EXPLANATORY STATEMENT

Select Legislative Instrument 2006 No. 200

Minute No. 19 of 2006 – Minister for Health and Ageing

Subject – *National Health Act 1953*

National Health (Pharmaceutical Benefits) Amendment Regulations 2006 (No. 2)

Subsection 140(1) of the *National Health Act 1953* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Part VII, Division 2 of the Act provides, in part, for the process by which a prescription for the supply of a pharmaceutical benefit may be authorised, prescribed and dispensed. Section 93 of the Act under Division 2 provides the authority for medical practitioners to supply pharmaceutical benefits to persons who are entitled to receive such benefits.

The *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) set out the operation of a paper-based process for prescribing and dispensing medicines. This currently excludes the operation of an electronic process.

The purpose of the Regulations is to enable the establishment of a new electronic process for prescribing and dispensing medicines. This new electronic process will be an alternative to the current paper-based process, and the Regulations will allow both methods of prescribing and dispensing medicines concurrently.

The Regulations will allow a prescription to be created, signed, retained, modified and communicated electronically, and will amend the definition of "signature" to encompass an "electronic signature".

Details of the Regulations are set out in the Attachment.

Consultation

The Australian Government Department of Health and Ageing (the Department) has consulted with a range of stakeholders in relation to electronic prescribing and dispensing. A wide range of healthcare, consumer and technical organisations with an interest in electronic prescribing and dispensing were consulted as part of the legal issues, technical solutions and workflow mapping consultancies commissioned by the Department in May-June 2005.

The Department has regularly consulted with each state and territory health department through the National Health Information Group (NHIG) since December

2004. NHIG is made up of senior health executives from all jurisdictions and reports to the Australian Health Ministers' Advisory Council. NHIG members support the Commonwealth amending the National Health (Pharmaceutical Benefits) Regulations 1960 to enable electronic prescribing and dispensing.

Since mid 2004, the Department has regularly consulted with Medicare Australia (the Australian Government Department of Human Services) regarding technical, legal and operational issues, as Medicare Australia administers the Pharmaceutical Benefits Scheme, on behalf of the Department. Medicare Australia supports the Commonwealth amending the National Health (Pharmaceutical Benefits) Regulations 1960 to enable electronic prescribing and dispensing.

The Department will continue to consult with Medicare Australia and each state and territory health department through NHIG. Consultation is also occurring with the Australian Government Department of Veterans' Affairs. The Australian Government Department of Veterans' Affairs is supportive of this electronic prescribing and dispensing initiative.

The Department has liaised with and will continue to work closely with the Australia Government Office of the Privacy Commissioner. The Office of the Privacy Commissioner has not raised any concerns at this stage.

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

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003.*

The Regulations commence on 1 March 2007 to ensure that all States and Territories have sufficient time to make their own corresponding legislative and regulatory amendments.

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

Authority: Subsection 140(1) of the *National Health Act 1953.*

Attachment

DETAILS OF THE *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) AMENDMENT REGULATIONS 2006 (No. 2)*

Regulation 1 – Name of Regulations

Specifies that the title of the Regulations is the *National Health (Pharmaceutical Benefits) Amendment Regulations 2006 (No. 2)*

Regulation 2 – Commencement

The Regulations commence on 1 March 2007.

Regulation 3 – Amendment of the *National Health (Pharmaceutical Benefits) Regulations 1960.*

Schedule 1 to the Regulations amends the *National Health (Pharmaceutical Benefits) Regulations 1960.*

Schedule 1 – Amendments

Item [1]: Part 1, heading

A new heading 'Division 1.1 Interpretation' is inserted before Regulation 1. The new Division covers Regulations 1 – 5.

Subregulation 5(1) amends the definitions of key terms necessary for enabling electronic prescribing and dispensing of medicines. Items [2] to [8] refer.

Item [2]: Subregulation 5(1), after definition of applicable amount

A definition of the term '*approved electronic communication*' was inserted in subregulation 5(1) after the definition of '*applicable amount*'. *Approved electronic communication* means an electronic communication of a kind approved in writing by the Secretary of the Department of Health and Ageing under regulation 5E for the purposes of the provision in which the expression is used.

Item [3]: Subregulation 5(1), after definition of approved hospital authority
A definition of the term '*approved information technology requirements*' was inserted in subregulation 5(1) after the definition of '*approved electronic communication'*. *Approved information technology requirements* means technology requirements of a kind approved in writing by the Secretary under regulation 5F for the purposes of the provision in which the expression is used.

Item [4]: Subregulation 5(1), after definition of dependent

A definition of the term '*electronic communication'* was inserted in subregulation 5(1) after the definition of '*dependant'*. *Electronic communication* has the same meaning in the Regulations as the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

This defines '*electronic communication'* as a communication of information in the form of data, text or images by means of guided and/or unguided electromagnetic energy, or as a communication of information in the form of speech by means of guided and/or unguided electromagnetic energy, where the speech is processed at its destination by an automated voice recognition system.

A definition of the term '*electronic order form*' was inserted in subregulation 5(1) after the definition of '*electronic communication*'. *Electronic order form* means a form approved in writing by the Secretary under subparagraph 16(1)(b)(ii) for the purposes of lodging an order under paragraph 16(1)(b).

A definition of the term '*electronic prescription'* was inserted in subregulation 5(1) after the definition of '*electronic order form'*. *Electronic prescription* means a prescription that is prepared and submitted in accordance with approved information technology requirements (if any) by means of an approved electronic communication in a form approved by the Secretary under sub-subparagraph 19(1)(a)(iia)(B).

Item [5]: Subregulation 5(1), after definition of entitlement card prescription

A definition of the term '*information technology requirements*' has been inserted in subregulation 5(1) after the definition of '*entitlement card prescription'*. Information technology requirements has the same meaning given in the Regulations as the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999.* This defines '*information technology requirements*' as including software requirements.

Item [6]: Subregulation 5(1), definition of Medicare Australia/DVA copy
In the definition of '*Medicare Australia/DVA Copy'* in subregulation 5(1) the words 'for a prescription' were omitted and replaced with the words 'for a paper-based prescription,'. This limits the application of this term and definition to paper-based prescriptions only; this definition does not apply to electronic prescriptions.

Item [7]: Subregulation 5(1), after definition of out-patient medication
A definition of the term '*paper-based prescription'* was inserted in subregulation 5(1) after the definition of '*out-patient medication'*. This defines '*paper-based prescription'* as a prescription, including an authority prescription, that is prepared in duplicate in accordance with one of the three methods in subparagraph 19(1)(a)(i), (ii) or (iii).

Item [8]: Subregulation 5(1), definition of pharmacist/patient copy
In the definition of '*pharmacist/patient copy'* in subregulation 5(1), the words 'paper-based' was inserted before the word 'prescription'. This limits the application of this term and definition to paper-based prescriptions only and this definition would not apply to electronic prescriptions.

A definition of the term '*prescription'* was inserted in subregulation 5(1) after the definition of '*pharmacist/patient copy'*. This defines '*prescription'* as a paper-based prescription or an electronic prescription. This is inserted to extend the current definition of a prescription beyond paper-based prescriptions only to include electronic prescriptions. Electronic prescriptions qualify under the definition of prescription in subregulation 5(1) for the purposes of the provisions in which the expression is used.

Item [9]: After section 5

A new Division 1.2 was inserted in Part I, with the heading "Division 1.2 Application of Regulations to electronic prescriptions and electronic orders"
after section 5. This Division covers the application of the Regulations to electronic prescriptions and electronic orders and would encompass new regulations 5A to 5F.

Regulation 5A applies to writing or preparing a prescription, repeat authorisation or deferred supply authorisation whether the expression "writing, preparing" or any other expression is used.

Paragraph 5A(a) provides that a reference anywhere in the Regulations to writing or preparing a prescription is taken to include, in relation to an electronic prescription, writing or preparing the prescription by means of an electronic form approved by the Secretary under sub-subparagraph 19(1)(a)(iia)(B) for the purposes of writing an electronic prescription.

Paragraph 5A(b) provides that a reference anywhere in the 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 authorised by the Secretary under subparagraph 26(1A)(a)(i) for the purposes of supplying a pharmaceutical benefit.

Paragraph 5A(c) provides that a reference anywhere in the 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 authorised by the Secretary under paragraph 26A(2)(a) for the purposes of deferring the supply of a pharmaceutical benefit.

'Regulation 5B Date when a prescription is written or a pharmaceutical benefit is prescribed' was inserted after regulation 5A and provides that a reference in these 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.
'Regulation 5C Requirement to give information in writing' was inserted after regulation 5B.

Regulation 5C was inserted to extend 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 Regulations.

Regulation 5C is included to define the requirement to give information in writing in relation to electronic prescriptions, authorisations and orders.

Subregulation 5C(1) 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.

Subregulation 5C(2) provides that the requirement to write information on a prescription is taken to be met/satisfied whether the expression “write, certify, indicate, mark, specify, state or any other expression is used.”

‘Regulation 5D Requirement to give a prescription’ were inserted after regulation 5C.

Regulation 5D provides the requirements to give or present a prescription to an approved practitioner, in relation to an electronic prescription, for the purposes of supplying a pharmaceutical benefit.

Regulation 5D provides that the requirement to give or present a prescription is taken to be met, in relation to electronic prescriptions in certain circumstances. Regulation 5D provides that the practitioner or pharmacist 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.

‘Regulation 5E Approval of kinds of electronic communications’ was inserted after regulation 5D.

Regulation 5E provides that the Secretary may approve in writing a kind of electronic communication for 1 or more of the purposes listed in paragraphs (a) to (h).

Paragraph 5E(a) provides that the Secretary may approve in writing a kind of electronic communication for preparing or submitting an electronic prescription.

Paragraph 5E(b) provides that the Secretary may approve in writing a kind of electronic communication for giving information in relation to an electronic prescription, authorisation and order that relates to an electronic prescription or an electronic order form..

Paragraph 5E(c) provides that the Secretary may approve in writing a kind of electronic communication for giving or presenting an electronic prescription to an approved practitioner or approved pharmacist.

Paragraph 5E(d) provides that the Secretary may approve in writing a kind of electronic communication for submitting a prescription to the Minister in accordance with paragraph 13(2)(b) of the Regulations .

Paragraph 5E(e) provides that the Secretary may approve in writing a kind of electronic communication for lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93 of the *National Health Act 1953*.

Paragraph 5E(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 16(1)(b) of the Regulations.

Paragraph 5E(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.

Paragraph 5E(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 Regulations.

'Regulation 5F Approval of information technology requirements' was inserted after regulation 5E.

Regulation 5F provides that the Secretary may, in writing, approve information technology requirements for 1 or more of the purposes listed in paragraphs (a) to (g).

Paragraph 5F(a) provides that the Secretary may, in writing, approve information technology requirements for preparing and submitting an electronic prescription.

Paragraph 5F(b) provides that the Secretary may, in writing, approve information technology requirements for giving information in relation to an electronic prescription, authorisation or order form.

Paragraph 5F(c) provides that the Secretary may, in writing, approve information technology requirements for giving or presenting an electronic prescription to an approved practitioner or approved pharmacist.

Paragraph 5F(d) provides that the Secretary may, in writing, approve information technology requirements for lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93 of the *National Health Act 1953*.

Paragraph 5F(e) provides that the Secretary may, in writing, approve information technology requirements for submitting a receipt for a pharmaceutical benefit received under paragraph 16(1)(b) of the Regulations.

Paragraph 5F(f) provides that the Secretary may, in writing, approve information technology requirements for giving an acknowledgement in the principal Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription.

Paragraph 5F(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 Regulations.

Items [10] to [51] make consequential amendments to the Principal Regulations following the introduction of new Division 1.2 above.

Item [10]:After subparagraph 13(3)(a)(iii)
Subparagraph 13(3)(a)(iiia) was inserted after subparagraph 13(3)(a)(iii).

Subparagraph 13(3)(a)(iiia) provides that an electronic prescription submitted for a variation, to the allowed maximum number of repeats or quantity of units of medication, must be in a form approved in writing by the Secretary under sub-subparagraph 19(1)(a)(iia)(B).

Item [11]: Subparagraph 13(3)(b)(ii)
In subparagraph 13(3)(b)(ii) the words 'by means of an electronic communication approved in writing by the Secretary' was omitted and replaced with the words 'by means of an approved electronic communication'.

This ensures consistency with the definition of "electronic communication" in subregulation 5(1).

Item [12]:Paragraph 13(5)(a)
A new paragraph 13(5)(a) was inserted to restrict the operation of paper-based prescriptions and insert new subparagraphs which are to apply to paper-based prescriptions.

Item [13]: After paragraph 13(5)(a)
Paragraph 13(5)(aa) was inserted after paragraph 13(5)(a).

Subparagraph 13(5)(aa)(i) provides the process for varying an electronic prescription when the Minister requires the medical practitioner to alter the prescription.

This refers to the process through which the Minister is authorised to vary the maximum number of repeats or maximum number or quantity of units of medicines being prescribed.

PBS prescriptions and repeats can be for any quantity up to a set maximum. If a doctor feels the maximum quantity or number of repeats should be increased for a particular patient, the doctor must seek approval from the Minister.

Subparagraph 13(5)(aa)(ii) provides the process for varying an electronic prescription when it is not required to be altered.

Item [14]:Subparagraph 13(6)(b)(ii)
Subparagraph 13(6)(b)(ii) was omitted and replaced with a new subparagraph 13(6)(b)(ii).

Subparagraph 13(6)(b)(ii) provides the same retention requirements for electronic prescriptions as is presently provided for paper-based prescriptions.

Item [15]: Subregulation 13(7)
Subregulation 13(7) was omitted and replaced with a new subregulation 13(7).

Subregulation 13(7) provides the date on which the Minister makes a variation in relation to electronic prescriptions. This is either the date on which the Minister tells the medical practitioner or on which the Minister sends the authorisation by electronic communication.

Item [16]: Subregulation 16(1)
Subregulation 16(1) was omitted and replaced with a new subregulation 16(1) that is divided into two paragraphs:

Paragraph 16(1)(a) provides the power for a medical practitioner to obtain a pharmaceutical benefit for the purpose of section 93 of the *National Health Act 1953*, using a paper-based form as part of the paper-based prescription process.

This process refers to the emergency drug (doctors' bag) supply process. Certain pharmaceutical benefits are provided without charge to doctors who in turn can supply them free to patients for emergency use.

Paragraph 16(1)(b) provides the power for a medical practitioner to obtain a pharmaceutical benefit for the purpose of section 93 of the *National Health Act 1953*, using an electronic form as part of the electronic prescription process.

A new subregulation 16(1A) was inserted after subregulation 16(1). Subregulation 16(1A) provides the requirements that must be satisfied for an order in an electronic form to be lodged.

Item [17]: Subregulation 16(3)
Subregulation 16(3) was omitted and replaced with a new subregulation 16(3).

Subregulation 16(3) provides the process for providing a receipt for a pharmaceutical benefit supplied under an order in subregulation 16(1).

Subregulation 16(3) has been divided into three paragraphs – paragraph 16(3)(a) covers the requirements for both paper-based and electronic orders, paragraph 16(3)(b) covers paper-based orders only and paragraph 16(3)(c) covers electronic orders only.

Item [18]: Paragraph 17(1)(a)
In paragraph 17(1)(a), the word ‘given’ was omitted and replaced with the word ‘lodged’. This change ensures consistency with the language used in regulation 16 in relation to orders.

Item [19]: Subparagraph 17(1)(b)(ii)(A)
In sub-subparagraph 17(1)(b)(ii)(A), the word ‘presented’ was omitted and replaced with the word ‘lodged’. This change ensures consistency with the language used in regulation 16 in relation to orders.

Item [20]: Regulation 18
In regulation 18, the words ‘order given’ was omitted and replaced with the words ‘order lodged’. This change ensures consistency with the language used in regulation 16 in relation to orders.

Item [21]: Paragraph 19(1)(a)
In paragraph 19(1)(a), the words ‘in duplicate’ were omitted.

This removes the requirement for duplicates from applying to both paper-based and electronic prescriptions in paragraph 19(1)(a) so that the requirement for duplicates would apply to paper-based prescriptions only.

Item [22]:Subparagraph 19(1)(a)(i)
In subparagraph 19(1)(a)(i), the words ‘in duplicate’ were inserted before the words ‘by handwriting’.

This provides that the requirement for duplicates applies to paper-based prescriptions only in subparagraph 19(1)(a)(i) and not to electronic prescriptions.

Item [23]: Subparagraph 19(1)(a)(ii)
In subparagraph 19(1)(a)(ii), the words ‘in duplicate’ were inserted before the words ‘by means of’.

This provides that the requirement for duplicates applies to paper-based prescriptions prepared by means of a computer in subparagraph 19(1)(a)(ii).

Item [24]:After subparagraph 19(1)(a)(ii)
After subparagraph 19(1)(a)(ii), a new subparagraph 19(1)(a)(iia) was inserted.

Subparagraph 19(1)(a)(iia) provides the requirements for the electronic prescription form.

Sub-subparagraph 19(1)(a)(iia)(A) provides what information is required to be on the electronic prescription.

Sub-subparagraph 19(1)(a)(iia)(B) provides that the electronic prescription must be in a form approved in writing by the Secretary.

Item [25]: Subregulation 19(5)
Subregulation 19(5) is omitted and replaced with a new subregulation 19(5).

This provides that the requirement in subregulation 19(5) that a prescription must not be prepared using a computer program that defaults to indicate that only the brand of pharmaceutical specified in the prescription is to be supplied would apply to both paper-based and electronic prescriptions.

Item [26]: Paragraph 19A(2)(a)
In paragraph 19A(2)(a), the words 'the face of' were omitted.

This ensures that paragraph 19A(2)(a) applies to both paper-based and electronic prescriptions.

This applies to both electronic and paper-based prescription forms as the prescribed information contained on both of these forms should be written or marked in accordance with a form approved by the Secretary.

Item [27]:Paragraph 21(1)(b)
In paragraph 21(1)(b), the words 'original and the duplicate' were omitted and replaced with the words 'prescription (including, for paper-based prescription, both original and the duplicate)'.

This limits the requirement for original and duplicates to paper-based prescriptions only on the first presentation of a prescription in the application of paragraph 21(1)(b).

Item [28]: Paragraph 21(2)(b)
In paragraph 21(2)(b), the words 'the original and the duplicate are marked' were omitted and replaced with the words 'the prescription (including, for a paper-based prescription, both the original and the duplicate) is marked,'.

This limits the requirement for original and duplicates to paper-based prescriptions only on the first presentation of a prescription in the application of paragraph 21(2)(b).

Item [29]: After Subregulation 21(2)
After subregulation 21(2), a new subregulation 21(3) was inserted. This provides that a reference to the first presentation of a prescription, in relation to an electronic prescription, means the first occasion that 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.

Item [30]: Subregulation 22(3), including penalty
In subregulation 22(3), the words ', for a paper-based prescription,' were inserted after the words 'must ensure that'.

This limits the operation of subregulation 22(3) to paper-based prescriptions only.

Subregulation 22(3) applies to paper-based prescriptions and provides that when pharmaceuticals are supplied to a person, in a case of urgency, by an approved pharmacist the original and duplicate of the prescription must be given to the pharmacist no later than 7 days after the pharmaceuticals are supplied.

After subregulation 22(3), a new subregulation 22(3AA) has been inserted.

Subregulation 22(3AA) applies to electronic prescriptions and provides that when pharmaceuticals are supplied to a person, in a case of urgency, by an approved pharmacist, the practitioner must ensure that the prescription is made accessible to the pharmacist no later than 7 days after the pharmaceuticals are supplied.

Item [31]: Subregulation 22(3A)
In subregulation 22(3A), the words ‘subregulation (3)’ were replaced with the words ‘subregulation (3) or (3AA)’. This would extend the operation of the subregulation 22(3A) to cover both paper-based and electronic prescriptions.

This is in relation to the supply of pharmaceutical benefits before the surrender of the written prescription (both paper-based and electronic).

This makes it an offence for the relevant pharmacist or medical practitioner not to supply a prescription, within 7 days of a pharmaceutical benefit being supplied, in the circumstances where a pharmaceutical benefit has been supplied before the written prescription has been presented.

Item [32]: Subregulation 22(4), including penalty
In subregulation 22(4), the words ‘for a paper-based prescription’ were inserted after the words ‘must ensure that’ which would limit the operation of subregulation 22(4) to paper-based prescriptions only.

Subregulation 22(4) applies to paper-based prescriptions and provide that when a medical practitioner or dental practitioner has communicated with an approved pharmacist or approved medical practitioner under subregulation 22(2), the original and duplicate of the prescription must be given to the pharmacist no later than 7 days after the pharmaceuticals are supplied.

After subregulation 22(4), a new subregulation 22(4AA) was inserted.

Subregulation 22(4AA) applies to electronic prescriptions and provide that when a medical practitioner or dental practitioner has communicated with an approved pharmacist or approved medical practitioner under subregulation 22(2), the practitioner must ensure that the prescription is made accessible to the pharmacist no later than 7 days after the pharmaceuticals are supplied.

Item [33]: Subregulation 22(4A)

In subregulation 22(4A) the words ‘subregulation (4)’ was omitted and replaced with the words ‘subregulation (4) or (4AA)’. This extends the operation of subregulation 22(4A) to cover both paper-based and electronic prescriptions.

The subregulation applies in relation to the supply of pharmaceutical benefits before the surrender of the written prescription (both paper-based and electronic).

This makes it an offence for the relevant pharmacist or medical practitioner not to supply a prescription, within 7 days of a pharmaceutical benefit being supplied, in the circumstances where a pharmaceutical benefit has been supplied before the written prescription has been presented.

Item [34]:Subparagraphs 25(3)(b)(ii) and (iii)
Current subparagraph 25(3)(b)(ii) is divided into two new sub-subparagraphs – subparagraph 25(3)(b)(ii)(A) which covers paper-based prescriptions and subparagraph 25(3)(b)(ii)(B) which cover electronic prescriptions.

Sub-subparagraph 25(3)(b)(ii)(A) requires the words ‘immediate supply necessary’ to be written on the Medicare Australia/DVA copy of the paper-based prescription.

Sub-subparagraph 25(3)(b)(ii)(B) requires the words ‘immediate supply necessary’ to be written on the electronic prescription.

Subparagraph 25(3)(b)(iii) is altered to cover signatures on both paper-based prescriptions and electronic prescriptions.

Item [35]:Subparagraphs 25 (3) (c) (ii) and (iii)
Current subparagraph 25(3)(c)(ii) is divided into two new sub-subparagraphs - Sub-subparagraph 25(3)(c)(ii)(A) which covers paper-based prescriptions and sub-subparagraph 25(3)(c)(ii)(B) which covers electronic prescriptions.

Sub-subparagraph 25(3)(c)(ii)(A) requires the words ‘immediate supply necessary’ to be written on the Medicare Australia/DVA copy of the paper-based prescription.

Sub-subparagraph 25(3)(c)(ii)(B) requires the words ‘immediate supply necessary’ to be written on the electronic prescription.

Subparagraph 25(3)(c)(iii) is altered to cover signatures on both paper-based prescriptions and electronic prescriptions.

Item [36]:Subparagraphs 25(4)(b)(ii) and (iii)
Current subparagraph 25(4)(b)(ii) is divided into two new sub-subparagraphs - sub-subparagraph 25(4)(b)(ii)(A) which covers paper-based prescriptions and sub-subparagraph 25(4)(b)(ii)(B) which covers electronic prescriptions.

Sub-subparagraph 25(4)(b)(ii)(A) requires the words ‘immediate supply necessary’ to be written on the Medicare Australia/DVA copy of the paper-based prescription.

Sub-subparagraph 25(4)(b)(ii)(B) requires the words ‘immediate supply necessary’ to be written on the electronic prescription.

Subparagraph 25(4)(b)(iii) is altered to cover signatures on both paper-based prescriptions and electronic prescriptions.

Item [37]: Subparagraphs 25 (4)(c) (ii) and (iii)
Current subparagraph 25(4)(c)(ii) is divided into two new sub-subparagraphs - sub-subparagraph 25(4)(c)(ii)(A) which covers paper-based prescriptions and sub-subparagraph 25(4)(c)(ii)(B) which covers electronic prescriptions.

Sub-subparagraph 25(4)(c)(ii)(A) requires the words ‘immediate supply necessary’ to be written on the Medicare Australia/DVA copy of the paper-based prescription.

Sub-subparagraph 25(4)(c)(ii)(B) requires the words ‘immediate supply necessary’ to be written on the electronic prescription.

Subparagraph 25(4)(c)(iii) is altered to cover signatures on both paper-based prescriptions and electronic prescriptions.

Item [38]: Subparagraph 26(1)(a)(i)
In subparagraph 26(1)(a)(i), the words ‘an Medicare Australia/DVA copy of a prescription’ were omitted and replaced with the words ‘a Medicare Australia/DVA copy of a paper-based prescription’. This limits the operation of subparagraph 26(1)(a)(i) to paper-based prescriptions only. The proposed subparagraph 26 (1)(a)(i) lists one of the paper-based prescription forms that can be used for repeat supplies (ie to supply a pharmaceutical benefit more than once).

Item [39]: Subparagraphs 26(1)(a)(ii) and (iii)
In subparagraphs 26(1)(a)(ii) and (iii), the words ‘of a paper-based prescription’ were inserted after the words ‘a pharmacist/patient copy’. This limits the operation of subparagraph 26(1)(a)(ii) and (iii) to paper-based prescriptions.

The subparagraphs 26(1)(a)(ii) and 26(1)(a)(iii) is in relation to one of the paper-based prescription forms that can be used for repeat supplies (ie to supply a pharmaceutical benefit more than once).

Item [40]: Subparagraph 26 (1)(a)(iii)
In subparagraph 26(1)(a)(iii) the words ‘once; and’ were omitted and replaced with the words ‘once; or’. This provides that paragraph 26(1)(a) be divided into two parts. Subparagraphs 26(1)(a)(i), (ii) and (iii) sets out three different types of repeat prescription scenarios that can apply to paper-based prescriptions and new subparagraph 26(1)(a)(iv) sets out the repeat prescription process applying to electronic prescriptions.

Item [41]:After subparagraph 26(1)(a)(iii)

After subparagraph 26(1)(a)(iii), a new subparagraph 26(1)(a)(iv) is inserted that sets out the repeat prescription process applying to electronic prescriptions.

This sets out the different ways that an electronic prescription could contain a direction to supply the pharmaceutical benefit more than once.

Item [42]: Subparagraph 26(1A)(a)(i)
In subparagraph 26(1A)(a)(i) the words '(including a paper-based or an electronic form)' were inserted after the words 'in accordance with a form'. This provides that the requirements for preparing a repeat authorisation under subparagraph 26(1A)(a)(i) apply to both paper-based and electronic forms.

Item [43]:Subparagraphs 26(1A)(a)(iii) and (iv)
Subparagraph 26(1A)(a)(iii) is modified so as to set out the process for attaching a repeat authorisation to a paper-based prescription.

Current subparagraph 26(1A)(a)(iv) has been moved to subparagraph 26(1A)(a)(iii) and applies to the paper-based process.

Subparagraph 26(1A)(a)(iv) is modified to set out the process for attaching a repeat authorisation to an electronic prescription.

Item [44]:Subregulation 26(2)
In subregulation 26(2), the words 'of a paper-based prescription' were inserted after the words 'pharmacist/patient copy' to limit the application of subregulation 26(2) to paper-based prescriptions only.

This provides the circumstances where an approved pharmacist, approved medical practitioner or approved hospital authority is authorised to supply a pharmaceutical benefit on the presentation of only the pharmacist/patient copy of the paper-based prescription.

Item [45]:Paragraph 26A(2)(a)
In paragraph 26A(2)(a), the words '(including a paper-based or an electronic form)' were inserted after the words 'in accordance with a form'. This clearly shows that the requirements for preparing a deferred supply authorisation under paragraph 26A(2)(a) would apply to both paper-based and electronic forms.

In paragraph 26A(2)(a) the word 'requested;' is omitted and replaced with the words 'requested; and'. This provides that paragraph 26A(2)(a) is one requirement of subregulation 26A(2) that must be fulfilled in connection with paragraph 26A(2)(b).

The paragraph 26A (2)(b) provides the requirement for an approved pharmacist, approved medical practitioner or approved hospital authority to mark the approval number, on the prescription, for authorising the deferral of the supply of a pharmaceutical benefit.

Item [46]: Paragraph 26A(2)(b)

In paragraph 26A(2)(b) the words ‘regulation 8A;’ were omitted and replaced with the words ‘regulation 8A; and’. This clearly shows that paragraph 26A(2)(b) is one requirement of subregulation 26A(2) that must be fulfilled in connection with paragraphs 26A(2)(a) and 26A(2)(c).

Paragraph 26A(2)(a) provides the requirement for an approved pharmacist, approved medical practitioner or approved hospital authority to prepare a supply authorisation in accordance with a form approved by the Secretary for each pharmaceutical benefit that is deferred.

Paragraph 26A(2)(c) provides the process for deferring the supply of a pharmaceutical benefit in relation to a paper-based prescription.

Paragraph 26A(2)(d) provides the process for deferring the supply of a pharmaceutical benefit in relation to an electronic prescription.

Item [47]: Paragraphs 26A (2)(d) and (e)

Paragraph 26A(2)(c) has been inserted to set out the process for deferring the supply of a pharmaceutical benefit for paper-based prescriptions. This would occur when a patient orders two or more pharmaceutical benefit items, but they do not require all of the items at the same time. A separate repeat authorisation for each item is prepared.

Subparagraph 26A(2)(c)(i) sets out the requirement to mark the prescription with the words ‘original supply deferred’.

Subparagraph 26A(2)(c)(ii) sets out the requirement to attach the document that authorises the supply of the a pharmaceutical benefit to be supplied to the pharmacist/patient copy of the prescription.

Subparagraph 26A(2)(c)(iii) sets out the requirement to give the documents referred to in subparagraph 26A(2)(d)(ii) to the person for whom the prescription is written.

Paragraph 26A(2)(d) has been inserted to set out the process for deferring the supply of a pharmaceutical benefit for electronic prescriptions.

Subparagraph 26A(2)(d)(i) sets out the requirement to mark the electronic prescription with the words ‘original supply deferred’.

Subparagraph 26A(2)(d)(ii) sets out the requirement to attach the authorisation for deferring supply of the pharmaceutical benefit to the electronic prescription.

Subparagraph 26A(2)(d)(iii) sets out the requirement to give a print-out of the deferred supply authorisation and prescription to the person for whom the prescription is written or ensure that the deferred supply authorisation and prescription are made accessible to that person.

Item [48]: Subregulation 28(1)
In subregulation 28(1), the words ‘, in the case of a paper-based prescription,’ were inserted before the words ‘marking being initialled’.

This provides that the requirement for a medical practitioner or dental practitioner to initial a prescription for the supply of a pharmaceutical benefit marked ‘urgent’ applies to paper-based prescriptions only.

Item [49]: Subregulation 28(1)
After subregulation 31(1), a new subregulation 31(1A) has been be inserted.

This provides that if a person is required to write an acknowledgement for the supply of a pharmaceutical benefit, in relation to an electronic prescription or authorisation, paragraph 31(1A)(a) provides that this requirement would be met if the acknowledgement is given. This would have to be in accordance with approved information technology requirements (if any) by means of an approved electronic communication. Alternatively, paragraph 31(1A)(b) provides that this requirement would be met by the patient writing the acknowledgement on a print-out of the electronic prescription or authorisation.

After new subregulation 31(1A), a new subregulation 31(1B) has been inserted.

This provides that an approved pharmacist, approved medical practitioner or approved hospital authority must write on the electronic prescription or authorisation that the person has written the acknowledgement on a print-out of the electronic prescription or authorisation.

A penalty (of 0.2 units) applies if a written acknowledgement is not received when a pharmaceutical benefit is supplied.

Item [50]: Subregulation 32(1), including the penalty
Subregulation 32(1) is omitted and replaced with a new subregulation 32(1).

Subregulation 32(1) provides that if an approved pharmacist, approved medical practitioner, or approved hospital authority supplies a pharmaceutical benefit (other than a supply of a dangerous drug), then he or she must retain the forms in subregulation 32(2) for at least 1 year from the date of supply.

The retention requirements in subregulation 32(1) applies to paper-based prescriptions or orders (paragraph 32(1)(a)) and to electronic prescriptions or orders (paragraph 32(1)(b)).

A penalty (of 0.2 units) applies if a written acknowledgement is not received when a pharmaceutical benefit is supplied.

Item [51]: Subregulation 32(2)
Subregulation 32(2) is omitted and replaced with a new subregulation 32(2).

Subregulation 32(2) specifies which forms are required to be retained under subregulation 32(1) in relation to both paper-based and electronic prescriptions.

Paragraphs 32(2)(a), 32(2)(b) and 32(2)(c) are each divided into two subparagraphs. Subparagraphs 32(2)(a)(i), 32(2)(b)(i) and 32(2)(c)(i) provides for the paper-based forms that must be retained, and subparagraphs 32(2)(a)(ii), 32(2)(b)(ii) and 32(2)(c)(ii) provides for the electronic forms that must be retained.