodgement of pharmaceutical benefits entitlement card applications and accompanying documents.

Division 4— Additional and replacement concession cards and entitlement cards

Section 23 – Purpose of this Division

Section 23 is a new section that states that Division 4 sets out matters relating to the issue of additional and replacement concession cards and entitlements cards for the purposes of subsections 84H(1) and (3) of the Act.

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

Section 24 retains the provisions contained in regulations 9AB (additional concession cards) and 9C (additional entitlement cards) of the 1960 regulations and combine them into a single new section. This section sets out the procedure for applying and issuing of additional concession cards and entitlement cards.

Subsection 24(1) provides that a person may apply to the Secretary for an additional card in the event that their concession card or entitlement card has been lost, stolen, damaged or destroyed.

Subsection 24(2) provides that a holder of a concession card or entitlement card may apply for an additional card for reasons not mentioned in subsection (1), either to the Secretary, or to the approved PBS supplier who supplied the original card. This provision will be used most commonly for a cardholder applying for additional cards for eligible family members.

Subsection 24(3) provides that an application for an additional concession card or entitlement card must be in a form approved, in writing, by the Secretary. The words “in writing” have been added to this provision in accordance with current standard drafting practice.

Subsection 24(4) provides that when a person with issuing authority receives an application under this section, they must issue an additional card to the applicant if:

- they have had regard to the matters contained in the application; and
- they have had regard to any other relevant matter; and
- they are satisfied that the applicant should be issued with an additional card.

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

Section 25 retains the provisions contained in regulations 9AC (replacement concession cards) and 9D (replacement entitlement cards) of the 1960 regulations and

combine them into a single new section. This section sets out the procedure for applying and issuing of replacement concession cards and entitlement cards.

Subsection 25(1) provides that an original card holder may apply for a replacement card.

Subsection 25(2) provides that an application for a replacement concession card or entitlement card must be made, in accordance with a form approved, in writing, by the Secretary, either to the Secretary or to the PBS supplier who issued an original concession card or entitlement card. The words “in writing” have been added to this provision in accordance with current standard drafting practice.

Subsection 25(3) provides that when a person with issuing authority receives an application under this section, they must issue a replacement card to the applicant if:

- they have had regard to the matters contained in the application; and
- they have had regard to any other relevant matter; and
- they are satisfied that the applicant is the original card holder within the meaning of subsection 84H(3) of the Act; and
- they are satisfied that each person identified in the application in accordance with subparagraph (2)(b)(iii) became, after the issue of that card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder’s family.

Sections 26 to 28

Sections 26 to 28 provide the conditions of refusal for an application for an additional or replacement concession card or entitlement card, and the avenues of review for the refused applicant. They retain the provisions previously contained in regulations 9AD, 9AE, 9E and 9F of the 1960 regulations, but instead of combining them into a single section which covers all refusal and review provisions, they have been drafted as three separate sections which most clearly demonstrate the chronology of processes and hierarchy of review pathways.

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

Section 26 takes provisions from regulations 9AD and 9E of the 1960 regulations. It provides that where an applicant had an application for an additional concession card or entitlement card under section 24, or a replacement concession card or entitlement card under section 25 refused by the PBS supplier who issued the original concession card or entitlement card, the applicant may make an application under subsection 24(2) or 25(1) to the Secretary.

Section 27 – Refusal to issue additional or replacement cards by the Secretary

Section 27 takes provisions from regulations 9AD and 9E of the 1960 regulations and revises the wording to bring it into line with current standard wording for Administrative Appeals Tribunal (AAT) review provisions. It provides the procedure for when the Secretary refuses to issue an additional concession card or entitlement card under section 24, or a replacement concession card or entitlement card under section 25.

Subsection 27(1) provides that where an applicant had an application for an additional concession card or entitlement card under section 24, or a replacement concession card or entitlement card under section 25 refused by the Secretary, the Secretary must inform the applicant to his or her decision in writing and include the reasons for the refusal.

Subsection 27(2) provides that a written notice of refusal by the secretary must include a statement informing the applicant that:

- applications may be made, subject to the *Administrative Appeals Tribunal Act 1975*, by or on behalf of a person whose interests are affected by the decision, to the Administrative Appeals Tribunal for review of the decision; and
- a person whose interests are affected by the decision may, except where subsection 28(4) of that Act applies, request a statement under section 28 of that Act.

Subsection 27(3) provides that a failure of the Secretary to provide written notice to the applicant, informing them of their review rights under subsection (2) does not invalidate the Secretary's refusal decision.

Section 28 – Review of decisions

Section 28 contains the same content as regulation 9AE of the 1960 regulations. It provides that applications may be made to the Administrative Appeals Tribunal for review of a decision to refuse to issue an additional or replacement card under section 24 or 25 of the new Regulations.

Part 4—Supply of pharmaceutical benefits

Division 1— General matters relating to supply

Section 29 – Meaning of *practitioner*

Section 29 retains the content of subregulation 13(8) of the 1960 regulations which defined the term practitioner for the purposes of Part 3 of the 1960 regulations. In the new Regulations, the definition has moved to the front of its equivalent Part as per modern drafting convention.

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

Section 30 retains the provisions contained in regulation 13 of the 1960 regulations. It provides the conditions and processes by which the Minister may vary the maximum quantity of units or number of repeats that can be prescribed by a particular class of prescriber.

Subsection 30(1) provides that under subsection 85A(3) of the Act, the Minister may vary the maximum quantity or number of units or the number of times a supply may be repeated in relation to persons included in a prescriber class.

Subsection 30(2) provides the class of prescribers to which this subsection applies.

Subsection 30(3) provides the method by which paper-based, electronic and medication chart prescriptions are to be submitted to the Minister for variation of the maximum quantity or number of units or number of repeats. It also provides that a practitioner or an agent of the practitioner may submit details of the prescription by telephone or by means of an approved electronic communication.

Subsection 30(4) provides the procedure by which the Minister may approve a variation to the maximum quantity or number of units or the number of repeats that can be prescribed by a particular prescriber class.

Subsection 30(5) provides that where the Minister authorises a variation to the maximum quantity or number of units or the number of repeats that can be prescribed by a particular prescriber class by telephone or by means of an electronic communication, the Minister will allot an approval number to that approval and will tell the practitioner, orally or by means of an approved electronic communication, the number that has been allotted to the authorised prescription. This section also provides that the practitioner must mark the approval number on the prescription and retain that prescription, or a copy of that prescription for one year.

The note at the bottom of subsection 30(5) provides that an electronic copy of the prescription is suitable for record-keeping purposes for this section.

Subsection 30(6) provides the date from which a prescription, or copy of a prescription, is required to be kept for one year for the purposes in subsection (5).

Division 2—Supply by particular PBS prescribers

Sections 31 to 37 retains the content of Part 4 (regulations 14 to 18A) of the 1960 regulations but have been renumbered, reordered and rewritten to modern drafting standards in the new Regulations. These sections set out the requirements relating to the supply of pharmaceutical benefits by medical practitioners in emergency situations. These pharmaceutical benefits are referred to as prescriber bag supplies.

Section 31 – Meaning of *practitioner*

Section 31 retains the content of regulation 14 of the 1960 regulations, which defined the term practitioner for the purposes of Part 4 of the 1960 regulations. The definition covers medical practitioners, authorised midwives and authorised nurse practitioners.

Section 32 – Prescriber bag supplies—practitioners on ships

Section 32 retains the content of regulation 15 of the 1960 regulations, but has been reworded in line with current drafting practices. It prevents a medical practitioner, authorised midwife or authorised nurse practitioner from supplying pharmaceutical benefits under the prescriber bag provisions whilst he or she is practising his or her profession on a ship.

Section 33 – Prescriber bag supplies—obtaining benefits by practitioners

Section 33 retains the content of regulation 16 of the 1960 regulations. It sets out the requirements that a medical practitioner, an authorised midwife or an authorised nurse practitioner must satisfy to supply pharmaceutical benefits under the prescriber bag provisions.

Section 34 – Prescriber bag supplies – supply of pharmaceutical benefits by approved pharmacists

Section 34 retains the content of regulation 17 of the 1960 regulations. It also retains a strict liability offence provision which applies to an approved pharmacist if he or she:

- supplies a pharmaceutical benefit on an order lodged under section 33; and
- neither of the following circumstances applies;
 - the pharmacist knows the practitioner whose signature appears on the order;
 - if the pharmacist does not know the practitioner whose signature appears on the order:
 - the person who lodged the order has given the pharmacist the full name and address of the practitioner; and
 - if the practitioner is a medical practitioner, the person who lodged the order has given the practitioner’s medical registration number to the pharmacist; and
 - in relation to a practitioner who is an authorised midwife or an authorised nurse practitioner, the person who lodged the order has given the pharmacist the number that was allotted to the approval of that practitioner by the Secretary under subsection 16(1); and
 - the pharmacist writes the details contained in the previous three dot points on the order.

The penalty for the strict liability offence in subsection 34(2) of the new Regulations remains at 0.4 penalty units which is currently \$72 for an individual (as defined by section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 34(2) as a strict liability offence is considered appropriate because:

- it deters approved pharmacists from supplying pharmaceutical benefits to an unknown prescriber without collecting sufficient details to confirm the identity, qualification and PBS prescriber status of the prescriber to whom they are supplying the pharmaceutical benefits. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

Section 35 – Prescriber bag supplies—payment for pharmaceutical benefits

Section 35 retains the content of regulation 18 of the 1960 regulations. It provides that an approved pharmacist who has supplied a pharmaceutical benefit to a medical practitioner, authorised midwife or authorised nurse practitioner for the purpose of the prescriber bag supplies is entitled to payment from the Commonwealth. It also provides for the rate of payment for prescriber bag supplies.

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

Section 36 retains the content of regulation 18A of the 1960 regulations. It relies on the “necessary or convenient” power under section 140 of the Act. It retains the content from regulation 18A of the 1960 regulations containing offence provisions for

unauthorised claiming by approved medical practitioners for PBS benefits for the purposes of section 93 of the Act.

Retaining the offences in subsections 36(2), (3), (4), (6), (7) and (9) as strict liability offences is considered appropriate to deter approved medical practitioners from:

- obtaining a pharmaceutical benefit for the purpose of section 93 of the Act (prescriber bag supply) by lodging a section 33 order with an approved pharmacist (subsection 36(2)); or
- obtaining a pharmaceutical benefit for the purpose of section 93 (prescriber bag supply) more than once each month (subsection 36(3)); or
- failing to give notice of obtaining the benefit when making a PBS claim using the manual system (subsection 36(4)); or
- failing to retain a copy of that notice of obtaining the benefit for at least two years from the date the notice was given (subsection 36(6)); or
- if a CTS claim is made, failing to create a written record of having obtained the benefit as soon as practicable after obtaining it (subsection 36 (7)); or
- failing to retain the record for at least two years from the date it was created (subsection 36(9)).

The penalty for the strict liability offences in section 36 remain at 0.2 penalty units, which is currently \$36 for an individual (as defined by section 4AA, *Crimes Act 1914*). It is consistent with the Attorney-General's Department publication A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers, as the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

Section 37 – Payment for pharmaceutical benefits obtained by approved medical practitioners for the purpose of section 93 of the Act

Section 37 retains the remaining provisions from regulation 18A of the 1960 regulations not included in section 36. It provides the conditions under which an approved medical practitioner is entitled to payment from the Commonwealth for obtaining a pharmaceutical benefit for the purpose of the supply of the benefit as a prescriber bag item under section 93 of the Act. It also sets out the rate of payment the approved medical practitioner is entitled to for the supply under section 93 of the Act.

Part 5—Prescriptions and supply

Section 38 – Purpose of this Part

Section 38 retains the content of regulation 18B of the 1960 regulations. However, where the 1960 regulations provided that this Part was made for the purposes of section 105 of the Act, this section clarifies that this Part is made for the purposes of sections 105 and 140 of the Act. This explains the legislative authority for offence provisions in sections 43, 48, 52, 55 and 57.

Section 39 – Writing prescriptions – general

Section 39 retains the content of regulation 18C of the 1960 regulations. It provides that a prescription for the supply of a pharmaceutical benefit must be written in accordance with the requirements set out in section 40 of the new Regulations for non-medication chart prescriptions and section 41 of the new Regulations for medication chart prescriptions.

The note under section 39 provides that other provisions in the new Regulations may also contain requirements for the writing of prescriptions. These additional requirements are necessary for writing prescriptions under particular circumstances.

Section 40 – Writing prescriptions—prescriptions other than medication chart prescriptions

Section 40 retains the content of regulation 19 of the 1960 regulations. It provides the requirements for writing prescriptions that are not medication chart prescriptions.

Subsection 40(1) provides the particulars which a prescriber must include on each prescription form they prepare in order for supply of a pharmaceutical benefit to occur.

Paragraph 40(1)(a) provides that when a PBS prescriber who is a participating dental practitioner, an authorised optometrist, an authorised midwife or an authorised nurse practitioner writes a prescription, it must state the number allotted to that prescriber under section 16.

Paragraph 40(1)(b) provides that when a PBS prescriber writes a prescription, it must state the name and residential address of the person for whom the pharmaceutical benefit is to be supplied.

Paragraph 40(1)(c) provides that when a PBS prescriber writes a prescription, it must be prepared in accordance with subsection 40(2).

Paragraph 40(1)(d) provides that when a PBS prescriber writes a prescription, it must contain sufficient particulars as are necessary to identify the pharmaceutical benefit.

Paragraph 40(1)(e) provides that when a PBS prescriber writes a prescription, it must state the quantity or number of units of the pharmaceutical benefit to be prescribed and the number of times (if any) the pharmaceutical benefit is to be repeated.

Paragraph 40(1)(f) provides that when a PBS prescriber writes a prescription for a pharmaceutical benefit that is not a ready-prepared pharmaceutical benefit, it must indicate the manner in which the pharmaceutical benefit is to be administered.

Paragraph 40(1)(g) provides that when a PBS prescriber writes a prescription, it must be signed by the prescriber after it is prepared.

Paragraph 40(1)(h) provides that when a PBS prescriber writes a prescription, it must specify the date on which the prescription is written.

Paragraph 40(1)(i) provides that when a PBS prescriber writes an authority prescription (other than an authority prescription referred to in subsection (5)), it must contain the relevant authority approval number unless the prescription is to be posted or delivered to the Minister or Chief Executive Medicare for authorisation; or it must contain the relevant streamlined authority code where applicable.

Paragraph 40(1)(j) provides that when a PBS prescriber writes a prescription directing supply of a quantity or number of units of a pharmaceutical benefit exceeding the quantity or number of units that could otherwise be prescribed to be supplied on a single occasion under section 49, the prescriber must certify this intent on the prescription.

Under regulation 19 of the 1960 regulations, when a PBS prescriber directs such a supply, they must write on the prescription “Reg 24” or “Regulation 24”. Because this practice is so well established and understood by prescribers and suppliers, paragraph 40(1)(j) of the new Regulations continues to allow these prescriptions to be certified as “Reg 24” or “Regulation 24”, despite the reordering and renumbering of the new Regulations moving this provision to section 49.

The new Regulations also introduce the new terms “one supply” or “1 supply”. These new terms may be used interchangeably with “Reg 24” or “Regulation 24”, thus ensuring this provision can remain in effect, regardless of future reordering of the regulations. This also gives prescribers and suppliers the opportunity to transition to use of the new terms over time, and gives Government time to transition publicly available information to reflect the new arrangements.

Subsection 40(2) provides the requirements for the form which must be used to prepare a prescription for supply of a pharmaceutical benefit in accordance with paragraph 1(c) for a handwritten prescription, a computer generated prescription, an electronic prescription or another method approved in writing by the Secretary. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Subsection 40(3) provides that a prescription, that is not a medication chart prescription, must not provide for the supply of a pharmaceutical benefit if the PBS prescriber has written another PBS prescription for the same person, on the same day, that is for any of the following:

- the same pharmaceutical benefit;
- another brand of the same pharmaceutical benefit; or
- a Schedule equivalent pharmaceutical benefit.

It further provides that a prescription, that is not a medication chart prescription, must not provide for the supply of a pharmaceutical benefit to more than one person.

Subsection 40(4) provides that a prescription must not be prepared using a computer program that defaults to indicate that only the brand of pharmaceutical benefit specified in the prescription is to be supplied. This applies to both paper-based and electronic prescriptions.

Paragraph 40(1)(i) requires that, for an authority prescription, the prescriber must include the authority approval number allotted to that prescription. Subsection 40(5) provides that this requirement does not apply to authority prescriptions that have been authorised in accordance with authority required procedures applying as part of the circumstances determined for a pharmaceutical benefit by the Minister under subsection 85B(4) of the Act.

Under subsection 85B(4) the Minister determines the circumstances in which the Commonwealth will pay the special patient contribution, which otherwise the patient receiving that pharmaceutical benefit would have to pay. The circumstances determined by the Minister may require that the prescription be authorised in accordance with authority required procedures.

The effect of excluding authority prescriptions relating to payment of the special patient contribution by the Commonwealth from paragraph 40(1)(i) is that non-compliance with that paragraph will not have the effect of invalidating the prescription for PBS purposes. The Commonwealth will not pay the special patient contribution because the circumstances determined under subsection 85B(4) have not been satisfied, but the prescription is not invalidated. However, the prescription may be invalid for PBS purposes if it does not comply with other authority required procedures it is required to comply with.

Compliance with authority required procedures may be required as part of the circumstances determined under paragraph 85(7)(b) for prescribing a pharmaceutical benefit. Some of the pharmaceutical benefits for which the Minister has made a determination under subsection 85B(4) requiring compliance with authority required procedures for payment by the Commonwealth of the special patient contribution, also are the subject of a determination under paragraph 85(7)(b) requiring compliance with authority required procedures for prescribing the pharmaceutical benefit. If compliance with authority required procedures is required under both determinations, failure to comply with the subsection 85B(4) circumstances means the Commonwealth will not pay the special patient contribution but the prescription is still duly written; but if there is also a failure to comply with the paragraph 85(7)(b) circumstances, the prescription will not be duly written and the patient will not be entitled to receive the pharmaceutical benefit.

Section 41 – Writing prescriptions—medication chart prescriptions

Section 41 provides for the use of medication chart prescriptions for pharmaceutical benefits for a person receiving treatment in or at a residential care service or approved hospital. It contains the same content as regulation 19AA of the 1960 regulations, with the exception that the period of validity for a medication chart for a person receiving treatment in or at an approved hospital has been amended in paragraph 41(2)(f).

Subsection 41(1) specifies what is required for a section of a medication chart completed by a PBS prescriber to be a “medication chart prescription” for a pharmaceutical benefit. This includes that the PBS prescriber completes the section of the chart in accordance with subsection (2) and if the prescription is an authority prescription, in accordance with subsection (3).

Subsection 41(2) prescribes the requirements for completing a section of a medication chart when prescribing a pharmaceutical benefit.

Paragraph 41(2)(a) provides that the details the PBS prescriber is required to write on a medication chart prescription are the particulars as sufficient to identify the pharmaceutical benefit; the date on which the order was written; the dose, frequency

and route of administration of the pharmaceutical benefit; and the letters PBS or RPBS.

Paragraph 41(2)(b) prescribes the relevant prescriber details, patient details and details of the residential care service or nursing home where the patient is receiving treatment that must appear on the medication chart.

Paragraph 41(2)(c) provides that a PBS prescriber must sign in the relevant section of the medication chart. The PBS prescriber must also sign the cover page of the medication chart, except in the case of an electronic prescription.

Paragraph 41(2)(d) provides that the section of the chart does not provide for the supply of a pharmaceutical benefit to more than one person.

Paragraph 41(2)(e) makes provisions for medication charts which correspond to the provisions for non-medication charts in subsection 40(4), that the section of the chart must not be completed using a computer program that defaults to indicate that only the brand of pharmaceutical benefit specified on the medication chart prescription is to be supplied. This applies to both paper-based and electronic prescriptions.

Paragraph 41(2)(f) contains the same content as paragraph 19AA(2)(f) of the 1960 regulations prescribing the three periods of validity of hospital medication chart (HMC) prescriptions, except that the new Regulations extend each of those periods by one day.

The 1960 regulations currently allow for a non-medication chart prescription to be supplied on or before the first anniversary date of the day the prescription was written. Currently, for HMC prescriptions, the chart must specify the day on which the chart's period of validity ends under paragraph 21A(3A) of the 1960 regulations. This must be the last day of a period of 1 month, 4 months or 12 months, starting on the day the first prescription for a pharmaceutical benefit is written in the chart.

This amendment means that HMC prescriptions remain valid until the day after the last day of a period of 1 month, 4 months or 12 months, starting on the day the first prescription for a pharmaceutical benefit is written in the chart.

Paragraph 41(2)(g) provides that if the patient is receiving treatment in or at a residential care service, the pharmaceutical benefit being prescribed cannot be referred to in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*).

Paragraph 41(2)(h) provides that for HMC prescriptions or residential care medication chart prescriptions, even where all other provisions have been satisfied, the section of the chart needs to be completed before the end of the chart's validity period as detailed in subsections 45 (3) and (4).

Subsection 41(3) prescribes the requirements for a hospital medication chart to be used for the purpose of writing an authority prescription.

Paragraph 41(3)(a) provides that for both HMC prescriptions and residential care medication chart prescriptions, streamlined authority required items are eligible for supply and PBS claiming, provided the prescriber includes the relevant PBS streamlined authority code in the appropriate area for each relevant medicine.

Paragraph 41(3)(b) provides that PBS authority required items requiring prior approval (written and telephone approval, including PBS/RPBS items with increased quantities) are eligible for supply and PBS claiming on HMC prescriptions only, provided the prescriber includes each authority approval number for the prescription. Residential care medication charts still require a traditional prescription to be written in order to prescribe an authority required item.

Subsection 41(4) defines a “medication chart” as a chart in a form (if any) approved under subsection 41(5) that is used for prescribing, and recording the administration of, pharmaceutical benefits to persons receiving treatment in or at a residential care service or a hospital, whether or not the chart:

- is used for any other purpose; or
- contains any other information.

Subsection 41(5) provides that the Secretary may, in writing, approve one or more forms for the purposes of subsection (4), including one or more forms for the purpose of writing an electronic prescription. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Section 42 – Information about the status of a person

Section 42 contains the same content as regulation 19A of the 1960 regulations. It prescribes the information relating to the status of a person under subsections 84AA(1) and 84AA(2) of the Act for a concessional beneficiary or dependant, and the information relating to the status of a person under subsections 84AA(1A) and 84AA(3) of the Act for a holder of a concession card or entitlement card.

Subsection 42(1) excludes the requirements of this section from applying to a medication chart prescription. The collection and use of a patient’s concessional information for a medication chart prescription is provided for in section 47.

Subsection 42(2) prescribes the information relating to the status of a person for whom a prescription relates for purposes of 84AA(1), (1A), (2) and (3) of the Act.

Subsection 42(3) prescribes the information relating to the status of a person for whom a prescription relates which must be written or marked on a prescription for the purposes of subsections 84AA(1) and (1A) of the Act. This provision prescribes that the required information must be written or marked on a prescription in accordance with a form approved, in writing by the Secretary. The words “in writing” have been added to this provision in accordance with current standard drafting practice.

Subsection 42(4) provides that for a prescription to which subsection 84AA(1) or (1A) of the Act applies, subsections (2) and (3) do not apply if the claim for a payment from the Commonwealth in relation to the supply of the pharmaceutical

benefit to which the prescription relates is a CTS claim; and the claim includes the card number that, under subsection (2), except for this subsection, is required.

Section 43 – Restriction on using PBS forms

Section 43 contains the same content as regulation 19B of the 1960 regulations. It ensures that it continues to be an offence of strict liability for a medical practitioner to write a prescription, which is not in accordance with, or for a purpose authorised by, the new Regulations (for example, to treat a condition which is not in a list in the schedule of pharmaceutical benefits of conditions for which the drug can be prescribed), on a PBS prescription form, without crossing out letters "PBS".

The penalty for the strict liability offence in subsection 43(1) remains at 0.4 penalty units, which is currently \$72 for an individual (as defined by section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 43(1) as a strict liability offence is considered appropriate to deter PBS prescribers from writing prescriptions that are not in accordance with, or for a purpose authorised by the new Regulations. It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*, as the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

Section 44 – Supply of pharmaceutical benefit on first presentation of prescription

Section 44 contains the same content as regulation 21 of the 1960 regulations. It makes provisions relevant to the supply of a pharmaceutical benefit on the first presentation of a prescription.

Subsection 44(1) excludes the requirements of this section from applying to a medication chart prescription. Supply of a pharmaceutical benefit on the basis of a medication chart prescription is provided for in section 45.

Subsection 44(2) provides the requirements to be satisfied before a pharmaceutical benefit can be supplied by an approved pharmacist or an approved medical practitioner on the first presentation of a PBS prescription.

Subsection 44(3) provides the requirements to be satisfied before a pharmaceutical benefit can be supplied by an approved hospital authority on the first presentation of a PBS prescription.

Subsection 44(4) defines the term "first presentation", for the purposes of this section, in relation to an electronic prescription means the first occasion when the prescription is accessed by an approved pharmacist or an approved medical practitioner for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written.

Section 45 – Supply of pharmaceutical benefit on basis of medication chart prescription

Section 45 contains the same content as regulation 21A of the 1960 regulations, though the provisions have been rewritten and reorganised for improved clarity and to

comply with modern drafting standards. It makes provisions relevant to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

Subsection 45(1) prescribes who may supply a pharmaceutical benefit on the basis of a medication chart prescription. It prescribes that an approved pharmacist or an approved medical practitioner may supply a pharmaceutical benefit on the basis of a residential care medication chart prescription, and that an approved pharmacist or approved hospital authority may supply a pharmaceutical benefit on the basis of a hospital medication chart prescription.

Subsection 45(2) allows a supplier in accordance with subsection (1), to supply the prescribed pharmaceutical benefits upon sighting the medication chart or a copy of the current chart containing the medication chart prescription, provided the date on which the pharmaceutical benefit is supplied is within the medication chart's validity period and the supplier writes on the chart or the copy (as the case may be):

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

Subsection 45(3) provides that the validity of a residential care medication chart prescription is no longer than four months from the date of prescribing of the first entry on the chart.

A residential care medication chart currently contains pre-printed administration dates in the sections of the chart in which the administration of medicines to the resident is recorded, for each of the four calendar months set out in the chart. Therefore, a residential care medication chart's validity period is always less than four full calendar months where the first order on the residential care medication chart is not started on the first day of the first calendar month, as the chart will expire on the last day of the fourth calendar month regardless of the day the chart commenced. For example, if the first prescription is written in a residential care medication chart on 11 June, the period of validity of the residential care medication chart starts on 11 June and ends on 30 September.

There are three possible scenarios that inform the duration of supply authorised by the medical practitioner from a residential care medication chart prescription:

- ongoing to the end of the validity period of the chart – “ongoing” being marked on the medication chart prescription (ongoing);
- stop date written on the medication chart prescription (stop date); or
- where neither option 1 nor option 2 is indicated, authorisation for supply defaults to up to one maximum PBS quantity (single quantity).

Subsection 45(4) prescribes that the period of validity of a HMC prescription starts on the day when the first prescription for a pharmaceutical benefit is written in the chart, and end at the end of the day specified in the chart as the day on which the chart's period of validity ends. While this provision remains unchanged from the corresponding provision in the 1960 regulations (subregulation 21A(3A)), the day specified in the chart as the day on which the chart's period of validity ends is one day later than currently provided for by the 1960 regulations by virtue of the amendment to paragraph 41(2)(f).

Subsections 45(5) to (7) prescribe the maximum quantity of a pharmaceutical benefit or pharmaceutical item that may be supplied on the basis of a medication chart prescription.

Where the prescriber has indicated an ongoing supply or a stop date on the chart, the supplier may supply multiples of up to the maximum PBS quantity, as determined under subparagraph 85A(2)(a) of the Act, if required by the prescriber's order. Each supply would be treated as an "original supply" and there would be no 'repeat authorisations'. The quantity required to be supplied on each occasion and the number of supplies required throughout the validity period of the chart would be determined by the prescribed dose and frequency of administration, the date of prescribing or start date of administration (if indicated) and the stop date (if indicated).

Where an ongoing supply or a single quantity has been indicated on the chart, the administration of the last quantity/single quantity supplied from the medication chart could overrun the chart validity period. Where a stop date is indicated, the quantity supplied must only be the quantity sufficient for administration to the resident up to and including the stop date, and not beyond that date.

The date of supply from a medication chart prescription must be during the validity period of the chart and no later than the stop date for that completed item (if any). The approved pharmacist or approved medical practitioner would endorse each supply on the copy of the medication chart from which they have supplied the pharmaceutical benefit.

Section 46 – Continued dispensing supply of a pharmaceutical benefit

Section 46 contains the same content as regulation 21B of the 1960 regulations. It provides that where an approved pharmacist supplies a pharmaceutical benefit in accordance with the continued dispensing supply arrangements under subsection 89A(1) of the Act, they are required to endorse a repeat authorisation form with the information necessary to make a claim.

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

Section 47 contains the same content as regulation 21C of the 1960 regulations. It requires an approved pharmacist, approved medical practitioner or approved hospital authority where applicable, to collect information about a person's status at the time of a continued dispensing supply or a supply on the basis of a medication chart prescription. This provision allows the approved supplier to collect information that, for standard prescriptions, would usually be included in the prescription by the prescriber, and requires that the information collected be included in the claim for the pharmaceutical benefit.

Section 48 – Supply of pharmaceutical benefits before surrender of written prescription

Section 48 contains substantially the same provisions as regulation 22 of the 1960 regulations, with an addition which prescribes that where a pharmaceutical benefit to be prescribed has a relevant streamlined authority code, a prescriber must inform the supplier of the code before the pharmaceutical benefit can be supplied.

Subsection 48(1) provides that in cases of urgency, a PBS prescriber can make arrangements for a person to be supplied a pharmaceutical benefit by an approved pharmacist or approved medical practitioner prior to surrendering a written prescription. This would be arranged by the prescriber providing the approved pharmacist or approved medical practitioner with a copy of the prescription, or by advising the supplier of the details of the prescription.

Subsection 48(2) provides for supply of authority prescriptions, in cases of urgency, prior to surrendering a written prescription. Under the corresponding provision in the 1960 regulations, a supplier cannot supply a PBS authority required item unless the Minister or the Chief Executive Medicare has notified the PBS prescriber (orally or by other means) that each relevant authorisation will be given, and the PBS prescriber informs the supplier of that notification before the pharmaceutical benefit is supplied. In practice, the prescriber informs the supplier of the authority number allotted to the authority approval. The current provision does not require a prescriber to inform the supplier of a streamlined authority code, even though it is necessary in order for the supplier to claim for the pharmaceutical benefit. Subsection 48(2) of the new Regulations extend the existing provision to prescribe that where a streamlined authority code applies to the pharmaceutical benefit prescribed, the PBS prescriber must inform the supplier of that code before the pharmaceutical benefit is supplied.

Subsections 48(3) to (6) prescribe the requirements for paper-based and electronic prescriptions to be surrendered or made accessible to the approved pharmacist or approved medical practitioner who supplied the benefit no later than 7 days after the benefit was supplied.

Subsection 48(7) provides that a PBS prescriber commits an offence if he or she fails to surrender or make accessible the prescription in line with subsections 48(3) to (6).

Subsection 48(8) provides that an offence against subsection 48(7) is an offence of strict liability.

The penalty for the strict liability offence in subsection 48(7) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 48(7) as a strict liability offence is considered appropriate because:

- it would deter approved prescribers from failing to provide prescriptions for pharmaceutical benefits supplied by an approved pharmacist or approved medical practitioner, on the prescribers instruction, without a valid PBS prescription in cases of urgency. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Subsection 48(9) provides that supply of a pharmaceutical benefit may not occur prior to surrender of a valid PBS prescription where a State or Territory law explicitly requires a prescription to be in writing, another law explicitly requires a prescription to be in writing or where the supply is to be made on the basis of a medication chart prescription.

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

Section 49 contains the same content as regulation 24 of the 1960 regulations. It prescribes the conditions under which a medical practitioner, authorised midwife or authorised nurse practitioner 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 pharmaceutical benefit allowable under subsection 88(6) of the Act.

Subsection 49(1) excludes this section from applying to a medication chart prescription. Provisions regarding the maximum quantity of a pharmaceutical benefit on the basis of a medication chart prescription are provided for in subsections 45(5) to (7).

Subsection 49(2) and (3) provides corresponding provisions for medical practitioners and for authorised midwives and authorised nurse practitioners which clarify the policy intention that this section is to be used in circumstances where the maximum quantity of the pharmaceutical benefit is insufficient for the medical treatment of the person for whom the prescription is written, that person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to that person's place of residence and that person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions. This section is not intended for other purposes such as where a person is travelling overseas and wishes to ensure supply of a pharmaceutical item for the duration of their trip.

Note 1 under subsection 49(3) provides that an authorised midwife or authorised nurse practitioner is not authorised to prescribe pharmaceutical benefits which have not been determined under subsections 88(1D) and 88(1E) of the Act respectively.

Note 2 under subsection 49(3) notes that the provisions in this section were previously contained in regulation 24 of the 1960 regulations. This information is particularly important for PBS prescribers writing a prescription in accordance with paragraph 40(1)(j), which provides the instructions for writing a prescription directing supply of multiple repeat supplies of a pharmaceutical benefit to be supplied in a single supply. Under the 1960 regulations, a PBS prescriber writing a prescription in accordance with this provision would be required to write "Regulation 24" or Reg 24" on the prescription. Under the new Regulations, a PBS prescriber still has the option to write "Regulation 24" or Reg 24" on the prescription, as this practice is already well established and understood by prescribers and suppliers, but also has the option to write "one supply" or "1 supply" for the purposes of paragraph 40(1)(j).

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

Section 50 contains the same content as regulation 24A of the 1960 regulations. It clarifies that when an approved pharmacist supplies a pharmaceutical benefit under continued dispensing provisions in subsection 89A(1) of the Act, the pharmacist cannot provide the patient with a supply of medicine greater than the PBS maximum quantity, regardless of the circumstances under which the previous supply to the patient was made, including a direction under section 49.

Section 51 – Repeated supplies of pharmaceutical benefits

Section 51 contains the same content as regulation 25 of the 1960 regulations. It provides for the repeated supply of pharmaceutical benefits.

Subsections 51(1) to (4) provide that the minimum interval between supplies of a pharmaceutical benefit to a person is four days. They further provide that for those pharmaceutical benefits for which more than four repeats are allowable (other than those used for the treatment of eye conditions), the minimum interval between supplies is to be twenty days. It is still possible to obtain a supply within that period if the supplier reasonably believes that a previous supply of the benefit has been destroyed, lost or stolen, or that having regard to the person's circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person. In such cases the pharmaceutical benefit may be supplied, provided the supplier writes the words “immediate supply necessary” on the Medicare /DVA copy (for a paper based prescription) or on the prescription (for an electronic prescription), and also signs the Medicare/DVA copy or the electronic prescription, as the case requires.

Subsection 51(5) provides that a repeated supply of a pharmaceutical benefit may be supplied by an approved supplier under the continued dispensing arrangements contained in subsection 89A(1) of the Act. Parallel with the requirements for a prescription in subsections 51(2) and (3), the pharmaceutical benefit may be supplied, provided the supplier completes a repeat authorisation form in accordance with section 46 of the new Regulations and also writes the words “immediate supply necessary” on the repeat authorisation form and signs the repeat authorisation form.

Subsection 51(6) provides that a repeated supply of a pharmaceutical benefit may be supplied by an approved supplier on the basis of a medication chart prescription. Because subsection 45(5) of the new Regulations allows a medication chart prescription to direct supply up to a maximum quantity of a pharmaceutical item or pharmaceutical benefit more than once under the circumstances prescribed in that subsection, subsection 51(1) prohibiting a pharmaceutical benefit from being supplied a number of times greater than the number specified in the prescription cannot reasonably apply. Parallel with the requirements for a prescription in subsections 51(2), (3) and (5), the pharmaceutical benefit may be supplied, provided the supplier writes the words “immediate supply necessary” and signs on the part of the copy of the chart that contains the completed section by which the prescription was written.

Section 52 – Repeat authorisations

Section 52 contains the same content as regulation 26 of the 1960 regulations. It provides the circumstances under which pharmaceutical benefits may be supplied more than once on the basis of a single prescription and the requirements for an approved supplier to prepare a repeat authorisation form.

Subsection 52(1) provides that repeat authorisation forms do not need to be prepared in relation to medication chart prescriptions as subsection 45(5) of the new Regulations allows a medication chart prescription to direct supply up to a maximum quantity of a pharmaceutical item or pharmaceutical benefit more than once under the circumstances prescribed in that subsection.

Subsection 52(2) provides the circumstances where a repeat authorisation form would need to be prepared by an approved supplier. The circumstances include a paper-based or an electronic prescription for a pharmaceutical benefit that is being supplied for the first time and contains a direction to supply the benefit more than once. The circumstances also include a paper-based or an electronic prescription for a pharmaceutical benefit that has been supplied previously, but contains an attached deferred supply authorisation or a repeat authorisation containing direction to supply additional repeat supplies.

Subsection 52(3) prescribes the details that an approved supplier must include on a repeat authorisation form on or before supplying a pharmaceutical benefit as directed in subsection (2).

Subsections 52(4) provides that an approved supplier commits an offence if the approved supplier does not correctly and fully complete a repeat authorisation form as prescribed in subsection (3).

Subsection 52(5) provides that an offence against subsection 52(4) is an offence of strict liability.

The penalty for the strict liability offence in subsection 52(4) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 52(4) as a strict liability offence is considered appropriate because:

- it deters approved suppliers from failing to record the necessary and correct information on the appropriate form to ensure correct and appropriate supply of pharmaceutical benefits via repeat supply arrangements. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Subsection 52(6) provides that an approved supplier must not supply a pharmaceutical benefit on the basis of a paper-based prescription when only the pharmacist/patient copy of the prescription is presented unless the approved supplier is also provided with a repeat authorisation or a deferred supply authorisation that is related to that pharmacist/patient copy by a number or numbers and indicates that the pharmaceutical benefit to be supplied has not been supplied for the total number of times directed in the prescription. Additionally, the repeat authorisation or deferred supply authorisation must contain the approval number given to the supplier under

section 16 and the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written.

Subsection 94(5) of the Act requires that a hospital authority shall not be approved under section 94 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. Subsection 52(7) of the new Regulations provides that where the approved supplier is an approved hospital authority completing a repeat authorisation under the circumstances set out in subsection 52(2) of the new Regulations, the approved hospital authority must cause the requirements in subsection (3) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the pharmaceutical benefit is supplied.

Section 53 – Deferred supply authorisations

Section 53 contains the same content as regulation 26A of the 1960 regulations. It provides the circumstances under which the supply of a pharmaceutical benefit may be deferred, and the requirements for an approved supplier to prepare a deferred supply authorisation form.

Subsection 53(1) provides that deferred supply authorisation forms do not need to be prepared in relation to medication chart prescriptions as medication chart prescriptions are not required to be surrendered in order to receive the supply of item on the chart.

Subsection 53(2) provides that where a prescription contains a direction to supply more than one pharmaceutical benefit, the approved supplier may supply one or more items on the prescription and defer the supply of one or more other items on the same prescription.

Subsection 53(3) prescribes the details that must be included on a deferred supply authorisation by an approved supplier. The deferred supply authorisation must be on and in accordance with a form approved by the Secretary (paper-based or electronic), and each pharmaceutical benefit being deferred must be written on its own individual form. It continues to be the case that an instrument approving a form is not a legislative instrument because it is covered by the exemption in item 6 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

Subsection 53(3) further provides that a deferred supply authorisation must contain the approval number allotted to the approved supplier under section 16, and the specific details to be included on paper-based prescriptions and electronic prescriptions.

Subsection 94(5) of the Act requires that a hospital authority shall not be approved under section 94 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. Subsection 53(4) of the new Regulations provides that where the approved supplier is an approved hospital authority completing a deferred supply authorisation as set out in subsection 53(2) of the new Regulations, the approved hospital authority must cause the requirements in subsection (3) to be

complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the pharmaceutical benefit is supplied.

Section 54 – Presentation of prescriptions in trading hours

Section 54 contains the same content as regulation 27 of the 1960 regulations. It provides that an approved pharmacist must ensure the normal trading hours for the pharmacy premises in respect of which he or she is approved are prominently displayed. It further provides that subject to section 55, a person is only entitled to be supplied with a pharmaceutical benefit from an approved pharmacist during normal trading hours.

Section 55 – Presentation of urgent prescriptions

Section 55 contains the same content as regulation 28 of the 1960 regulations. It makes provision for a prescriber to mark a prescription as “urgent”, which in turn provides that it may be presented to an approved pharmacist at the premises at which the pharmacist is approved at any time and the approved pharmacist must supply the pharmaceutical benefit as soon as practicable, provided that any charge lawfully demanded for the prescription is paid.

Subsection 55(3) provides that an approved supplier commits an offence if the approved supplier does not supply the pharmaceutical benefit as soon as reasonably practicable after being presented with an urgent prescription.

Subsection 55(4) provides that an offence against subsection 55(3) is an offence of strict liability.

The penalty for the strict liability offence in subsection 55(3) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 55(3) as a strict liability offence is considered appropriate to deter approved suppliers from wilfully delaying or refusing the supply of urgent medication. The offence is not punishable by imprisonment and the fine does not exceed 60 penalty units.

Subsection 55(5) provides that it is a defence to a prosecution for an offence against subsection (3) if the pharmacist had a reasonable excuse. The Attorney-General’s Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers* generally advises against the use of reasonable excuse unless it is not possible to rely on the general defences in the Criminal Code or to design more specific defences. However, due to the very broad nature of this offence, it is unlikely that the Criminal Code defences could adequately account for situations where a patient presents to a pharmacy outside of the pharmacy’s trading hours (where a pharmacist would likely not be present nor necessarily available to attend) or where the pharmacist does not have the medication in stock, or does not have the patient’s preferred brand. To restrict the use of reasonable excuse as a defence risks placing unreasonable pressure on approved pharmacists to be available at all times or to stock all PBS products. Given the broad nature of the offence provision and the very low penalty associated with this offence (0.2 Penalty

points/\$36), the Government has chosen to retain the “reasonable excuse” defence, rather than potentially limiting the defences available to pharmacists.

Section 56 – Special charge for delivery

Section 56 retains the content of regulation 30 of the 1960 regulations. It provides that an approved pharmacist or an approved medical practitioner may, for the purposes of subsection 87(4) of the Act, charge for delivery of a pharmaceutical benefit to a place other than the place from which the pharmacist or medical practitioner is approved to supply. The charge must not exceed the cost of delivery of the pharmaceutical benefit.

Section 57 – Receipt of pharmaceutical benefit

Section 57 retains the content of regulation 31 of the 1960 regulations. It makes provisions for acknowledging receipt of pharmaceutical benefits.

Subsection 57(1) provides that a person commits an offence if they received a pharmaceutical benefit under Part VII of the Act (other than a continued dispensing supply or a supply on basis of medication chart prescription) from an approved supplier and refused to acknowledge the receipt of the pharmaceutical benefit in the manner prescribed, despite being asked by the approved supplier, and it being reasonably practicable for the person to do so.

Subsection 57(2) provides corresponding provisions for a person who is requested to write an acknowledgement in accordance with subsection (1) for the supply of a pharmaceutical benefit under an electronic prescription, whereby a person is required to write the acknowledgement on a print-out of the electronic prescription or the authorisation to which the electronic prescription relates.

Subsection 57(3) provides that an approved supplier commits an offence if a person writes an acknowledgement on a print-out in accordance with subsection 57(2), and the approved supplier does not subsequently write on the electronic prescription, or the authorisation that relates to an electronic prescription, that the person has written the acknowledgement on a print out of the prescription or authorisation.

Subsection 57(4) provides that an approved supplier commits an offence if they supply a pharmaceutical benefit under Part VII of the Act (other than a continued dispensing supply or a supply on basis of medication chart prescription) to a person, but do not certify in the manner prescribed, the reason it was not practicable to obtain an acknowledgment from the person.

Subsection 57(5) provides that a person commits an offence if they received a pharmaceutical benefit under subsection 89A of the Act (a continued dispensing supply) from an approved supplier and refused to acknowledge the receipt of the pharmaceutical benefit in the manner prescribed, despite being asked by the approved supplier, and it being reasonably practicable for the person to do so.

Subsection 57(6) provides that an approved pharmacist commits an offence if they supply a pharmaceutical benefit under subsection 89A of the Act and it is not practicable to obtain a written acknowledgement that the person received the benefit, and the approved pharmacist does not certify in the manner prescribed, the reason it was not practicable to obtain an acknowledgment from the person.

Subsection 57(7) provides that an approved pharmacist commits an offence if the approved supplier knowingly asks for an acknowledgement for supply of a pharmaceutical benefit to a person, without supplying the benefit to that person.

Subsection 57(8) provides that an offence against subsection (1), (3), (4), (5), (6) or (7) is an offence of strict liability.

The penalty for the strict liability offences in subsections 57(1), (3), (4), (5), (6) and (7) remains at 0.2 penalty units, which is currently \$36 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offences in subsections 57(1), (3), (4), (5), (6) and (7) as strict liability offences is considered appropriate because it:

- deters persons receiving pharmaceutical benefits (whether or not for their own use) and approved suppliers from failing to adequately acknowledge receipt (in the case of a person) or supply (in the case of an approved supplier) of a pharmaceutical benefit. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

Part 6—Other matters relating to prescriptions and supply

Section 58 – Purpose of this Part

Section 58 retains the content of regulation 31B of the 1960 regulations. It provides that unless otherwise specified, this Part is made for the purposes of sections 105 and 140 of the Act.

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

Section 59 retains the provisions contained in regulation 32 of the 1960 regulations.

Subsection 59(1) applies an offence provision to an approved supplier who fails to keep appropriate documentation, as prescribed under subsections (3), (4) and (5) of this section, for at least two years following the supply of a pharmaceutical benefit. The offence does not apply to supply of a pharmaceutical benefit that is a dangerous drug, a pharmaceutical benefit supplied under a continued dispensing arrangement under subsection 89A(1) of the Act, or a pharmaceutical benefit supplied on the basis of a medication chart prescription.

Subsection 59(2) provides that an offence against subsection 59(1) is an offence of strict liability.

The penalty for the strict liability offence in subsection 59(1) remains at 0.4 penalty units, which is currently \$72 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 59(1) as a strict liability offence is considered appropriate because:

- it deters approved suppliers from failing to keep the required documents. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Note 1 under subsection 59(2) explains that corresponding arrangements for pharmaceutical benefits excluded from this section by virtue of subparagraph (1)(a)(ii) or (iii), are covered in sections 60 and 61.

Note 2 subsection 59(2) clarifies that a document prescribed for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transactions Act 1999*.

Subsection 59(3) prescribes the documentation which must be kept by an approved supplier for supply of a pharmaceutical benefit which was supplied on the basis of an electronic prescription under subsection 59(1). The approved supplier in such case must keep the electronic prescription and any repeat authorisation or deferred supply authorisation on the basis of which the supply was made.

Subsection 59(4) prescribes the documentation which must be kept by an approved supplier for supply of a pharmaceutical benefit which was supplied on the basis of a paper-based prescription under subsection 59(1). The documents to be kept for paper-based prescriptions depend on whether deferred or repeat supplies are required for any items on a prescription and whether a CTS claim is being made for the supply. The specific documents required for each scenario are set out in the table under this subsection.

Subsection 59(5) prescribes the documentation which must be kept by an approved supplier for supply of a pharmaceutical benefit which was supplied under prescriber bag arrangements under section 33 of the new Regulations. Where an approved supplier makes a CTS claim for the supply, they must keep the form on which the prescriber bag item or items were ordered. Furthermore, where a claim is made for the supply using the manual system referred to in section 99AAA of the Act, the duplicate of the order must be kept.

Subsection 59(6) would retain the definition of the term *dangerous drug* from regulation 32(4) of the 1960 regulations. It provides the definition for the purposes of the new Regulations.

Section 60 – Keeping documents –continued dispensing supplies

Section 60 retains the provisions contained in regulation 32A of the 1960 regulations.

Subsection 60(1) applies an offence provision to an approved pharmacist who fails to keep appropriate information, for two years, for supply of a pharmaceutical benefit to a person under continued dispensing arrangements under subsection 89A(1) of the Act. The information prescribed to be kept for the purposes of this section includes

information that supports a claim for a pharmaceutical benefit under section 99AAA of the Act and information about the supply provided to the PBS prescriber who most recently prescribed the pharmaceutical benefit to the person.

Subsection 60(2) provides that an offence against subsection 60(1) is an offence of strict liability.

The penalty for the strict liability offence in subsection 60(1) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 60(1) as a strict liability offence is considered appropriate because:

- it deters approved pharmacists from failing to keep the required documents. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

A note under subsection 60(2) clarifies that a document prescribed for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transactions Act 1999*.

Section 61 – Keeping documents – medication chart prescriptions

Section 61 retains the provisions contained in regulation 32A of the 1960 regulations.

Subsection 61(1) applies an offence provision to an approved supplier who fails to keep appropriate information, for two years, for supply of a pharmaceutical benefit on the basis of a medication chart prescription. The information prescribed to be kept for the purposes of this section includes the medication chart, or the copy of the medication chart, on which the approved supplier wrote the details referred to in paragraph 45(2)(c) in relation to the prescription.

Subsection 61(2) provides that an offence against subsection 61(1) is an offence of strict liability.

The penalty for the strict liability offence in subsection 59(1) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 61(1) as a strict liability offence is considered appropriate because:

- it deters approved suppliers from failing to keep the required documents. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

A note under subsection 61(2) clarifies that a document prescribed for record-keeping purposes under this section may be kept in electronic form by virtue of subsection 12(2) of the *Electronic Transactions Act 1999*.

Section 62 – Proper stocks to be kept

Section 62 retains the provisions contained in regulation 33 of the 1960 regulations.

Subsection 62(1) applies an offence provision to an approved pharmacist who fails, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits.

Subsection 62(2) provides that an offence against subsection 62(1) is an offence of strict liability.

The penalty for the strict liability offence in subsection 62(1) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 62(1) as a strict liability offence is considered appropriate because:

- it deters approved pharmacists from failing to keep an adequate supply of stock which they could reasonably foresee that they might be expected to supply. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Section 63 – Standards of composition and purity of pharmaceutical benefits and ingredients

Section 63 retains the provisions contained in regulation 35 of the 1960 regulations. It provides the standards of composition and purity that an ingredient or substance must meet in order to be supplied as a pharmaceutical benefit for the purposes of paragraph 103(5)(f) of the Act. It provides that a pharmaceutical benefit or an ingredient of a pharmaceutical benefit must comply with any standard for that drug, medicine or substance provided for by the *Therapeutic Goods Act 1989*.

Section 64 – Labelling of pharmaceutical benefits—full cost

Section 64 retains the provisions contained in regulation 36 of the 1960 regulations. It provides that the full cost of a pharmaceutical benefit must appear on the label of that pharmaceutical benefit, preceded by the words "full cost", unless:

- the approved supplier is exempted under section 99AAB of the Act from the requirement to use the Claims Transmission System; or

- the pharmaceutical benefit is supplied by an approved hospital authority; or
- the pharmaceutical benefit is obtained under prescriber bag provisions for the purpose of subsections 93(2), 93AA(2) or 93AB(2) of the Act; or
- subsections 99(2A), 99(2AB) or 99(2B) of the Act apply to that pharmaceutical benefit; or
- the supply of the pharmaceutical benefit is on the basis of a medication chart prescription.

It also defines "full cost" to be the sum of the Commonwealth price of that pharmaceutical benefit as defined by Part VII of the Act, plus any special patient contribution charged under 87(2A) of the Act and calculated under subsection 85B(2) of the Act.

Section 65 – Surrender of forms

Section 65 retains the provisions contained in regulation 37 of the 1960 regulations.

Subsection 65(1) provides that the Secretary may, by notice in writing served on a person, require that person to surrender to the Secretary or to a person specified in the notice, within a time specified in the notice, any forms that have been supplied to that person by or on behalf of the Commonwealth under or for the purpose of Part VII of that Act or these Regulations and that are in the possession of the person.

Subsection 65(2) applies an offence provision to a person upon whom a notice has been served by the Secretary under subsection 65(1), who does not comply with that notice.

Subsection 65(3) provides that an offence against subsection 65(2) is an offence of strict liability.

The penalty for the strict liability offence in subsection 65(2) remains at 0.2 penalty units, which is currently \$36 for an individual (as defined in section 4AA, *Crimes Act 1914*).

Retaining the offence in subsection 65(1) as a strict liability offence is considered appropriate because:

- it deters non-compliance by persons who have been served such a notice by the Secretary. This deterrence is necessary to ensure the integrity of the Pharmaceutical Benefits Scheme; and
- the penalty does not include imprisonment and the fine does not exceed 60 penalty units.

It remains consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Part 7—Price reduction and price disclosure

Division 1—Price reduction

Section 66 – Reduction day

Section 66 retains the provision contained in regulation 37A of the 1960 regulations. It prescribes for the purposes of paragraph 99ADH(2)(b) of the Act, the reduction day must be 1 August and 1 December in any year.

Division 2—Price disclosure

Subdivision A—Interpretation

Section 67 – Meaning of data collection period

Section 67 retains the provisions contained in regulation 37C of the 1960 regulations. It provides for the meaning of “data collection period”.

Start of first data collection period

Subsection 67(1) provides that the first data collection period for a brand starts on the brand’s start day.

The term “start day” is defined in section 5 of the new Regulations as the day on which the brand was first required to comply with price disclosure requirements under section 99ADD of the Act. This could occur because it is the day section 99ADD price disclosure requirements first apply to a drug, the manner of administration (MoA) for a drug, or the particular brand.

End of first data collection period

Subsection 67(2) deals with the situation where the drug/MoA is already subject to price disclosure requirements.

In this case, the first data collection period for the new brand ends when the data collection period for any brand with the same drug/MoA ends. This is 31 March or 30 September. That is, the new brand joins the disclosure cycle already underway for related brands. The first data collection period for the new brand is usually six months or less, depending on the start date (date of PBS listing) of the new brand. However, across the drug/MoA, a minimum of six months of data is provided by responsible persons.

If the related brands that the new brand is joining are also in a first data collection period (see subsection 67(3) below), the new brand’s first data collection period may be more than six months.

Subsection 67(3) deals with the situation where the drug/MoA is not already subject to price disclosure requirements. The first data collection period ends:

- if the start day occurs between 2 April and 1 October – the next 31 March; or
- if the start day occurs between 2 October and 1 April – the next 30 September.

If a drug/MoA enters price disclosure on the following PBS price change points, the first data collection period for brands listed on the PBS on those dates will be:

- 1 April – six months;
- 1 August – eight months;
- 1 December – 10 months.

This ensures that at least six months data is provided by responsible persons for the drug/MoA.

Start and end of subsequent data collection periods

Subsection 67(4) deals with the start and end of subsequent data collection periods. After the first data collection period for a listed brand, each data collection period starts immediately after the end of the last data collection period, and ends on the next 31 March or 30 September, whichever is sooner.

Example 1 illustrates the operation of subsections 67(2), and 67(4). This example is for a new brand with a drug/MoA for which related brands are already subject to price disclosure.

The example indicates that, if the new brand's start day is 1 July 2014, and the data collection period for a related brand ends on 30 September 2014, the first data collection period for the new brand will be 1 July 2014 to 30 September 2014 (three months, although across the drug/MoA there will be six months). Subsequent six month data collection periods will run from 1 October 2014 to 31 March 2015, 1 April 2015 to 30 September 2015, 1 October 2015 to 31 March 2016, and so on.

Examples 2 and 3 illustrate the operation of subsections 67(3) and 67(4). These examples are for brands with a drug/MoA new to price disclosure.

Example 2 indicates that, if the brand's start day is 1 August 2014, the first data collection period will be 1 August 2014 to 31 March 2015 (eight months). Subsequent six month data collection periods will run from 1 April 2015 to 30 September 2015, 1 October 2015 to 31 March 2016, 1 April 2016 to 30 September 2016, and so on.

Example 3 indicates in a similar fashion that if a brand's start day is 1 December 2014, the first data collection period will be 1 December 2014 to 30 September 2015 (10 months). Subsequent periods will run from 1 October 2015 to 31 March 2016, 1 April 2016 to 30 September 2016, 1 October 2016 to 31 March 2017, and so on.

Section 68 – Meaning of “price sampling day”

Section 68 retains the provisions contained in regulation 37D of the 1960 regulations. It provides for the meaning of “price sampling day”.

The term “price sampling day” is used when obtaining an “average approved ex manufacturer price” in section 73.

The same “average approved ex manufacturer price” would be obtained for all brands (listed and delisted) with the same pharmaceutical item, as the “price sampling day” may be within the data collection period for another brand of the same pharmaceutical item (if it commenced earlier). The same “average approved ex manufacturer price” for all brands of the same pharmaceutical item would be the expected result as section

85C of the Act requires each brand of a pharmaceutical item to have the same “approved ex manufacturer price”.

Section 69 – Special rules for certain listed brands

Section 69 retains the provisions contained in regulation 37E of the 1960 regulations.

Subsection 69(1) provides that subsections (3), (4) and (5) apply to a listed brand of a pharmaceutical item if:

- paragraphs 99ADB(3B)(a) and (b) of the Act apply to the listed brand; and
- a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

Subsection 69(2) provides that subsections (4) and (5) apply to a listed brand of a pharmaceutical item if:

- the start day for the listed brand is the relevant day; and
- a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

Approved ex-manufacturer price on relevant day

Subsection 69(3) works out an approved ex manufacturer price for a listed brand on the relevant day in situations where a brand lists on the PBS after the “relevant day” and before reduction day, and there is no other listed brand of the same pharmaceutical item to rely upon for a flow-on price disclosure reduction (if any) under section 99ADHA of the Act.

The “ten per cent test” in paragraph 99ADH(1)(c) of the Act provides that no price disclosure reduction for a listed brand will occur unless there is at least a ten per cent difference between the brand’s “applicable approved ex manufacturer price” (that is, its “approved ex manufacturer price” on the relevant day) and the brand’s determined “weighted average disclosed price” (WADP).

The “relevant day” is the day after the last day of the data collection period (subsection 99ADB(1) of the Act). The term “applicable approved ex manufacturer price” is defined in section 99ADB of the Act, and the term “approved ex manufacturer price” is defined in subsection 84(1) of the Act.

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

Subsections 69(4) and (5) provide for an average approved ex manufacturer price to be worked out in situations where a brand lists on the PBS on or after the “relevant day” and before reduction day, and there is no other listed brand of the same pharmaceutical item to rely upon for a flow-on price disclosure reduction (if any) under section 99ADHA of the Act. The average approved ex manufacturer price is worked out in Step 3 for use in Step 11 of the Subdivision 2 weighted average disclosed price (WADP) method. The other steps in the WADP method are not applicable as there are no data for the listed brand in the data collection period.

Subdivision B—Weighted average disclosed price

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

Section 70 retains the provisions contained in regulation 37F of the 1960 regulations. It provides that Subdivision B is made for the purposes of subsection 99ADB(6) of the Act. It provides the method to be used by the Minister (or delegate) in determining the weighted average disclosed price of a listed brand of a pharmaceutical item in respect of the data collection period (the WADP method) and it provides that when using the method, the Minister (or delegate) may disregard information provided under section 85 for a data collection period if it is incomplete.

Section 71 – Step 1—net revenue for brand

Section 71 retains the provisions contained in regulation 37G of the 1960 regulations. It defines the net revenue for the listed brand for the data collection period. The net revenue is the revenue from sales of the listed brand for the data collection period, minus the value of any incentive given in relation to sales of the listed brand, and not including the listed brand's initial month.

Section 72 – Step 2—adjusted volume for brand

Section 72 retains the provisions contained in regulation 37H of the 1960 regulations. It defines the adjusted volume of the listed brand sold for the data collection period.

The terms “initial month” and “final day” which are used in section 72 are defined in regulation 5 of the new Regulations. The number of packs sold, and the separately disclosed initial month's number of packs sold, are all information disclosed by a responsible person in accordance with section 85.

Section 73 – Step 3—average approved ex manufacturer price for brand

Section 73 retains the provisions contained in regulation 37J of the 1960 regulations. It provides the method for calculating the average approved ex manufacturer price of the listed brand of the pharmaceutical item for the data collection period for the brand.

The same “average approved ex-manufacturer price” will be obtained for all brands (listed and delisted) with the same pharmaceutical item, as the “price sampling day” may be within the data collection period for another brand of the same pharmaceutical item (if it commenced earlier). The same “average approved ex-manufacturer price” for all brands of the same pharmaceutical item would be the expected result as section 85C of the Act requires each brand of a pharmaceutical item to have the same “approved ex-manufacturer price”.

Section 74 – Step 4—disclosed price for brand

Section 74 retains the provisions contained in regulation 37K of the 1960 regulations. It provides the method for calculating the disclosed price of the listed brand. The disclosed price is the amount worked out by dividing the net revenue for the listed brand (Step 1) by the adjusted volume for the listed brand (Step 2).

If the result is more than the average approved ex manufacturer price for the listed brand (Step 3), the disclosed price will be the average approved ex manufacturer price for the listed brand. This “capping” occurs, where triggered, in Step 4 because the

method is not interested in that portion of sales which may be above the average approved ex manufacturer price. The result at subparagraph 74(2)(b)(i) might be above the average approved ex manufacturer price due, for example, to special patient contributions, sales direct to pharmacists or other variations relating to the reporting of sales.

The PBS subsidy price used for comparison in the WADP calculation method is an average approved ex manufacturer price over the data collection period.

The disclosed price is zero if the adjusted volume (Step 2) is zero or less.

Section 75 – Step 5—price percentage difference of brand

Section 75 retains the provisions contained in regulation 37L of the 1960 regulations. It provides the method for calculating the price percentage difference of the listed brand. It is the disclosed price for the brand (Step 4) subtracted from the average approved ex manufacturer price (Step 3), divided by the average approved ex manufacturer price, and the result expressed as a percentage to two decimal places.

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

Section 76 retains the provisions contained in regulation 37M of the 1960 regulations. It provides for Steps 1 to 5 to be repeated for each brand of the same pharmaceutical item (including delisted brands).

Subsection 76(3) provides for pricing quantity adjustment, where needed, for delisted brands, based on the pricing quantity for another listed brand of the same pharmaceutical item. Where there is no remaining listed brand, the pricing quantity used for delisted brands is the pricing quantity of the last listed brand (the one that is delisted last).

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

Section 77 retains the provisions contained in regulation 37N of the 1960 regulations. It provides the method for calculating the total adjusted volume of the brands of the pharmaceutical item by adding together the adjusted volume (Step 2) for each brand of the same pharmaceutical item.

Section 78 – Step 8—Weighted average percentage difference of brands of pharmaceutical item

Section 78 retains the provisions contained in regulation 37P of the 1960 regulations. It provides that to obtain the weighted average percentage difference of the brands of the pharmaceutical item, sum the adjusted volume (Step 2) multiplied by the price percentage difference (Step 5) for each brand of the same pharmaceutical item, and divide the result by the total adjusted volume (Step 7).

The weighted average percentage difference of the brands of the pharmaceutical item is zero if the total adjusted volume (Step 7) is zero or less.

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

Section 79 retains the provisions contained in regulation 37Q of the 1960 regulations. It provides for Steps 1 to 8 to be repeated for each pharmaceutical item with the same

drug and MoA (including delisted brands). Subsection 79(3) provides for pricing quantity adjustment, where needed, for delisted brands.

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

Section 80 retains the provisions contained in regulation 37R of the 1960 regulations. It provides the method for calculating the weighted average percentage difference for the listed brand and all brands of all pharmaceutical items with the same drug and MoA.

The new Regulations provides that, to obtain the weighted average percentage difference (also known as the “WAPD”) which applies across the drug/MoA, for each pharmaceutical item:

- (a) multiply the total adjusted volume (Step 7) by the average approved ex manufacturer price for a brand of the pharmaceutical item (Step 3);
- (b) multiply that amount by the weighted average percentage difference of the brands of the pharmaceutical item (see Step 8);
- (c) add up the amounts obtained using (b) (that is, for all pharmaceutical items with same drug and MoA);
- (d) add up the amounts obtained using (a) (that is, for all pharmaceutical items with same drug and MoA);
- (e) divide the amount worked out in (c) by the amount worked out in (d).

The weighted average percentage difference is zero if the amount worked out in (d) is zero or less.

The WAPD for the drug/MoA will be 99 per cent if the WAPD would otherwise be 99 per cent or more.

If the WAPD for the drug/MoA in Step 10 were to be equal to or greater than 100 per cent, the result in section 81, Step 11, would then be a nil or negative weighted average disclosed price for a listed brand. This means that on reduction day the approved ex manufacturer price for the listed brand would be nil or negative. To avoid this outcome, a maximum of 99 per cent applies for a WAPD across the drug/MoA in Step 10.

For consistency, the 99 per cent maximum applies to all WAPD results 99 per cent or greater at Step 10. For example, if the result would otherwise be 99.15 per cent, it becomes 99 per cent.

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

Section 81 retains the provisions contained in regulation 37S of the 1960 regulations. It provides the method for calculating the weighted average disclosed price for a listed brand for the data collection period, which is the average approved ex-manufacturer price for the listed brand (Step 3) reduced by the weighted average percentage difference for the drug/MoA (Step 10).

Subsection 81(3) provides for pricing quantity adjustment, if the pricing quantity of the listed brand on the final day is different from the pricing quantity on the relevant day. The pricing quantity adjustment ensures that the “ten per cent test” in paragraph 99ADH(1)(c) of the Act works appropriately and compares “like with like” when applied.

A note refers to section 99ADHA of the Act for price reductions for brands listed after the end of the data collection period.

Subsection 81(4) provides that section 81 is subject to section 82. The effect of subsection 81(4) is that notwithstanding the weighted average disclosed price of a listed brand worked out under section 81 (in Step 11), that would otherwise become the approved ex manufacturer price of the brand, if the circumstances set out in section 82 are met, the weighted average disclosed price for the brand is taken to be the applicable approved ex manufacturer price. That is, the price of the brand is not reduced by the weighted average percentage difference calculated in Step 10 for the data collection period and a price disclosure price reduction does not occur for that or any brand of the pharmaceutical item. The applicable approved ex manufacturer price is defined under section 99ADB of the Act to be the approved ex manufacturer price of the brand on the day after the end of the period for which the weighted average price of the brand is determined. The applicable approved ex manufacturer price is used in paragraph 99ADH(1)(c) of the Act (the “10% test”). Since the 10 per cent test is failed, a price disclosure reduction does not occur.

Section 82 –When weighted average disclosed price is the same as the applicable approved ex-manufacturer price

Section 82 retains the provisions contained in regulation 37SA of the 1960 regulations. It sets out when the weighted average disclosed price of a listed brand of a pharmaceutical item calculated under section 81 for the data collection period is taken to be the amount of the applicable approved ex manufacturer price of the brand. Under subsection 81(4), application of the weighted average disclosed price of a listed brand has effect subject to section 81.

The effect of section 82 is that price disclosure reductions do not apply in certain circumstances when there is little discounting and low sales volumes for brands of a pharmaceutical item.

Section 82 provides that application of the weighted average disclosed price calculated in section 81 is subject to whether:

- the total adjusted volume for brands of the pharmaceutical item worked out under section 77 (Step 7) is more than zero and no more than ten per cent of the sum of the total adjusted volumes for the brands of each pharmaceutical item sharing the same drug and manner of administration, also worked out under section 77 (Step 7), and including the total adjusted volume of the pharmaceutical item of the listed brand;
- the weighted average percentage difference worked out for brands of the pharmaceutical item under section 78 (Step 8) is not more than three per cent;
- there is not a brand of a pharmaceutical item with the same drug and manner of administration as the listed brand that is bioequivalent or biosimilar to the listed brand of the pharmaceutical item and to which paragraph 82(a) (a total

adjusted volume of no more than ten per cent of summed total adjusted volumes) and paragraph 82(b) (a weighted average percentage difference of no more than three per cent) do not apply;

- the Pharmaceutical Benefits Advisory Committee has not advised the Minister that the pharmaceutical item does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies.

If all of the above apply, the weighted average disclosed price of the brand is taken to be the amount of the applicable approved ex manufacturer price of the listed brand of the pharmaceutical item.

Disclosed originator brand data is not excluded when determining whether the conditions in section 82 all apply due to Subdivision C and subsection 82(3).

Subdivision C— Information that must not be taken into account

Section 83 – Information that must not be taken into account

Section 83 retains the provisions contained in regulation 37SB of the 1960 regulations. This subdivision is made for subsection 99ADB(6A) of the Act, which provides that the regulations may prescribe information that the method used to determine the weighted average disclosed price for a brand must not take into account (including information that has been provided in compliance with the price disclosure requirements). Subsection 83(3) provides that the information not to be taken into account may include information relating to originator brands.

Section 84 – Originator brands

Section 84 retains the provisions contained in regulation 37SC of the 1960 regulations. It sets out the circumstances where disclosed data for an originator brand would be excluded when determining the weighted average disclosed price of a brand, and the timing for when this would first occur.

Data is disclosed by the responsible person for a brand in accordance with subsection 99ADC(1) of the Act and section 85 of the new Regulations. The disclosed data essentially relates to sales (revenue, incentives, volume of sales). It is only disclosed data that is excluded. Originator brands continue to contribute otherwise to the method, for example, when using PBS pricing and PBS “pricing quantity” in the method.

Section 84 provides that disclosed data about an originator brand must not be taken into account if three requirements are met.

Paragraph 84(1)(a) requires that on the first day of each calendar month on which the originator brand is a listed brand in the data collection period, there is another listed brand of the same pharmaceutical item that is not another originator brand.

Paragraph 84(1)(b) requires that by the end of the previous data collection period, the drug in the WADP brand must have been on F2 for at least 30 months.

Paragraph 84(1)(c) requires that on a day at least 30 months before the end of the previous data collection period, there must have been a related brand of the WADP

brand that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the WADP brand, or there must have been two or more related brands of the WADP brand that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.

A “related brand” has the same drug and manner of administration: subsection 5(1) of the new Regulations. By assessing whether at least 30 months has run at “the end of the previous data collection period”, the 30 months is always applied at the beginning of 1 April or 1 October of the data collection period for which the weighted average disclosed price is being determined.

The two 30 month tests mean that once a drug and manner of administration has a “match” (either two brands of the same pharmaceutical item, or different pharmaceutical items that are bioequivalent or biosimilar to each other) a minimum of three years pass before the weighted average disclosed price is determined without the originator brand data, and a minimum of three and a half years pass before an affected reduction can occur.

The Act considers competition to have entered the PBS market for a drug when at drug level there is a bioequivalent or biosimilar match (or across different drugs if the drugs are in a therapeutic group): section 85AB of the Act. Once this occurs, the drug moves to F2 and price disclosure starts. Situations can arise where there is no bioequivalent or biosimilar match at the level of a particular drug or manner of administration– in these cases the 30 months does not start until there is a match within the same drug and manner of administration. This allows further delay, for example, in situations where a drug has moved to F2 because it is in a therapeutic group, or a particular manner of administration does not have a “match”.

On an ongoing basis, even when the 30 month test is met, paragraph 84(1)(a) does not require the removal of an originator brand for a particular pharmaceutical item within a manner of administration unless there is a non-originator brand match. Otherwise, due to removal of the originator brand data, the price disclosure calculations would not have data at the pharmaceutical item level, either because the pharmaceutical item only has an originator brand, or, all brands of the pharmaceutical item are originator brands.

Subsection 84(2) ensures that paragraph 84(1)(a) still works, provided there is a match, if the particular originator or non-originator listed brand is not constant.

Subsection 84(3) provides that the requirement to exclude originator brand data does not apply if taking the originator brand data in to account would result in a higher weighted average percentage difference calculated under section 80 for the WADP brand and related brands. The method is applied twice, with originator brands excluded, and with them included, and the result that is more likely to achieve a reduction is chosen.

Subdivision D— Price disclosure requirements

Section 85 – Price disclosure requirements

Section 85 retains the provisions contained in regulation 37T of the 1960 regulations. It provides for price disclosure requirements.

Subsection 85(1) provides that this section is made for the purposes of subsection 99ADC of the Act.

Subsection 85(2) sets out the information the responsible person must provide in relation to the supply of a brand of a pharmaceutical item, other than the supply to a public hospital.

Subsection 85(3) provides that, if information is provided under revenue from sales, the same information must not also be provided as an incentive.

Subsection 85(4) provides that number of packs sold, revenue from sales, and incentives, to the extent the information relates to the brand's initial month, must be provided separately. The definition of "initial month" appears in section 5 of the new Regulations.

Subsection 85(5) provides that revenue from sales, and incentives, must be expressed in Australian dollars and rounded to the nearest whole dollar, rounding 50 cents upwards. The packs must fit the description of the brand (i.e., drug, form, MoA, brand), and may equal a "pack quantity" (subsection 84(1) of the Act), or any other pack size for the brand. The raw pack data is adjusted as if the size of the pack equals the pricing quantity, in all cases, to ensure that like is compared with like.

Prescribed person

Subsection 85(6) provides that the responsible person must provide the information to Australian Healthcare Associates Pty Ltd (ABN 82 072 790 848), or, if the responsible person receives written notice from the Department, the Secretary.

Prescribed manner and form

Subsection 85(7) and (8) provides that the responsible person must provide the information in a form approved, in writing, by the Secretary. The words "in writing" have been added to this provision in accordance with current standard drafting practice.

Prescribed times

Subsection 85(9) specifies the timeframes and deadlines for provision of information by a responsible person.

Subject to subsection 85(10), the responsible person is required to provide the information for each period:

- between 1 April and 30 September in a year – before the end of 11 November in that year; and
- between 1 October and the next 31 March – before the end of the next 12 May.

Subsection 85(10) provides that for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person must provide the information:

- if the start day happens between 1 April and 30 September in a year – before the end of 11 November in that year; or
- if the start day happens between 1 October and the next 31 March – before the end of the next 12 May.

Subsection 85(10) recognises that a brand is not required to report on information prior to its start day. It also requires that data for the period, which may be less than six months, between the brand's start day and the next 31 March or 30 September (whichever is sooner), be submitted as a batch on a one-off basis in a brand's first data collection period.

A responsible person for a delisted brand will have an accrued obligation to provide information up to the date of delisting, on the next due date.

Part 8— Arrangements for the Pharmaceutical Benefits Advisory Committee

Division 1— Matters relating to the appointment of members of the Committee

Section 86 – Nominating bodies

Section 86 retains the provisions contained in regulation 38A of the 1960 regulations. It specifies the nominating bodies for Pharmaceutical Benefits Advisory Committee (PBAC, or Committee) membership.

Paragraph 100A(3)(aa) of the Act refers to “industry” as one of the member groups from which members of the PBAC may be nominated and selected. Appointment of an industry member is not mandatory as it is not one of the groups of interests or professions from which at least one member must be selected. The reference to an “industry” member in the Act is intended to provide for the appointment of a member with expertise in a pharmaceutical or health-related industry relevant to the work of the PBAC.

Subsection 100B(1AA) of the Act provides for an industry member to be appointed from nominations made by industry organisations specified by the regulations, and by industry organisations invited by the Minister to make nominations for an industry member.

Subsection 86(1) provides that for paragraph 100B(1AA)(a) of the Act, the industry organisations prescribed as bodies which can nominate persons for appointment of an industry member to the Committee are: Medicines Australia Limited, the Generic Medicines Industry Association Pty Ltd trading as the Generic and Biosimilar Medicines Association, and Ausbiotech Ltd.

Subsection 100B(1AB) of the Act provides for a consumer member to be appointed by the Minister from nominations made by consumer organisations specified in regulations, and also provides for individuals and consumer organisations to be invited by the Minister to make nominations for a consumer member.

Subsection 86(2) provides that for paragraph 100B(1AB)(a) of the Act, the consumer organisations prescribed as bodies which can nominate persons for appointment of a consumer member to the Committee are: the Consumers Health Forum of Australia Ltd, the Australian Federation of AIDS Organisations Incorporated, and the Australian Consumers' Association.

Subsection 100B(1A) of the Act provides for members to be appointed by the Minister from nominations made by various health bodies.

Subsections 86(3) to (7) prescribe the bodies that may make nominations from which the Minister will select members of the Committee under subsection 100A(3) of the Act. It sets out the names of the bodies relating to each of the groups specified in paragraphs 100A(3)(b) to (f) of the Act.

Section 87 – Number of nominations for appointment

Section 87 retains the provisions contained in regulation 38B of the 1960 regulations. It is made for the purposes of subsection 100B(1B) of the Act and prescribes that the number of nominations that each of the bodies prescribed in section 85 are to be asked make is three.

This section does not apply to nominations that the Minister may choose to invite from bodies not specified in the regulations, from industry organisations for an industry member, or individuals or consumer organisations for a consumer member.

Section 88 – Resignation

Section 88 retains the provisions contained in regulation 40 of the 1960 regulations. It provides that a member of the PBAC may resign by giving notice, in writing, to the Minister.

Division 2— Matters relating to the procedure of the Committee

Section 89 – Purpose of this Division

Section 89 is a new section that states that Division 2 of Part 8 of the new Regulations makes provision, for the purposes of subsection 101(5) of the Act, for and in relation to the procedure of the Pharmaceutical Benefits Advisory Committee.

Section 90 – Presiding member

Section 90 retains the provisions contained in regulation 41 of the 1960 regulations. It provides for the Chairperson to be the presiding member if the Chairperson is present at a meeting. The Deputy Chairperson would preside at a meeting if the Chairperson is absent. If neither is present, the members attending the meeting would elect a member to preside at the meeting.

Section 91 – Meetings of the Committee

Section 91 retains the provisions contained in regulation 42 of the 1960 regulations. It provides that the Chairperson may, from time to time, by notice in writing to all members, convene a meeting of the Committee. Section 91 also requires the Committee keep minutes of its meetings.

Section 92 – Quorum

Section 92 retains the provisions contained in regulation 43 of the 1960 regulations. It provides for a majority of the members of the Committee to constitute a quorum for a meeting.

Section 93 – Voting

Section 93 retains the provisions contained in regulation 44 of the 1960 regulations. It provides that at a meeting of the Committee, the Chairperson and other members present each have a deliberative vote. At a meeting of the Committee, the members present each have a deliberative vote. The reference to members includes the Chairperson and the Deputy Chairperson.

Subsection 93(2) provides that a decision at a meeting must be determined by a majority of the votes of the Chairperson and other members present and voting

Subsection 93(3) provides for the situation where an equal number of votes is cast for and against a matter at a meeting. In such situations the Chairperson, or the member elected to preside at the meeting, may exercise a casting vote, or that if they decline to do so, the matter is resolved in the negative.

Subsection 93(4) provides that decisions of the Committee must be recorded in the minutes of the Committee.

Section 94 – Disclosure of pecuniary interests by members

Section 94 retains the provisions contained in regulation 45 of the 1960 regulations. It requires each member of the Committee to provide an annual written statement to the Minister of any direct or indirect pecuniary interests of the member which could conflict with the member's duties. It also requires any member to disclose any direct or indirect pecuniary interest in a matter which is to be considered at a meeting, and for that member not to take part in the meeting during the consideration of that matter, unless participation is agreed to by the Committee. Such disclosures have to be recorded in the minutes.

Section 95 – Resolutions without a formal meeting

Section 95 retains the provisions contained in regulation 46 of the 1960 regulations. It provides that where a majority of the members sign a document in support of a resolution set out in the document, the resolution is to be taken to have been passed at a meeting of the Committee.

Section 96 – Reports and recommendations

Section 96 retains the provisions contained in regulation 47 of the 1960 regulations. It requires that reports or recommendations by the Committee to the Minister be in writing, and allows for a minority report when requested by a dissenting member.

Division 3— Matters relating to sub-Committees

Section 97 – Remuneration for chair and members of sub committees

Section 97 retains the provisions contained in regulation 48 of the 1960 regulations. It provides that the fees and allowances for the Chair and members of the Drug Utilisation Sub-Committee and the Economics Sub-Committee (these sub-committees

of the Pharmaceutical Benefits Advisory Committee are established under section 101A of the Act).

The fees and allowances are the same as that payable to the Chair and members of the Pharmaceutical Services Federal Committee of Inquiry, as determined by the Remuneration Tribunal as in force from time to time. The current Remuneration Tribunal determination reference is Determination 2016/18 Remuneration and Allowances for Holders of Part-Time Public Office, Schedule B, Table B4.

Part 9— Application, savings and transitional provisions

Section 98 – Definitions

Section 98 is a new section that states that for this Part, “old regulations” means the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Section 99 – Things done under old regulations

Section 99 is a new section that provides that if a thing was done for a particular purpose under the old regulations as in force immediately before those regulations were repealed, and that thing could be done for that purpose under the new Regulations, then that thing has effect, for the purposes of the new Regulations, as if it has been done under the new Regulations. A reference to a thing being done includes a reference to a notice, approval or other instrument being given or made.

Section 100 – Savings—document retention provisions relating to obtaining pharmaceutical benefits

Section 100 is a new section that provides that where subregulation 60(2) of the old regulations applied immediately before the repeal of the old regulations by Schedule 2 to the new Regulations, despite that repeal, regulation 18A of the old regulations as in force immediately before 1 April 2015, and any other provision of those regulations that is necessary for the effectual operation of regulation 18A, continues to apply in relation to the obtaining of the pharmaceutical benefit, as if the repeal had not happened. This section will be repealed automatically on 1 April 2019.

Section 101 – Savings—document retention provisions relating to the supply of pharmaceutical benefits

Section 101 is a new section that provides that, in relation to the supply of a pharmaceutical benefit to which subregulation 60(4) of the old regulations applied immediately before the repeal of the old regulations by Schedule 2 to the new Regulations, despite that repeal, regulations 31, 32 and 32A of the old regulations as in force immediately before 1 April 2015, and any other provision of those regulations that is necessary for the effectual operation of regulation 31, 32 or 32A, will continue to apply in relation to the supply of the pharmaceutical benefit, as if the repeal had not happened. This section will be repealed on 1 April 2019.

Schedule 1— Prescribed offices

Schedule 1 sets out the offices which are prescribed offices for lodgement of safety net concession card application, pharmaceutical benefits entitlement card applications and accompanying documents.

Schedule 2— Repeals

This item repeals the old regulations which are being replaced by the new Regulations.