EXPLANATORY STATEMENT

Select Legislative Instrument No. 23, 2015

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015

Authority
Section 140 of the *National Health Act 1953* (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.

Purpose
The regulation amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to provide for a medication chart prescription to be used for hospital patients for prescribing, dispensing, and claiming on the Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS). These legal requirements for the hospital medication chart prescription build on the existing medication chart prescription for persons at a residential aged care facility which already allows for PBS/RPBS claiming directly from a chart.

The amendments are necessary to implement the PBS Medication Charts for Public and Private Hospitals measure, announced by the Australian Government as part of the 2014-15 Budget. The amendments reduce the regulatory burden currently placed on PBS prescribers, approved suppliers and nurses in hospitals. It will remove the need for duplication of PBS/RPBS prescription information, and improve work flows for health professionals, and health outcomes, through a reduction of transcription errors.

The amendments are aligned with and supported by the Australian Commission on Safety and Quality in Health Care (ACSQHC) PBS Hospital Medication Chart project. The ACSQHC is developing national standardised medication charts appropriate for use in hospital settings to support PBS/RPBS subsidy directly from a PBS prescriber's medication chart prescription without the need for separate PBS/RPBS prescriptions.

The regulation amendments:

- apply to all PBS prescribers noting that as for all PBS prescriptions under the Act, particularly for PBS prescribers who are not medical practitioners, the PBS prescriber must be otherwise allowed under the Act to prescribe the medicine on the PBS/RPBS;
- continue to allow approved suppliers and approved medical practitioners (dispensing doctors) to supply from a medication chart prescription for persons at a residential aged care facility (for ease of reference referred to as 'National Residential Medication Chart' or NRMC);
- allow approved pharmacists or approved public or private hospital authorities to supply from a medication chart for patients in the hospital (for ease of reference referred to as 'Hospital Medication Chart' or HMC);
- require the medication chart prescription to be in one or more 'approved forms', which will be made publicly available via the ACSQHC website;
- rely on the same PBS legal requirements for the prescribing/dispensing method as used for the NRMC, with the period of validity of each medication chart prescription in the NRMC being set at no more than four months, and the PBS prescriber setting the period

of validity of each medication chart prescription in the HMC at either no more than one, four or twelve months;

- rely on the same relationship with maximum quantity and repeat limitations as the NRMC, with these controls continuing to apply within the context of medication chart prescriptions. No separate 'repeat authorisation' form will need to be filled out as that separate form is not necessary or appropriate for a medication chart prescription;
- for the NRMC, streamlined authorities will remain available. For the HMC, streamlined authorities and other authorities will be available, subject to practical limitations imposed by complex written authorities;
- continue to exclude controlled drugs (e.g. Schedule 8 medicines) from the NRMC, but not from the HMC. Further consideration, including during the HMC trial period, and possibly amendments to state and territory law, will be needed for it to be possible to use a hospital medication chart prescription for controlled drugs;
- make changes associated with enabling an electronic supply certification by approved suppliers for all PBS prescriptions on and from 1 April 2015. This change will apply except in the limited instances where a claim is made manually (that is, by sending in the prescription);
- adjust approved supplier prescription retention requirements to incorporate retention of documents previously not retained as these were sent to the Commonwealth as part of the PBS claim. The retention period will be standardised to two years; and
- make minor and mechanical amendments including updating the fees and allowances for the Chair and members of the Drug Utilisation Sub-Committee and the Economics Sub-Committee (sub-committees of the Pharmaceutical Benefits Advisory Committee), simplifying drafting, and removing spent regulations that no longer have legal effect.

The amendments provide for a transitional period for the HMC during which a patient must be in an approved hospital specified in a legislative instrument. The transitional period ends before 1 July 2016 for a HMC 'medication chart prescription', and before 1 April 2017 for a HMC medication chart prescription that is also an 'electronic prescription'. The transitional period will support testing through trial access, prior to national release. Trials for the paper-based HMC medication chart prescriptions commence on 1 April 2015.

These amendments do not override state and territory (jurisdictions) laws. Jurisdictions laws must continue to be obeyed. Jurisdictions have been consulted and informed of the intended Commonwealth changes, and have been asked to consider amendments required to their law to allow use of the HMC. To assist transition by jurisdictions needing time to update poisons law subordinate legislation references, the old legal pathway relying on section 93A of the Act for the NRMC will also remain open until 1 April 2017. This old pathway does not allow access for all PBS prescribers.

Consequential amendments to other instruments under the Act commencing on 1 April 2015 are also required. This includes the claiming and under PBS co-payment data rules made under sections 98AC and 99AAA of the Act, and the special arrangements under section 100 of the Act and special arrangements under section 100 of the Act for highly specialised drugs and efficient funding of chemotherapy.

Details of the amending regulation are set out in the Attachment.

Consultation

Since the announcement of the PBS Medication Charts for Public and Private Hospitals measure in 2014, the Department of Health has undertaken an extensive consultation process involving all key health stakeholders. These consultations indicate widespread and strong support for the trial of the PBS Hospital Medication Chart and amendments required to the

Principal Regulations and associated legislative instruments to support the measure. Consulted stakeholders include States and Territories, Australian Private Hospital Association, Society of Hospital Pharmacists of Australia, Pharmaceutical Society of Australia, Pharmacy Guild of Australia, Australian Medical Association, Cancer Voices Australia, Consumers Health Forum of Australia, National Prescribing Service, the ACSQHC, and the National E-Health Transition Authority. Similarly, the Department of Human Services has received strong support from a range of stakeholders for the implementation of paperless (electronic) claiming of PBS/RPBS medicines. This includes support for transitional arrangements to ensure stakeholder readiness for the implementation of paperless PBS/RPBS claiming.

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

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on 1 April 2015.

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

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*

Section 1 Name
This section provides that the title of the regulation is the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015.*

Section 2 Commencement
This section provides that the regulation commences on 1 April 2015.

Section 3 Authority
This section provides that the regulation is made under the *National Health Act 1953*.

Section 4 Schedules
This section provides that each instrument specified in a Schedule to the regulation is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Schedule 1 – Medication chart prescriptions

Part 1 – Amendments
National Health (Pharmaceutical Benefits) Regulations 1960

1 to 14 Subregulation 5(1)
Items 1 to 14 amend subregulation 5(1) (Interpretation) of the Principal Regulations, including adding medication chart prescriptions to the definition of 'electronic prescription', and inserting definitions for 'approved hospital', 'CTS claim', 'medication chart' and 'special patient contribution' aligned with Part VII of the Act, for the convenience of the reader.

The definition of 'prescription' is repealed as all prescription sub-types referred to in the regulations are a 'prescription' for the purpose of the Act and instruments under the Act.

15 Subregulation 5(4)
Item 15 repeals subregulation 5(4) of the Principal Regulations which provides for the required content of a paper-based 'supply certification form' for a 'paperless claim for payment'. The definition of 'paperless claim for payment' and 'supply certification form' in subregulation 5(1) (repealed by items 7 and 14), and subregulation 5(4), were used for residential medication chart prescriptions (NRMC) only. Subregulation 5(4) is no longer as under associated consequential amendments to the claiming and under PBS co-payment data rules made under sections 98AC and 99AAA of the Act ('the claims rules') an electronic supply certification system is enabled on and from 1 April 2015 for all prescriptions including medication chart prescriptions.

16 Paragraph 5A(a)
Item 16 amends regulation 5A (Preparing electronic prescriptions) of the Principal Regulations to include a reference to subregulation 19AA(5), which is the Secretary's power to approve one or more forms for the purpose of writing a medication chart prescription, including for writing an electronic prescription.

17 and 18 Regulation 5D
Items 17 and 18 amend regulation 5D (Requirement to give a prescription) of the Principal Regulations, relating to 'electronic prescriptions', to refer to 'approved supplier' a defined term in the Act which includes all three kinds of suppliers approved to supply on the PBS – an approved pharmacist, an approved hospital authority, and an approved medical practitioner (dispensing doctor).

19 to 21 Paragraphs 5E(c), (d) and (e)
Items 19 to 21 amend regulation 5E (Approval of kinds of electronic communication) of the Principal Regulations, to refer to 'approved supplier', update a cross-reference to regulation 13, and include a reference to sections 93AA and 93AB of the Act relating to prescriber bag supplies by authorised nurse practitioners and midwives.

22 and 23 Paragraphs 5F(c) and (d)
Items 22 and 23 amend regulation 5F (Approval of information technology requirements) of the Principal Regulations to refer to 'approved supplier', and include a reference to sections 93AA and 93AB of the Act relating to prescriber bag supplies by authorised nurse practitioners and midwives.

24 to 38 Regulation 13
Items 24 to 38 amend regulation 13 of the Principal Regulations which is made for subsection 85A(3) of the Act, permitting the regulations to make provision authorizing variation of application of the determined maximum quantity or repeats under paragraph 85A(2)(a) or (b) of the Act.

The amendments provide for a procedure for obtaining written, telephone or electronic authorisation to increase the determined maximum quantity or repeats for a medication chart prescription for a pharmaceutical benefit for a person who is receiving treatment in or at an approved hospital. If a telephone or electronic authority is obtained for a medication chart prescription, an authority approval number is to be issued.

Regulation 13 increased maximum quantities and repeats are not available for a NRMC medication chart prescription, and this continues to be the case.

39 Regulation 18
Item 39 substitutes a new regulation 18 (Prescriber bag supplies – payment for pharmaceutical benefits), made for the purpose of subsections 93(3), 93AA(4) and 93AB(4) of the Act, to simplify drafting by including the content of the determination currently made under regulation 18 in regulation 18 itself.

40 to 47 Regulation 18A
Items 40 to 47 amend regulation 18A (Benefits obtained by approved medical practitioners for the purposes of section 93 of the Act) of the Principal Regulations, which relates to prescriber bag supplies by an approved medical practitioner (dispensing doctor), to reflect the introduction, through amendments to the claims rules, of electronic supply certification for PBS claims, and the associated removal of the requirement to provide the prescription as part of the PBS claim (unless the claim is made using the manual system).

Consistent with this change, the prescriber bag forms under regulation 16, and under regulation 18 for a dispensing doctor, will continue to be completed, but will no longer be provided as part of the PBS claim (unless made using the manual system). The regulation 18A form must be retained for two years, consistent with the requirement for

approved suppliers to retain prescriptions previously sent to the Commonwealth as part of the claim for two years.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of $2000 (which converts to $3400, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offences in regulation 18A remains at 0.2 penalty units, which is currently $34 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offences in subregulations 18A(1), (2), (3) and (5) 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) using a regulation 16 order (subregulation 18A(1));
- obtaining a pharmaceutical benefit for the purpose of section 93 (prescriber bag supply) more than once each month (subregulation 18A(2));
- failing to give notice of obtaining the benefit when making a PBS claim using the manual system (subregulation 18A(3)); 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 (subregulation 18A(5)).

It is considered appropriate to insert strict liability offences in subregulations 18A(5A) and (5C) to deter approved medical practitioners from:

- if a CTS claim is made, failing to create a written record of having obtained the benefit as soon as practicable after obtaining it (subregulation 18A(5A)); or
- failing to retain the record for at least two years from the date it was created (subregulation 18A(5C)).

Regulation 18A continues to be consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

48 After regulation 18B

Item 48 inserts regulation 18C which states that prescriptions for the supply of a pharmaceutical benefit must be written in accordance with regulation 19 or regulation 19AA (medication chart prescriptions).

49 Regulation 19 (heading)

Item 49 substitutes a new heading to regulation 19 'Writing prescriptions – prescriptions other than medication chart prescriptions'.

50 to 52 Regulation 19

Items 50 to 52 are minor drafting simplifications to remove cross-references to regulation 19AA from regulation 19 of the Principal Regulations, and to reflect that an authority approval number could be issued by the Minister (under regulation 13) or by the Chief Executive Medicare.

53 Regulation 19AA

Item 53 amends regulation 19AA of the Principal Regulations, including changing the heading to 'Writing prescriptions – medication chart prescriptions'.

The amendment to regulation 19AA:

- retains the ability for a medication chart prescription (NRMC) to be used for a person receiving treatment in or at a residential care service at which the person is receiving residential care (ie residential aged care facility);
- adds an ability for PBS prescribers to use a medication chart prescription for a person receiving treatment in or at an approved hospital;
- relies on the same PBS legal requirements for the prescribing/dispensing method as used for the NRMC, with the period of validity of each medication chart prescription in the NRMC remaining at no more than four months, and the PBS prescriber setting the period of validity of each medication chart prescription in the HMC at either no more than one, four or twelve months;
- includes some detail currently appearing in the subsection 93A determination for the NRMC in the regulations, for example, the pharmaceutical benefit must not be mentioned in Schedule 8 to the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989*; and
- requires the medication chart prescription to be in one or more 'approved forms', which will be publicly available via the ACSQHC website.

54 Subregulation 21(1A)

Item 54 amends regulation 21 (Supply of pharmaceutical benefit on first presentation of prescription) of the Principal Regulations, to remove a reference to subsection 93A(4) of the Act when it is indicated that regulation 21 does not apply to medication chart prescriptions.

55 to 69 Regulation 21A

Items 55 to 69 amend regulation 21A (Supply of pharmaceutical benefits on basis of medication chart prescription) of the Principal Regulations.

The amendments:

- continue to provide that an approved pharmacist or approved medical practitioner (dispensing doctor) can supply pharmaceutical benefits from a medication chart prescription for the NRMC;
- provide that an approved pharmacist or approved hospital authority (ie, approved hospital) can supply pharmaceutical benefits from a medication chart prescription for a HMC;
- provide for the period of validity of a medication chart for a person receiving treatment in or at a hospital (linked to the PBS prescriber choosing one, four or twelve months as for regulation 19AA);
- provide that the approved supplier must see either the medication chart, or, a copy of the relevant portions of the medication chart; and
- make drafting amendments associated with the above, for example, removing section 93A references, removing references to 'residential', and referring to 'approved supplier'.

70 Subregulation 21B(2)

Item 70 is a minor drafting change to subregulation 21B(2) of the Principal Regulations to refer to 'a repeat' and not 'the repeat'.

71 to 73 Regulation 21C
Items 71 to 73 are minor drafting simplifications to regulation 21C (Information about status of persons – continued dispensing and medication chart prescriptions) of the Principal Regulations, and remove a reference to subsection 93A(4) of the Act while continuing to provide that regulation 21C applies for medication chart prescriptions.

74 to 79 Regulation 22
Items 74 to 79 are minor drafting simplifications to regulation 22 (Supply of pharmaceutical benefits before surrender of written prescription) of the Principal Regulations, and remove a reference to subsection 93A(4) of the Act while continuing to provide that regulation 22 does not apply for medication chart prescriptions.

80 Subregulation 25(6)
Item 80 makes minor drafting simplifications to regulation 25 (Repeated supplies of pharmaceutical benefits) of the Principal Regulations, removing a reference to subsection 93A(4) of the Act, while continuing to provide that regulation 25 applies the four/twenty day rule in regulation 25 for medication chart prescriptions, with the usual ability to provide for 'immediate supply necessary' when appropriate.

81 Subregulation 26(1AA)
Item 81 amends regulation 26 (Repeat authorisations) of the Principal Regulations to remove a reference to subsection 93A(4) of the Act while continuing to provide that regulation 26 does not apply for medication chart prescriptions. This means that a repeat authorisation form is not used for medication chart prescriptions.

82 Regulation 26AA
Item 82 repeals regulation 26AA (Repeat authorisation form – continued dispensing) of the Principal Regulations as the repeat authorisation form will no longer be sent to the Australian Government as part of the PBS claim. The approved pharmacist is still required to complete the repeat authorisation form for continued dispensing as required by regulation 21B.

83 Subregulation 26A(1A)
Item 83 amends regulation 26A (Deferred supply authorisations) by removing a reference to subsection 93A(4) of the Act while continuing to provide that regulation 26A does not apply for medication chart prescriptions. This means that a deferred supply authorisation form is not used for medication chart prescriptions.

84 to 90 Regulation 31
Items 84 to 90 amend regulation 31 (Receipt of pharmaceutical benefit) of the Principal Regulations.

Items 84 and 88 amend subregulations 31(1) and 31(3) to exclude medication chart prescriptions from the requirement for the patient or agent to acknowledge receipt on the prescription, or, alternatively, the approved supplier to certify on the prescription that it was not reasonably practicable to obtain the patient or agent acknowledgement of receipt. The phrase 'paperless claim for payment' is removed from subregulations 31(1) and 31(3).

Items 84 and 88 also reflect, and item 90 reflects, the introduction, through amendments to the claims rules commencing on 1 April 2015, of electronic supply certification for PBS claims, and the associated removal of the requirement to provide the prescription as part of the PBS claim (unless the claim is made using the manual system). Essentially, a 'paperless claim for payment' will become the rule rather than the exception to the rule.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of $2000 (which converts to $3400, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offences in regulation 31 remains at 0.2 penalty units, which is currently $34 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offences in subregulations 31(1), (1B), (2), (3), (5) and (6) as strict liability offences is considered appropriate to:

- deter patients and their agents from failing to provide the appropriate acknowledgement of receipt of the pharmaceutical benefit (subregulation 31(1), or subregulation 31(5) for continued dispensing);
- deter an approved supplier from failing, when required, to record the acknowledgement on the electronic prescription (subregulation 31(1B));
- deter an approved supplier from inappropriately demanding an acknowledgement if pharmaceutical benefit not supplied (subregulation 21(2)); or
- deter an approved supplier from failing to provide the required certification that it was not reasonably practicable to obtain the patient or agent acknowledgement of receipt (subregulation 21(3), or subregulation 31(6) for continued dispensing).

The current subregulation 31(4) offence relating to paperless claims for payment and supply certification is repealed. The claims rules require the electronic supply certification as part of the PBS claim. The offences in the *Criminal Code* may then apply.

The claims rules require as part of the electronic procedures for CTS claiming that a warning be provided to approved suppliers, when asked to give their electronic supply certification, that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*. Section 137.1 of the *Criminal Code* has a penalty of imprisonment for twelve months.

Regulation 31 continues to be consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

Items 85 to 87, and item 89, simplify the drafting in regulation 31.

91 Regulation 32 (heading)

Item 91 substitutes a new heading to regulation 32 'Keeping documents – other than for continued dispensing or medication chart prescriptions'.

92 to 93 Regulation 32

Items 92 to 93 amend regulation 32 of the Principal Regulations to reflect the introduction, through amendments to the claims rules, of electronic supply certification for PBS claims, and the associated removal of the requirement to provide the prescription as part of the PBS claim (unless the claim is made using the manual system). The amendments require the documents previously sent to the Commonwealth as part of the claim to be retained. The retention requirement is also adjusted from one to two years.

The amendments also apply to regulation 16 prescriber bag order forms.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of $2000 (which converts to $3400, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offence in regulation 32 remains at 0.2 penalty units, which is currently $34 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offence in subregulation 32(1) as a strict liability offence is considered appropriate to deter approved suppliers from failing to retain the required prescription documents. It is considered appropriate to increase the period for keeping the documents from one year to two years to reflect the fact that the prescription is no longer provided to the Australian Government with the PBS claim. The increase to two years retention is consistent with NRMC medication chart prescriptions (regulation 32B) which are currently kept for two years and not provided to the Australian Government as part of the PBS claim.

Regulation 32 continues to be consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

94 to 96 Regulation 32A

Items 94 to 96 amend regulation 32A (Keeping documents – continued dispensing) of the Principal Regulations to require an approved pharmacist to keep the repeat authorisation form for a continued dispense for two years, as this document is no longer to be sent to the Commonwealth as part of the PBS claim.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of $2000 (which converts to $3400, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offence in regulation 32A remains at 0.2 penalty units, which is currently $34 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offence in regulation 32A as a strict liability offence is considered appropriate to deter approved suppliers from failing to retain the required documents.

Regulation 32A continues to be consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

97 Subregulations 32B(1) and (2)

Item 97 amends regulation 32B (Keeping documents – medication chart prescription) of the Principal Regulations, to remove a reference to subsection 93A(4) of the Act and provide for the approved supplier to keep the medication chart, or a copy of the medication chart (whichever was completed by the supplier) for two years from the date of supply of the pharmaceutical benefit.

Section 140 of the Act permits penalties for offences against the regulations provided that the penalty does not exceed a fine of $2000 (which converts to $3400, sections 4AA and 4AB, *Crimes Act 1914*). The penalty for the strict liability offence in regulation 32B remains at 0.2 penalty units, which is currently $34 for an individual (section 4AA, *Crimes Act 1914*).

Retaining the offence in regulation 32B as a strict liability offence is considered appropriate to deter approved suppliers from failing to retain the required documents.

Regulation 32B continues to be consistent with the Attorney-General's Department publication *A Guide to Framing Commonwealth Offences, Infringement notices and Enforcement Powers*.

98 to 100 Regulation 36

Items 98 to 100 amend regulation 36 (Labelling of pharmaceutical benefits – full cost) of the Principal Regulations, by removing reference to subsection 93A(4) of the Act, while continuing to provide that regulation 36 does not apply for medication chart prescriptions. Minor drafting amendments simplifying the reference to special patient contribution are also included.

101 Regulation 37AA

Item 101 repeals regulation 37AA of the Principal Regulations, relating to the NRMC relying on section 93A of the Act.

Part 2 – Application and transitional provisions
National Health (Pharmaceutical Benefits) Regulations 1960

102 At the end of Part 8

Item 102 inserts Division 4 into Part 8 (Transitional provisions) of the Principal Regulations.

Regulation 57

Regulation 57 provides that, except as set out in Division 4, the amendments made by Part 1 of Schedule 1 of the regulation apply in relation to a prescription written on or after 1 April 2015.

Regulation 58

Regulation 58 saves a provision to assist transition by state and territory jurisdictions needing time to update poisons law subordinate legislation references to the old legal pathway relying on section 93A of the Act for the NRMC. The previous section 93A legal pathway for NRMC medication chart prescriptions remains open, in addition to the NRMC medication chart prescription legal pathway relying on the regulations, until 1 April 2017.

Subregulation 58(3) excludes regulation 31. This means that even if in a particular state or territory the old section 93A legal pathway was relied upon, on and from 1 April 2015 regulation 31 as amended applies and, together with the claims rules amendments, an approved supplier is permitted to provide an electronic, instead of a paper-based, supply certification.

Regulation 59

Regulation 59 is a transitional provision for medication chart prescriptions for persons receiving treatment in or at an approved hospital, to support paper-based and then electronic trials of the HMC, prior to national release.

The patient must be in or at an approved hospital declared by the Minister under subregulation 59(3) (a trial hospital) if the prescription is written before 1 July 2016, or, the prescription is written on or after 1 July 2016 and before 1 April 2017 and the prescription is also an electronic prescription.

The paper-based trials commence on 1 April 2015. The transitional provision requires at least one declared approved hospital (paragraph 59(1)(b)) or access to the medication chart prescription is not limited to (trial) declared approved hospitals.

Regulation 60
Regulation 60 is an application provision which provides, in effect, when combined with the amendments to the claims rules for commencement 1 April 2015 that:

- electronic supply certification is permitted for approved suppliers on and from 1 April 2015 (together with no longer providing a prescription as part of the PBS claim, unless the manual system is used);
- electronic supply certification is required for approved suppliers on and from 1 July 2015 (together with the prescription no longer being provided with the PBS claim, unless the manual system is used). There is an exceptional circumstances option in the claims rules for the Chief Executive Medicare to set a later date for an approved supplier which ceases 1 April 2017; and
- the application of the increased documentation retention requirements (keeping the documents no longer sent in with the PBS claim, for two years) aligns to when the approved supplier changes over to electronic supply certification.

Regulation 61
Regulation 61 provides that Division 4 is repealed on 1 April 2019.

Schedule 2 – Other amendments
National Health (Pharmaceutical Benefits) Regulations 1960

1 - 3 Regulations 3 and 4, Part 2A and Regulation 37B
Items 1 to 3 repeal regulations 3 and 4, Part 2A and regulation 37B of the Principal Regulations as they are spent and no longer have legal effect.

4 Regulation 48
This item relates to paragraph 140(a) of the Act, and substitutes a new regulation 48 to update 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 2014/08 Remuneration and Allowances for Holders of Part-Time Public Office,* Schedule B, Table B4.

5 and 6 Division 2 of Part 8, and Schedules 3, 5, and 9
Items 5 and 6 repeal Division 2 of Part 8, and Schedules 3, 5, and 9 of the Principal Regulations as they are spent and no longer have legal effect.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015

This regulation 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 regulation
The purpose of this regulation, made under section 140 of the *National Health Act 1953* (the Act), is to amend the *National Health (Pharmaceutical Benefits) Regulations 1960*.

The regulation provides for hospital medication chart prescriptions to be used for prescribing, dispensing and claiming for supply of pharmaceutical benefits (medicines), without the need to produce a separate prescription for Pharmaceutical Benefits Scheme (PBS) purposes. This improves workflow for health professionals, as a duplication burden is removed, and the risk of transcription error is reduced.

The regulation provides for trial access initially, for paper-based hospital medication charts until 1 July 2016, and for electronic hospital medication charts until 1 April 2017. This is to allow for testing to identify any further improvements that can be made. The measure is aligned with standardised hospital medication charts produced by the Australian Commission on Safety and Quality in Health Care, and builds on existing medication chart prescriptions for persons at a residential aged care facility.

The regulation implements the PBS Medication Charts for Public and Private Hospitals measure, announced by the Australian Government as part of the 2014-15 Budget.

The regulation also assists with streamlined payment of claims submitted electronically by all approved suppliers of pharmaceutical benefits (ie, pharmacists, hospitals, dispensing doctors). Approved suppliers will no longer be required to send in prescriptions as part of their PBS/RPBS claim, instead providing an electronic supply certification, and keeping prescription documents previously provided to the Commonwealth for two years.

Human rights implications
This regulation engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS assists with advancement of these human rights by providing for subsidised access to medicines. The amendments made by the regulation are a positive step towards attaining the highest standard of health for all Australians. Increased efficiencies from the use of hospital medication charts for PBS purposes, and removing the requirement to provide a prescription with a claim, assist to reduce duplication and improve workflow for health professionals. This in turn can assist health professionals to achieve improved health outcomes for patients.

Conclusion
This regulation is compatible with human rights because it advances the protection of human rights.

Sussan Ley
Minister for Health