

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH (REMOTE AREA ABORIGINAL HEALTH SERVICES
PROGRAM) SPECIAL ARRANGEMENT 2017
PB 107 of 2017

Authority

This instrument is made under section 100 of the *National Health Act 1953* (the Act). Subsection 100(1) of the Act enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

Purpose

This purpose of the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (the instrument) is to revoke and remake the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (the previous instrument) to introduce changes to allow the Department of Human Services (Human Services) to process and pay claims for the section 100 Remote Area Aboriginal Health Services (RAAHS) Patient Specific Medicine Supply Fee (PSMSF) from 1 January 2018.

The previous instrument enabled Pharmaceutical Benefits Scheme (PBS) pharmaceutical benefits to be ordered by an approved Aboriginal health service from an approved pharmacist or approved hospital authority on a bulk basis for supply to patients of the service without the need for a prescription. The instrument continues to enable this special arrangement for the bulk supply of pharmaceutical benefits to Aboriginal health services in remote areas. The instrument also enables approved Aboriginal health services to submit orders for medicines labelled for individual patients as requested using a remote area Aboriginal health service prescription.

From 1 January 2018 approved pharmacists and approved hospital authorities will submit claims for the section 100 RAAHS PSMSF to Human Services for processing using an updated version of the form PB042 which is currently used to claim the section 100 RAAHS bulk supply fee.

The instrument sets out:

- the eligibility requirements and the process for an Aboriginal health service to be approved to participate in the section 100 RAAHS program;
- how an approved Aboriginal health service orders supplies of eligible pharmaceutical benefits for its patients;
- how approved pharmacists and approved hospital authorities claim the fees associated with supplying eligible pharmaceutical benefits to approved Aboriginal health services; and
- the requirement that patients must not be charged any fees in respect of the supply of pharmaceutical benefits supplied to approved Aboriginal health services under this arrangement.

Further details of the instrument are set out in the Attachment.

Consultations

Human Services was consulted in regards to the development of the instrument, including in relation to defining the administration arrangements for payment of both the section 100 bulk handling fee and the section 100 RAAHS PSMSF for supply to approved Aboriginal health services of pharmaceutical benefits prepared and labelled in accordance with a remote area Aboriginal health service prescription.

The Pharmacy Guild of Australia (the Guild) was responsible for the administration of the section 100 RAAHS PSMSF from 1 January 2017 until 31 December 2017 as an interim arrangement. As part of the 2017-2018 Budget process Government agreed for Human Services to implement an ongoing process for payment to approved pharmacists and approved hospital authorities of the section 100 RAAHS PSMSF. Human Services already had the responsibility for administration and payment of the section 100 bulk handling fee. The Guild was consulted in relation to transition of the administration of the section 100 RAAHS PSMSF to Human Services.

Human Services and the Guild have both developed respective communications material, in consultation with the Department of Health, to advise approved pharmacists and approved hospital authorities of the changes made by the instrument.

The instrument commences on 1 January 2018.

The instrument is a legislative instrument for the purpose of the *Legislation Act 2003*.

ATTACHMENT

NATIONAL HEALTH (REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM) SPECIAL ARRANGEMENT 2017

Part 1 – Preliminary

Section 1 – Name

This section provides that the name of this instrument is the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (the instrument). It may also be cited as PB 107 of 2107.

Section 2 – Commencement

This section provides that the instrument commences on 1 January 2018.

Section 3 – Authority

This section provides that the instrument is made under section 100 of the *National Health Act 1953*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned. It also provides that any other item in a Schedule to the instrument has effect according to its terms. The *National Health (Remote Aboriginal Health Services Program) Special Arrangements 2010* is repealed, in its entirety, by Schedule 1 of the instrument.

Section 5 – Simplified outline of this instrument

This section sets out a simplified outline of the instrument. It explains that Aboriginal health services may be approved by the Secretary of the Department of Health (the Health Secretary) to participate in the special arrangements established by the instrument. It also explains that payment may be made to approved pharmacists or approved hospital authorities that supply pharmaceutical benefits under the special arrangements to approved Aboriginal health services. The section also outlines the different manner in which pharmaceutical benefits must be supplied under the special arrangement.

Section 6 – Definitions

This section defines certain terms used in the instrument.

An ‘eligible pharmaceutical benefit’ is any ready-prepared pharmaceutical benefit,

other than a benefit that:

- can only be supplied under the PBS under another special arrangement made under section 100 of the *National Health Act 1953* (the Act);
- can only be supplied under the PBS under the prescriber bag provisions; or
- is referred to in Schedule 8 to the current Poisons Standard, being the latest document prepared under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989*. The current Poisons Standard is available at the Federal Register of Legislation at www.legislation.gov.au.

A ‘ready-prepared pharmaceutical benefit’ is a brand of pharmaceutical benefit determined under subsection 85(6) of the Act.

A ‘remote zone’ has the meaning given by the *Rural, Remote and Metropolitan Area Classification, 1991 Census Edition*, published by the Departments of Primary Industries and Energy and Human Services and Health, as in force in November 1994. The document is available for free on the Productivity Commission website at <http://www.pc.gov.au/inquiries/completed/nursing-home-subsidies/submissions/subdr096/subdr096.pdf>.

A number of terms used in the instrument have the same meaning as in the Act, as in force from time to time, including ‘approved hospital authority’, ‘approved pharmacist’, ‘medicare number’ and ‘PBS prescriber’.

Section 7 – Purpose of this instrument

This section explains that the purpose of the instrument is to make a special arrangement providing that an adequate supply of pharmaceutical benefits will be available to persons who live in isolated areas.

Part 2 – Approval of Aboriginal health services

Section 8 – Applications for approval of Aboriginal health Services

This section sets out that an Aboriginal health service can apply for approval to supply pharmaceutical benefits under the instrument.

Subsection 8(1) provides that an Aboriginal health service may apply to the Health Secretary to be approved. Subsection 8(2) specifies that such an application must be made in writing, and in the form (if any) approved by the Health Secretary. Subsection 8(3) gives the Health Secretary the authority to approve, in writing, a form in which the application must be made.

Section 9 – Approval of Aboriginal health services

This section sets out the procedures for considering and approving applications made under section 8.

Subsection 9(1) requires the Health Secretary to approve an application if satisfied the conditions in subsection 9(2) are met. An approval must be notified in writing to the applicant Aboriginal health service and the Chief Executive of Medicare must also be

notified in writing. If the Health Secretary is not satisfied the conditions in subsection 9(2) are met, the Health Secretary must refuse the application by notice in writing to the applicant Aboriginal health service.

Subsection 9(2) sets out the conditions that the Health Secretary must be satisfied of in order to approve an application. These conditions include:

- the Aboriginal health service has a primary function of meeting the health care needs of Aboriginal and Torres Strait Islander people (paragraph 9(2)(a));
- each clinic or health care facility operated by the Aboriginal health service is in a remote zone (paragraph 9(2)(b));
- the Aboriginal health service is not an approved pharmacist or an approved hospital authority - this is to ensure that an approved pharmacist or an approved hospital authority is not eligible for payment under these special arrangements for supplying a pharmaceutical benefit to itself (paragraph 9(2)(c));
- at least one of the employees or contractors of the service is qualified under the relevant state or territory law to prescribe all eligible pharmaceutical benefits; and
- if the Aboriginal health service were approved, it would meet certain requirements relating to the safe storage and supply of pharmaceutical benefits (paragraph 9(2)(e)).

Subsection 9(3) specifies, for paragraph 9(2)(e), how an Aboriginal health service must store pharmaceutical benefits. These include that the storage facilities must be secure and maintain the quality of the pharmaceutical benefits.

A decision whether to approve an Aboriginal health service under subsection 9(1) is not subject to external merits review. The Health Secretary has no discretion to refuse to approve an applicant Aboriginal health service Secretary once the Health Secretary is satisfied that the specified conditions are met. The conditions are primarily factual in nature, such as the location of the Aboriginal health service and the prescribing status of employees or contractors to the service.

Section 10 – Registration number

This section provides that once an Aboriginal health service is approved it must be issued with a unique number referred to in this instrument as its registration number. It also provides that the registration number is issued by the Chief Executive Medicare.

Part 3 – Orders for supply of pharmaceutical benefits to Aboriginal health Services

Section 11 – Eligible orders

This section describes the circumstances in which an order for pharmaceutical benefits will be considered to be an eligible order for the purposes of the instrument.

For an order to be considered eligible under this instrument subsection 11(1) requires

it to be made:

- by an approved Aboriginal health service, to an approved pharmacist or an approved hospital authority, for supply directly to the Aboriginal health service; and
- in writing, and in the form (if any) approved by the Chief Executive Medicare.

Subsection 11(2) gives the Chief Executive Medicare the authority to approve, in writing, a form in which the application referred to in subsection 11(1) must be made.

Section 12 – Remote area Aboriginal health service prescriptions

This section defines a ‘remote area Aboriginal health service prescription’ (a RAAHS prescription) and provides the minimum information required in, and who can write, this type of prescription.

The information required in a RAAHS prescription includes:

- the name, address and (if known) medicare number of the patient; and
- such particulars of the pharmaceutical benefit as are necessary to identify that benefit; and
- the required quantity or number of units, the required form and the required strength; and
- the pharmaceutical benefit’s dose, frequency of administration and route of administration; and
- the name and address of the person writing the prescription, the name and registration number of the approved Aboriginal Health service; and
- the date the prescription was written.

Subsection 12(2) provides that to be able to write a RAAHS prescription the person must be:

- a PBS prescriber; and
- an employee or contractor of the Aboriginal health service; and
- qualified under the law of the relevant State or Territory to supply the eligible pharmaceutical benefits.

Subsection 12(3) enables the Health Secretary to approve a form for RAAHS prescriptions. If the Health Secretary approves a form under subsection 12(3), a RAAHS prescription must be made using the approved form.

Part 4 – Payments for supply of pharmaceutical benefits to Aboriginal health Services

Section 13 – When a pharmaceutical benefit is supplied under this special arrangement

This section sets out the circumstances in which an eligible pharmaceutical benefit is considered to have been supplied by an approved pharmacist or an approved hospital

authority under the special arrangement for the purposes of a claim for payment.

For an order to be considered to have been supplied under this special arrangement subsection 13(1) requires it to have been supplied under the following circumstances:

- by an approved pharmacist or an approved hospital authority; and
- in response to an eligible order made by an approved Aboriginal health service; and
- directly to the approved Aboriginal health service; and
- in a pack quantity; and
- as part of a bulk supply to the Aboriginal health service or as provided for an individual patient as requested using a remote area Aboriginal health service prescription.

Subsection 13(2) provides that the supply of pharmaceutical benefits for an individual patient must be prepared and labelled in accordance with the remote area Aboriginal health service prescription.

Section 14 – Payments for supply of pharmaceutical benefits to Aboriginal health services

Subsection 14(1) establishes the entitlement of an approved pharmacist or approved hospital authority to be paid by the Commonwealth for supplying a pack quantity of a pharmaceutical benefit to an approved Aboriginal health service under the special arrangements established by the instrument. It also specifies that the amount of payment will be calculated in accordance with section 15 of the instrument.

Subsection 14(2) provides that a reference to payment in relation to the supply of pharmaceutical benefit in Part VII of the Act includes a reference to payment under subsection 14(1). This provision is for the avoidance of doubt.

Section 15 – Amount of payments

This section describes the components that make up the amount to be paid to approved pharmacists or approved hospital authorities under section 14 for supply of eligible pharmaceutical benefits to approved Aboriginal health services.

Subsection 15(1) provides that for each PBS medicine supplied in bulk to an approved Aboriginal health service an approved pharmacist or approved hospital authority is entitled to the following:

- the price to pharmacists for the pack quantity quantity (worked out in accordance with the determination that is in force under paragraph 98B(1)(a) of the Act at the time of the supply of the pharmaceutical benefit); and
- an amount equal to the administration, handling and infrastructure fee for the pack quantity (worked out in accordance with that determination); and
- a handling fee of \$3.

If pharmaceutical benefits have been supplied to an approved Aboriginal health service in response to a RAAHS prescription then an approved pharmacist or

approved hospital is also entitled to the section 100 RAAHS PSMSF of \$4.67.

Subsection 15(2) makes clear that no additional amount for the cost of transportation or cold chain maintenance is payable to an approved pharmacist or approved hospital authority.

Section 16 – Claims for payments

This section sets out how an approved pharmacist or approved hospital authority must claim for the payment for supply of eligible pharmaceutical benefits under this instrument. Subsections 16(1) and (2) provide that a claim must be made to the Chief Executive Medicare, in writing, and using the approved form, if such a form has been approved.

Subsection 16(3) provides that the Chief Executive Medicare may, in writing, approve a form for claims.

Subsection 16(4) provides that subsections 99AAA(2), (4) and (5) of the Act do not apply in relation to the claim for payment. This means that the approved pharmacist or approved hospital authority does not need to follow the claiming rules determined under subsection 99AAA(8) of the Act, or use the standard PBS manual system or Claims Transmission System or to submit a claim for payment.

Part 5 – Miscellaneous

Section 17 – No charge for supply of eligible pharmaceutical benefits by approved Aboriginal health services

This section provides that an Aboriginal health service must not demand or receive payment for a pharmaceutical benefit supplied under the special arrangements established by the instrument.

Section 18 – Modified application of conditions of approval for approved pharmacists

Section 18 provides that subsection 9(3) of the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* (PB 70 of 2017) (Conditions of Approval Determination) does not apply to the supply of pharmaceutical benefits to an approved Aboriginal health service under this instrument.

Subsection 9(3) of the Conditions of Approval Determination provides that an approved pharmacist can only make a claim in relation to the supply of pharmaceutical benefits under the PBS if the pharmacist, or agent of the pharmacist, was present at the time the benefit was dispensed.

This instrument establishes special arrangements to facilitate the supply of pharmaceutical benefits to patients in isolated areas who find it difficult to physically access an approved pharmacist. Under these arrangements, eligible pharmaceutical benefits are supplied by approved pharmacists to approved Aboriginal health services,

for dispensing by the health service, and so the requirement in subsection 9(3) of the Conditions of Approval Determination would not be able to be met.

Part 6 – Transitional provisions

Section 19 – Previously registered Aboriginal health services

Section 19 provides transitional arrangements for Aboriginal health services that were approved under the previous instrument.

Subsection 19(1) provides that Aboriginal health services that were approved under the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* are taken to have been approved for the purpose of the instrument.

Subsection 19(2) provides for approval numbers previously allocated under the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* to be taken to have been allocated under section 10 of the instrument.

Schedule 1 – Repeals

This schedule repeals the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010*.

Statement of Compatibility with Human Rights

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

NATIONAL HEALTH (REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM) SPECIAL ARRANGEMENT 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

This purpose of this legislative instrument is to revoke and remake the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (the previous instrument) to introduce changes to allow the Department of Human Services (Human Services) to process and pay claims for the section 100 Remote Area Aboriginal Health Services (RAAHS) Patient Specific Medicine Supply Fee (PSMSF) from 1 January 2018. The Pharmacy Guild of Australia previously paid the RAAHS PSMSF under interim arrangements.

The previous instrument enabled Pharmaceutical Benefits Scheme (PBS) pharmaceutical benefits to be ordered by an Aboriginal health service from an approved pharmacist or approved hospital authority on a bulk basis for supply to patients of the service. This legislative instrument continues to enable a special arrangement for the bulk supply of pharmaceutical benefits to Aboriginal health services in remote areas. It also enables approved Aboriginal health services to submit orders for medicines labelled for individual patients, and provides for a Commonwealth subsidy to be payable where this occurs.

Human rights implications

This legislative instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 this human right by providing access by patients to subsidized medicines. The special arrangement established by this instrument ensures more ready and equitable access to PBS medicines for Indigenous Australians through the section 100 Remote Area Aboriginal Health Services (RAAHS) Program. This addresses three identified barriers that Aboriginal and Torres Strait Islander people living in remote communities experience in accessing essential medicines, being geographical, cultural and financial.

The extension of the scope of the RAAHS Program to enable pharmaceutical benefits to be ordered for specific individuals will ensure that patients are receiving appropriate medicines for their medical condition and will promote increased medication adherence and quality use of medicines.

Finally, the legislative instrument provides legal authority for Human Services to pay claims for the section 100 RAAHS PSMSF.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

Julianne Quaine
Assistant Secretary
Private Health Insurance and Pharmacy Branch
Technology Assessment and Access Division
Department of Health