1987

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA HOUSE OF REPRESENTATIVES

NATIONAL HEALTH AMENDMENT BILL (NO. 2) 1987

EXPLANATORY MEMORANDUM

(CIRCULATED BY AUTHORITY OF THE MINISTER FOR COMMUNITY SERVICES AND HEALTH THE HON NEAL BLEWETT MP)

NATIONAL HEALTH AMENDMENT BILL (No. 2) 1987

OUTLINE

The purposes of this Bill are -

- (a) to improve the efficiency of the system by which the Commonwealth pays pharmacists and medical practitioners for the supply of pharmaceutical benefits by introducing a new alternative method of calculating the amount payable;
- (b) to provide for the payment of a financial incentive to pharmacists and other approved persons to encourage the use of this new alternative method;
- (c) to provide for the payment of a financial incentive to pharmacists and other approved persons to encourage the making of claims for payment through electronic forms;
- (d) to tighten procedures for listing new drugs as Pharmaceutical Benefits and encourage a reduction in the prescribing of expensive drugs where more cost-effective alternatives are available;

- (e) to allow for an increase in membership of the Pharmaceutical Benefits Advisory Committee;
- (f) to provide for the establishment of specialist sub-committees of the Pharmaceutical Benefits Advisory Committee;
- (g) to empower the Minister to remove, at his own discretion, a drug from the Pharmaceutical Benefits Scheme list; and
- (h) to make consequential and other minor amendments to the <u>National Health Act 1953</u>.

The Bill follows the report of a review of the system by which payments are made for the supply of pharmaceutical benefits. The system, known as "Pharmpay" and operated by the Department of Community Services and Health, currently relies upon the assessment of every individual prescription which is provided by an approved pharmacist (or an approved medical practitioner or an approved hospital authority) as proof that a pharmaceutical benefit has been supplied. Although it is possible for this assessment to be made by the presentation of electronic data, the majority of claims for payment are submitted on paper and assessed manually.

In order to improve the efficiency of the Pharmpay system, and to reduce the physical assessment, administrative delay and time taken to make payments, the Bill will authorise the calculation of amounts payable by the application of estimates derived from the sampling of prescriptions. This alternative method will be used if the pharmacist agrees to its use, and will be subject to rules made by the Minister, tabled in Parliament and subject to disallowance.

Because it cannot be guaranteed that use of this sampling method will provide precisely the same financial return as the current assessment method, the Bill will authorise the payment of financial incentives to pharmacists who elect to use the sampling method.

The Bill will also authorise the payment of financial incentives to pharmacists who made claims for payment using the current assessment method, but who make the claim in electronic form.

The Bill will make consequential amendments to the National Health Act 1953 which reflect the introduction of the sampling method. The areas affected are interpretation provisions and provisions authorising the recovery of unauthorised payments. The Bill will make a further amendment to those latter provisions as part of the standardisation of different provisions in the Act.

The Bill will also amend the National Health Act 1953 to tighten procedures followed in the process of listing new drugs as Pharmaceutical Benefits for the purposes of the Act. The Pharmaceutical Benefits Advisory Committee, which recommends to the Minister which drugs should be listed as Pharmaceutical Benefits, will be required, when deciding whether to recommend that a new drug be so listed, to take the relative cost-effectiveness of the drug when compared with other available drugs and therapies into account and to state if recommended drugs or medicinal preparations are more costly that it is satisfied there are advantages in their use for some patients. Such amendments are aimed at discouraging the prescription of expensive drugs where more cost-effective alternatives are available.

The Bill will empower the Minister to remove a drug from the list of Pharmaceutical Benefits at his own discretion without first having received a recommendation to that effect from the Pharmaceutical Benefits Advisory Committee.

The Bill will also provide for an increased membership of the Pharmaceutical Benefits Advisory Committee by allowing the Minister to appoint up to three extra medical practitioners, and provide for the establishment of specialist sub-committees of the above Committee. Such amendments are broadly aimed at allowing the Committee to perform its functions in a more efficient and detailed manner.

FINANCIAL IMPACT STATEMENT

The amendments to the provisions regarding operation of the Pharmaceutical Benefits Advisory Committee require the Committee and the Minister to take account of the effectiveness and costs of therapies when recommending or listing a drug or medicinal preparation. While it is impossible to be precise about the resultant savings, these have been estimated at \$5m in this financial year. This will be offset by the additional expenditure of \$0.5m for additional staffing and consultancies.

The amendments to allow approved suppliers to elect alternative methods of providing information by the computer transmission of claims (CTS) or the alternative payment method will result in operational savings. Incentive payments of 2.5 cents per prescription are being offered in certain circumstances to encourage participation in either scheme.

The savings will depend on the number of approved suppliers participating. If 50% of approved suppliers participate in the CTS and a further 25% elect to have their claims processed by the alternative payment method, the gross operational savings are estimated at \$7m and \$3.5m respectively in a full year. Offsetting these savings would be the incentive payments themselves, amounting to \$1.25m and \$0.6m per annum respectively.

NATIONAL HEALTH AMENDMENT ACT (No 2) 1987

Clause 1 : Short Title

Sub-clause (1) cites the short title of the proposed Act as the National Health Amendment Act (No 2) 1987.

Sub-clause (2) identifies the <u>National Health Act 1953</u> as the Principal Act for the purposes of the Bill.

Clause 2 : Commencement

This clause provides for the dates on which various sections of the Act will come into operation.

Clause 3: Interpretation

This clause will provide definitions of the terms "alternative payment election", "approved supplier" and "pharmaceutical benefits payment rules".

The clause will also set out the circumstances in which an approved supplier will be taken to have made a claim for payment in respect of the supply of pharmaceutical benefits.

Clause 4: Pharmaceutical Benefits

This clause amends section 85 of the Principal Act be inserting sub-sections (2AA) and (2AB). Sub-section (2AA) allows the Minister to declare, by instrument in writing, that a drug or medicinal preparation or class thereof ceases to be a pharmaceutical benefit for the purposes of Part VII of the Principal Act. Sub-section (2AB) requires the Minister to have regard to views previously expressed by the Pharmaceutical Benefits Advisory Committee relating to the drug or medicinal preparation or class thereof before he makes any such declaration.

Paragraph 4(b) of the clause has the effect of applying certain sections of the <u>Acts Interpretation Act 1901</u> to declarations the Minister has made. Declarations made under new sub-section (2AA) must be notified in the gazette, tabled before both Houses of Parliament and made subject to possible disallowance. Provisions already in section 85 of the Principal Act will require that copies of declarations be available for purchase on the date of notification in the Gazette.

Clause 5: Payment for supply of benefits

Section 99 of the Principal Act provides authority for the making of payments in respect of the supply of pharmaceutical benefits where an approved pharmacist has sought payment under

the existing method of assessment. This clause will amend section 99 to limit the application of that section in respect of approved suppliers who have made an election to receive payments under the proposed alternative payment system. Where an approved supplier has made that alternative payment election, the supplier will not be entitled to have payments assessed under the existing method of assessment, nor to receive a payment under the existing method.

Clause 6: Incentive payments to persons providing information by the preferred method

Alternative method of payments - payments in accordance with

the pharmaceutical benefits payment rules

Elections to have alternative method of payment apply

Clause 6 inserts new sections 99AAA, 99AAB and 99AAC into the Principal Act.

Section 99AAA

Proposed section 99AAA will entitle an approved supplier to a payment of an incentive payment where that person has supplied a pharmaceutical benefit and has then used the "preferred manner" to make a claim for payment under section 99.

Pursuant to proposed subsection 99AAA(4) the Minister will be required to make rules ("the information provision incentive payment rules") which define the "preferred manner". The rules may define a method of providing information, specify the kinds of prescriptions that are eligible for the purposes of the preferred manner, specify the period for which the incentive payment is payable, and may also include any other provisions relating to entitlement to payment of the incentive as the Minister thinks necessary. The rules, and any variation or revocation of the rules must be published in the Gazette, and be laid before the Parliament within 15 sitting days after the making, variation or revocation of the rules. The rules, variations or revocations will be disallowable by the Parliament.

The incentive payment is the amount of 2.5 cents per eligible benefit. The Commonwealth may aggregate the incentive payments to which an approved supplier is entitled during a claim period. Where the aggregated amount payable includes a fraction of a cent, provision is made for the amount to be increased to the nearest whole cent.

Section 99AAB

Proposed section 99AAB will introduce an alternative method of payment by the Commonwealth to an approved supplier in respect of the supply of a pharmaceutical benefit.

The use of the alternative method of payment will be by election, provided for in new section 99AAC.

Pursuant to proposed subsection 99AAB(3), the Minister will be required to make rules ("the pharmaceutical benefits payment rules") relating to the alternative method of payment. The rules may define a method for the calculation of the amounts payable by the Commonwealth to approved suppliers who have elected to be paid by the alternative method, for the cancellation or suspension of an election, and may also include any other provisions relating to entitlement to payment as the Minister thinks necessary.

The method of calculation set out in the rules will not need to be based on amounts payable for individual pharmaceutical benefits, but may be based on estimates calculated by the use of sampling techniques. The rules must make provision for the payment of an amount which is payable because the approved supplier has made an election to be paid by an alternative method.

The rules will be required to be published in the Gazette, and be laid before the Parliament within 15 sitting days after the making of the rules. The rules will be disallowable by the Parliament.

Section 99AAC

Proposed section 99AAC will provide for the manner in which an approved supplier may make an alternative payment election. The proposed section will deal with:

- (a) the form in which the election will be made;
- (b) the circumstances in which the election will cease to be in force;
- (c) the revocation of the election by the approved supplier;
- (d) the effect of the suspension of the election by the Secretary; and
- (e) the time at which an approved supplier may make a further election after an election has been cancelled by the Secretary, being a time at least 6 months after the cancellation of the election.

Clause 7: Unauthorised payments etc

Proposed section 99AA of the Principal Act will provide authority for the recovery by the Commonwealth of payments made without lawful authority in respect of the supply of pharmaceutical benefits. This clause will amend section 99AA

to provide for the recovery of unauthorised payments made under the proposed alternative payment system:

- (a) Proposed subsection 99AA(1A) will deal with an approved supplier who has received a payment under the existing method of assessment, despite the existence of an alternative payment election. Proposed subsection 99(1A) will not authorise such a payment. Where that person has received an unauthorised payment in this way, the person will be taken to have been paid the amount which would have been payable but for the existence of the alternative payment election.
- (b) Paragraph 99AA(2)(b) of the Principal Act will be amended to include an appropriate cross reference.
- (c) Proposed subsection 99AA(2A) will deal with an approved supplier who has received a payment pursuant to proposed section 99AAB (ie through the proposed alternative payment system). Where the person has provided information for the purpose of calculating the payment, and the person knew, or ought reasonably to have known, that the information was false or misleading in a material particular, and the payment is greater than the person could otherwise have expected, the Secretary will be empowered to seek the recovery of the amount in excess of the amount which the person could otherwise have expected.

- (d) Paragraphs 99AA(3)(a) and 99AA(3)(b) of the Principal Act will be amended to include appropriate cross references.
- (e) Proposed subsection 99AA(4) is identical to the existing subsection 99AB(5) (which deals with advance payments) and is intended to improve administrative efficiency by standardising the Commonwealth's powers to recover unauthorised payments.

Clause 8 : Pharmaceutical Benefits Advisory Committee

This clause amends section 101 of the Principal Act as follows:

Paragraph (1)(a) of this clause substitutes a new sub-section 101(2) which permits the Minister to appoint up to three additional medical practitioners to be members of the Pharmaceutical Benefits Advisory Committee. These members need not be nominated by any medical association or society and are in addition to the six medical practitioners whose appointment is already provided for in the Principal Act.

Paragraph (1)(b) of this clause inserts new sub-sections 101(3A), 101(3B) and 101(3C).

Sub-section 101(3A) requires the Pharmaceutical Benefits

Advisory Committee to consider the effectiveness and cost of
therapy involving the use of any drug or medicinal preparation

or class thereof when deciding whether to recommend to the Minister that that drug, preparation or class should be made available as a pharmaceutical benefit. The Committee, in considering effectiveness and cost must have regard not only to the use of therapies involving other drugs but also to therapies which do not necessarily involve the use of drugs at all.

Sub-section 101(3B) provides that the Pharmaceutical Benefits Advisory Committee shall not recommend to the Minister that a drug, or medicinal preparation or class thereof be made available as a pharmaceutical benefit if therapy involving that particular drug, preparation or class is substantially more costly than other types of therapy including those which do not involve the use of drugs or preparations unless therapy involving the use of that drug or medicinal preparation provides a significant improvement in efficacy or reduction of toxicity over those other therapies for at least some patients. In making a recommendation in these circumstances the Committee must include a statement in its recommendation to the Minister that it is satisfied there are such benefits flowing from therapy using that drug or medicinal preparation.

Sub-section 101(3C) provides that if the Pharmaceutical
Benefits Advisory Committee is of the view that a drug or
medicinal preparation or class thereof should be made available
as a pharmaceutical benefit only in certain circumstances the

Committee shall specify those circumstances in its recommendation to the Minister.

Sub-clause 8(2) provides that persons who are members of the Pharmaceutical Benefits Advisory Committee immediately before these amendments to Section 101 of the Principal Act come into operation continue to be members of that Committee following the coming into operation of these amendments.

Clause 9 : Sub-Committees of the Pharmaceutical Benefits Committee

This clause inserts a new section, section 101A, into the Principal Act to permit sub-committees of the Pharmaceutical Benefits Advisory Committee to be established. Sub-section 101(A)(1) permits the Committee to establish sub-committees to assist it in performing its functions as it thinks fit and permits the Minister to require in writing the Committee to establish a sub-committee to assist the Committee in advising the Minister on a particular matter referred to the Committee by the Minister under his power of referral contained in sub-section 101(3) of the Principal Act.

Sub-section 101(A)(2) provides that a sub-committee will consist of persons appointed by the Committee or nominated by the Minister whether or not they are already members of the Committee.

Sub-section 101A(3) provides that only persons having special qualifications or experience in relation to the matter referred to the sub-committee shall be appointed by the Committee or nominated by the Minister.

Sub-section 101A(4) provides that a sub-committee shall be taken to be a committee established under the Principal Act for the purposes of section 140 of the Principal Act thereby enabling regulations to be made for prescribing fees and allowances payable to members of sub-committees.

Clause 10 : Certain instruments subject to disallowance etc

Section 139B of the Principal Act provides for the <u>Acts</u>

<u>Interpretation Act 1901</u> to apply to certain instruments so that they must be notified in the Gazette, tabled in both Houses of Parliament and made subject to disallowance. The section also applies provisions of the <u>Statutory Rules Publications Act 1903</u> and the <u>Evidence Act 1905</u> to those instruments.

This clause will apply those Acts to:

- (a) the information provision incentive payment rules to be made pursuant to proposed subsection 99AAA(4); and
- (b) the pharmaceutical benefits payment rules to be made pursuant to proposed subsection 99AAB(3).

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