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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

HEALTH LEGISLATION AMENDMENT BILL (NO.2) 1986

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health, the
Hon. Neal Blewett, MP)

HEALTH LEGISLATION AMENDMENT BILL (NO.2) 1986

GENERAL OUTLINE

The purpose of the Bill is to:

1. Amend the Health Insurance Act 1973 to:
 - (a) increase the maximum gap payment between the medicare rebate and the schedule of fees from \$10 to \$20;
 - (b) provide for the deregulation of Commonwealth controls over private hospitals and the abolition of bed day payments to private hospitals;
 - (c) enable the Minister to determine that medicare benefits are to be paid for the treatment of conditions causing facial deformities (in addition to cleft lip and cleft palate conditions) in persons under 22 years of age;
 - (d) amend the secrecy provisions to further limit the permissible disclosure of information under the exceptions to the provisions; and
 - (e) make other minor or consequential amendments.
2. Amend the National Health Act 1953 to:
 - (a) abolish the present Isolated Patients' Travel and Accommodation Assistance Scheme;
 - (b) provide for new arrangements under the Pharmaceutical Benefits Scheme whereby:
 - (i) a safety-net is introduced to protect general and concessional beneficiary patients against excessive costs incurred in purchasing pharmaceutical benefits by providing that no person or family need pay for more than 25 pharmaceutical benefits in any year;
 - (ii) the existing maximum general patient contribution for pharmaceutical benefits is increased from \$5 to \$10;
 - (iii) the existing maximum concessional beneficiary contribution for pharmaceutical benefits is increased from \$2 to \$2.50;

- (iv) certain repatriation beneficiaries are to benefit from the Pharmaceutical Benefits Scheme under the National Health Act; and
 - (v) Commonwealth controls over after hours-fees charged by pharmacists are removed and other requirements upon cessation of business or practice are relaxed;
 - (c) remove the British Pharmacopoeia as the basic list of pharmaceutical items included in the Pharmaceutical Benefits Scheme and substitute it with new arrangements for including and varying items under the Scheme;
 - (d) provide that a basic table offered by a health benefits fund must pay a benefit for a prosthesis provided at a day hospital facility;
 - (e) provide for the prescribing in regulations of diseases in respect of which the Commonwealth may provide free vaccines;
 - (f) revise various provisions to remove sexist terminology; and
 - (g) make certain other minor or consequential amendments.
3. Amend the Therapeutic Goods Act 1966 to:
- (a) empower the Secretary of the Department of Health to require, on a standing basis, information about, and samples of, batches of biological products for therapeutic use produced, or to be produced, in Australia; and
 - (b) enable regulations to be made permitting the inspection of premises where goods for therapeutic use are, or are to be, produced, to ensure that quality, safety and efficacy requirements are also observed.
4. The Bill also makes a number of minor and drafting amendments to other Health legislation. The Bill repeals the Hospitals and Health Services Commission (Repeal) Act 1978.

FINANCIAL IMPACT STATEMENT

Health Insurance Act 1973

The increase in the maximum amount payable for a medicare service will result in savings of \$18 million in 1986/87 and \$29 million in a full year.

The deregulation of private hospitals will result in savings of a \$0.25 million in 1986/87 and \$0.5 million in a full year. The associated abolition of the private hospital subsidy will save \$90 million in 1986/87 and \$143 million in a full year.

National Health Act 1953

Abolition of the Isolated Patients Travel and Accommodation Assistance Scheme will occur on 1 January 1987. \$13.3 million is to be provided in 1986/87 for the remaining life of the Scheme. As part of the 1986/87 Budget, \$10.9 million is to be provided to the States and Territories in the second half of 1986/87 for patient travel.

The changes to the Pharmaceutical Benefits Scheme are expected to result in a savings of \$56.6 million in 1986/87 and \$67 million in 1987/88, after allowing \$73 million for the new safety net arrangements.

It is envisaged that regulations will be made, pursuant to the amendments proposed to section 9B, to provide for a program of hepatitis B immunisation for at-risk babies. The estimated annual cost of such a program is \$2.8 million.

PART I - PRELIMINARY

Clause 1: Short Title

Formal.

Clause 2: Commencement

This clause outlines the commencement dates of various provisions of the Bill.

PART II - AMENDMENTS OF THE HEALTH INSURANCE ACT 1973

Clause 3: Principal Act

This clause identifies the Health Insurance Act 1973 as the Principal Act for the purposes of Part II of the Bill.

Clause 4: Interpretation

This clause makes several amendments to section 3 of the Principal Act.

Sub-clause (1) of this clause omits from sub-section 3(1) of the Principal Act the definition of "approved bed" and substitutes a new definition of "in-patient" which removes references to in-patients of a private hospital as defined for the purposes of provisions in Part III of the Principal Act. These amendments are consequential upon the amendment made in clause 7 and take account of the proposed removal of Commonwealth controls over private hospitals.

Sub-clause (1) also omits the current definition of "private hospital" from sub-section 3(1) and substitutes a new definition of "private hospital" which is also inserted in consequence of the repeals made in clause 7 of the Bill.

The new definition provides for premises regarded as private hospitals on 1 October 1986 to continue within the definition and takes account of the Minister's powers to declare premises as private hospitals under proposed section 23EA.

Sub-clause (2) of this clause omits the current paragraph (d) of the definition of "patient contribution" from sub-section 3(1) and substitutes a new paragraph (d) which removes the reference to amounts set by the Minister for Community Services pursuant to the National Health Act 1953 as the patient contributions for the purposes of the Health Insurance Act 1973 and enables the Minister for Health to specify the amounts that are to be the patient contributions.

Sub-clause (3) of this clause omits the current definition of "prescribed dental patient" from sub-section 3(1) and substitutes a new definition of "prescribed dental patient". The effect of the new definition is to enable the Minister to determine other forms of facial deformities suffered by persons under the age of 22 in respect of which medicare benefit may be payable.

Sub-clause (3) also makes a minor consequential amendment to paragraph (ba) of the definition of "professional service" in sub-section 3(1) of the Principal Act.

Clause 5: Entitlement to medicare benefit

This clause amends section 10 of the Principal Act by omitting "\$10" from paragraph 10(2)(b) and substituting "\$20". The effect of this amendment will be that the maximum difference between the schedule fee for a professional service and the medicare benefit payable in respect of that service will be \$20, instead of the current \$10. Sub-clause (2) of this clause provides that this new maximum difference will only apply in respect of professional services rendered after the commencement of the clause (1 November 1986).

Clause 6: Interpretation

This clause substitutes a new section 23E which omits the references in the Principal Act relating to the interpretation of provisions dealing with the regulation of private hospitals. This amendment is consequent upon the amendments made by clause 7 to remove Commonwealth controls over private hospitals.

The clause also inserts new sections 23EA and 23EB into the Principal Act. While the Bill removes controls over private hospitals, the concept of a 'private hospital' remains necessary in the Act for other purposes (for example, see the definition of "patient contribution" in sub-section 3(1)).

New Section 23EA enables the Minister to declare, in writing, what hospitals are to be private hospitals for the purposes of the Health Insurance Act 1973 and the National Health Act 1953. Pursuant to sub-section 23EA (2), the Minister may also declare, in writing, that certain hospitals having the status of private hospitals before 1 October 1986 will no longer be treated as private hospitals.

New Section 23EB provides for a review by the Administrative Appeals Tribunal of the Minister's decision to refuse to declare a hospital to be a private hospital, to revoke a declaration declaring a hospital to be a private hospital or to revoke, pursuant to sub-section 23EA, the status of a hospital as a private hospital.

Clause 7: Repeal of sections 23H to 38A

This clause omits sections 23H to 38A inclusive from the Principal Act. Those sections place legislative controls on the approval and categorisation of private hospitals and private hospital beds for the purposes of the payment of Commonwealth bed day subsidies. The effect of this clause is to remove Commonwealth controls over private hospitals and abolish the payment of subsidies. The clause is to be deemed to take effect from 1 October 1986.

Clause 8: Bribery

This clause makes consequential amendments to section 129AA of the Principal Act by omitting provisions so as to take account of the repeal of sections effected by clause 7 of the Bill.

Clause 9 - Officers to observe secrecy

The clause omits paragraph 130(3)(b) of the Principal Act and inserts in its stead a new sub-section 130(3A). The effect of this amendment is to limit the existing capacity for the Secretary of the Department of Health or the General Manager of the Health Insurance Commission to divulge any information acquired under the Principle Act to a prescribed authority or person, to information of a kind that may, in accordance with the regulations, be provided to the authority or person. Under the new provision, both the authority or person and the kind of information to be divulged must be prescribed before release of information can occur.

The amendments made in paragraphs 9(c), (d) and (e) of the Bill are consequential upon the above amendment and ensure that those persons acquiring information pursuant to new sub-section 130(3A) shall be subject to the same rights, obligations, liabilities and penalties as officers under the Principal Act.

Clause 10: Regulations

This clause makes consequential amendments to section 133 of the Principal Act to omit certain regulation-making provisions in consequence of the repeal of sections effected by clause 7 of the Bill.

Clause 11: Schedule 2

This clause makes a consequential amendment to Schedule 2 of the Principal Act to take into account the repeal of provisions regulating private hospitals effected by clause 7 of the Bill. Clause 8 of Schedule 2 specifies the requirement to include in Medicare agreements the assumption by a State of the responsibility to make daily bed payments to private hospitals.

Clause 12 - Transitional

This clause provides for transitional arrangements consequent on the amendment and repeal of certain provisions of the Act dealing with the regulation of private hospitals.

Paragraph 12(a) provides for the preservation, after the intended commencement date of clauses 6, 7, 8 and 10 of the Bill (1 October 1986), of all the provisions of the Principal Act which had application to the sections repealed by those clauses where any payments, or applications for payments, were made or lodged in respect of an occupancy of a bed which occurred prior to 1 October 1986.

Paragraph 12(b) provides that an application for approval or approval in principle as a private hospital which was made before 1 October 1986 may continue to be processed. Although a subsequent decision given as to the hospital's category will not result in any subsidy from the Commonwealth, the provisions are preserved to allow those applicants who wish to continue to pursue existing claims to do so, for example, in order to provide a basis for the applicant to pursue with a private health fund the question of the appropriate level of benefits payable by that fund.

Paragraph 12(c) also enables applications for a variation to the existing categorisation applying to a private hospital to continue to be processed if the applications were lodged before 1 October 1986.

Paragraph 12(d) permits the continuation of the Ministerial reconsideration and appeal processes connected with decisions regarding the approval of premises as private hospitals and their classification.

PART III - AMENDMENTS OF NATIONAL HEALTH ACT 1953

Clause 13: Principal Act

This clause identifies the National Health Act 1953 as the Principal Act for the purposes of Part III of the Bill.

Clause 14: Interpretation

This clause amends section 4 of the Principal Act as follows:

Sub-clause (1) of this clause inserts the words "or a day hospital facility" in paragraph 4(1)(dd) of the definition of "basic private table" or "basic table". This amendment will enable an in-patient who is given a prosthesis in a day hospital facility to be covered under a basic table offered by a health benefits fund. The amendment would remove the discrepancy in treatment of the same in-patient being entitled to a benefit under a basic table if given a prosthesis in a hospital, but not if he or she received it in a day hospital facility.

Sub-clause (2) of this clause amends the definition of "basic hospital benefits table" or "basic table" in sub-section 4(1) of the Principal Act to remove references to payments payable in accordance with a provision in the Health Insurance Act 1973 repealed by clause 7 of the Bill.

Similarly, the definition of "basic private table" or "basic table" in sub-section 4(1) of the Principal Act is amended to exclude references to payment payable in consequence of the amendments made in clause 7.

Sub-clause (3) extends the definition of 'pensioner' for the purposes of the Principal Act to include those beneficiaries described in sub-section 86(1) or (2) of the Veterans' Entitlements Act 1986 as being eligible to receive treatment under Part V of that Act.

Clause 15 - Provision of vaccines

This clause inserts a regulation making power in section 9B of the Principal Act to enable diseases other than those already mentioned in the section to be prescribed as diseases for which vaccines may be provided by the Commonwealth for immunisation purposes.

Clause 16 - Repeal of Part III

This clause repeals Part III of the Principal Act, which deals with the provision of Commonwealth assistance for persons living in isolated areas of Australia who require medical treatment (the Isolated Patients' Travel and Accommodation Assistance Scheme).

By virtue of sub-clause 2(3) of the Bill, the repeal of Part III will operate from 1 January 1987. However, a transitional provision is included in Clause 38 of the Bill to preserve any rights accruing under Part III of the Principal Act to a person who has commenced his or her journey to seek medical treatment before 1 January 1987. Correspondingly, all obligations, conditions and procedures applicable to persons who undertake journeys are covered by virtue of the transitional provisions continued in effect for the purposes of establishing eligibility for assistance.

Clause 17: Interpretation

This clause inserts a number of new definitions, or amends or omits existing definitions, in section 84 of the Principal Act in consequence of the changes made by the Bill to establish the new pharmaceutical benefits scheme.

The new or revised definitions inserted by sub-clause (1) of this clause are as follows:

- a definition of "entitlement card" which includes the pharmaceutical benefits entitlement card or an additional or replacement card to be issued in accordance with new sections 84E and 84H proposed to be included by Clause 19 of this Bill

- a definition of "entitlement card prescription" which is defined as a prescription written for the supply of a pharmaceutical benefit to a person who is a holder of an entitlement card

- the definition of "general benefit prescription" is amended by adding "an entitlement card prescription" as a further exclusion to the kinds of prescriptions already listed as falling outside the description of a "general benefit prescription"

- a definition of "record form" which will be a pharmaceutical benefits prescription record form (issued under proposed new section 84D) to be used to record the accumulated numbers of purchases of pharmaceutical benefit prescriptions

Once the specified number of purchases of pharmaceutical benefit prescriptions is reached, an entitlement card will be issued in accordance with the amended Principal Act

a definition of "relevant entitlement period" to specify the period during which an entitlement card will be valid. This period is defined as one calendar year from the year 1988 onwards. However in the first year of the operation of the new provisions the period will be from the proposed commencement date of 1 November 1986 through to 31 December 1987 inclusive

a new sub-section 84(2A) is inserted to describe what is meant by a prescription for the supply of a pharmaceutical benefit to a holder of an entitlement card. A prescription will be treated as such if, at the time the prescription is written for a person, or communicated in accordance with Part VII of the Principal Act, the person is a holder of an entitlement card or becomes one after the prescription is written or communicated but before the pharmaceutical benefit is supplied to the person.

Sub-clause (2) of this clause omits from the Principal Act the definition of 'British Pharmacopoeia', which is the compendium of drugs currently serving as the principal list of drugs and medicinal preparations from which the Commonwealth list of pharmaceutical benefits is drawn. The reference to the British Pharmacopoeia is being replaced to allow for the declaration by the Minister (as provided for by amendments in clause 20 of the Bill) of the drugs and medicinal preparations to which Part VII of the Principal Act will apply. Sub-clause (2) also omits sub-sections 84(4) and (4A) in consequence of the omission of references to the British Pharmacopoeia.

Clause 18: Concessional benefit prescriptions,
pensioner benefit prescriptions
and entitlement card prescriptions

Clause 18 amends section 84AA of the Principal Act.

New sub-section 84AA(1A) provides that a prescription written for a holder of an entitlement card by a medical practitioner or by a participating dental practitioner and presented to an approved pharmacist will be treated as an entitlement card prescription when the prescription is marked in the manner prescribed by regulation to indicate the status of the holder as that of an entitlement card holder.

New sub-section 84AA(3) mirrors the requirement in existing sub-section 84AA(2) that a prescription communicated to an approved pharmacist shall not be treated as a prescription which entitles its holder to free drugs or drugs at a concessional rate unless the prescribed information is properly communicated to the pharmacist that the supply is for, in the case of new sub-section 84AA(3), a holder of an entitlement card.

The effect of new sub-section 84AA(4) is that an approved pharmacist, approved medical practitioner or approved hospital authority remains under an obligation to be satisfied that a person presenting a prescription purporting to entitle that person to pharmaceutical benefits free of charge or at the concessional rate is entitled to be supplied with the pharmaceutical benefits in accordance with the Principal Act before supplying the benefit to the person.

Clause 18 should be read in conjunction with clause 19 of the Bill. These clauses are intended to set up a mechanism, to commence from 1 November 1986, under which persons or families whose illness cause them to use large numbers of drugs or medicinal preparations will be protected from the resulting financial burden. These people will be entitled to free drugs or medicinal preparations under the pharmaceutical benefits scheme after having purchased a qualifying number (ie 25) of pharmaceutical benefit prescriptions.

Clause 19: Insertion of New Division

(Division 1A - Pharmaceutical benefits entitlement cards)

Clause 19 inserts a new Division 1A into Part VII of the Principal Act.

New section 84B (Family relationships) describes who is to be included in a family for the purposes of issuing entitlement cards to a family. Family members will be a person's spouse and any dependent children under the age of 16 years and includes student children between the age of 16 years and 25 years who are receiving full time education at a school, college or university. A definition of a spouse is also included to restrict the meaning of that word for the purposes of the new scheme to a person who is legally married to someone and who is not living permanently apart from that person, and to de facto spouses.

New section 84C (Eligibility for pharmaceutical benefits entitlement cards) sets out the conditions for eligibility to receive pharmaceutical benefits entitlement cards. The conditions are as follows:

a person or family must have been supplied with pharmaceutical benefits on at least 25 occasions during the relevant entitlement period. This number can be an aggregate of all pharmaceutical benefits supplied during the relevant entitlement period to a person, or in the case of a family, to persons who were, during that period, either at the time of supply or at the time when an application for the issue of an entitlement card under new section 84E is made, members of the person's family. Sub-section 84C(3) allows for an agent of the patient to purchase pharmaceutical benefits on behalf of the patient

the supply of a pharmaceutical benefit must be by an approved pharmacist, approved medical practitioner or approved hospital authority (which is consistent with the current arrangements under the Principal Act)

the supply of pharmaceutical benefits to pensioners (and their dependants) and to persons who are already holders of entitlement cards shall not be counted as supplies for the purposes of qualifying for an entitlement card - pensioners already receive free pharmaceutical benefits

in the case where a pharmaceutical benefit is supplied upon either a general benefit prescription or a concessional benefit prescription and the Commonwealth price for that drug is or exceeds \$10 or \$2.50 respectively, the amount paid for the drug must not be less than the aggregate of \$10 plus any special patient contribution, if it is paid by a general beneficiary, or the aggregate of \$2.50 plus any special patient contribution, if paid by a concessional beneficiary

the amount received for the supply of a pharmaceutical benefit is to be an amount calculated in accordance with the formula set out in new paragraph 84C(4)(e) and, if at the time of supply of the pharmaceutical benefit, there is in force in respect of that drug, a determination made by the Minister pursuant to paragraph 85A(2)(a) of the Principal Act, the quantity of the drug supplied is the maximum quantity specified in that determination (Paragraph 85A(2)(a) enables the Minister to specify the maximum quantity of drugs that may be supplied at any one time.)

New sub-section 84C(5) deals with the situation where repeats of a drug are permitted to be prescribed in the same prescription for possible purchase on one occasion. Supply of what amounts to each repeat is to be treated as a separate supply towards reaching the specified number of occasions on which a person or family is to be treated as being 'supplied' with pharmaceutical benefits for the purpose of qualifying for an entitlement card.

New sub-sections 84C (6), (7) and (8) will establish, for the purposes of new paragraph 84C(4)(e)(i), the basis for calculating the agreed price referred to in that paragraph.

The agreed price for ready-prepared pharmaceutical benefits will have as its basis the aggregate of the approved price to pharmacists of the pharmaceutical benefit concerned, the addition of such fees and amounts as may be determined by the Pharmaceutical Benefits Remuneration Tribunal, to which may be added any other fees and amounts which the Minister and the Pharmacy Guild of Australia may together agree to.

The agreed price for other pharmaceutical benefits will have as its basis the aggregate of the basic wholesale price for each ingredient of the drug, being the wholesale price applicable on the day on which supply of the drug occurs, the addition of such fees and amounts as may be determined by the Pharmaceutical Benefits Remuneration Tribunal and any other fees and amounts which the Minister and the Pharmacy Guild may together agree to.

The terms "approved price", "basic wholesale price" and "ready-prepared pharmaceutical benefit" are to have the same meaning as in section 98B of the Principal Act (sub-section 84C(11)).

New sub-section 84C(10) provides for a determination for an agreed price to be made by notice in writing, for the notice to be gazetted and for it to come into operation on such date as is specified in that determination.

New Section 84D (Pharmaceutical benefits prescription record forms) provides for the issue of pharmaceutical benefit prescription record forms (record forms), the inclusion of certain information in the record form and the manner in which it is to be included.

New sub-section 84D(1) provides that the Secretary shall, on application by any person, issue a record form and new sub-section (2) provides that an approved pharmacist, approved medical practitioner or an approved hospital authority may issue a record form.

New sub-sections 84D(3) and (4) provide that record forms issued must be in a form approved by the Secretary and must include prescribed particulars of the person to whom the record form is issued and may also include the prescribed particulars of the members of that person's family who are not already receiving free pharmaceutical benefits (that is pensioners and their dependants and those who are already holders of entitlement cards).

Sub-section 84D(5) provides that each person whose name and other prescribed particulars appear on a record form which has been issued to one of those persons shall be treated as holders of the same record form so that supplies of pharmaceutical benefits to any of these holders may be counted as supplies towards obtaining an entitlement card for a relevant entitlement period.

Sub-section 84D(6) provides that the approved pharmacist, approved medical practitioner or approved hospital authority, when presented with a record form, is to record on it prescribed particulars relating to each supply of drugs upon a pharmaceutical benefit prescription which may be taken into account for the purposes of determining eligibility for an entitlement card. A person or family can have any number of record forms. The aggregate entries of all relevant supplies on these record forms are counted towards assessing eligibility for an entitlement card.

Sub-section 84D(7) provides that a record made pursuant to sub-section 84D(6) must include details of any prescribed particulars of the prescription upon which a pharmaceutical benefit has been supplied, the date of its supply and any other prescribed particulars relating to its supply. The signature of the approved pharmacist (or a person authorised by him or her for this purpose), the approved medical practitioner, the medical practitioner or pharmacist dispensing a pharmaceutical benefit under the supervision of an approved hospital authority, who dispensed or administered the pharmaceutical benefit must appear against each record of a supply of a benefit appearing in the record form.

New Section 84E (Issue of pharmaceutical benefits entitlement card) provides for the manner and circumstances in which an entitlement card may be issued. The entitlement card, which allows for all subsequent pharmaceutical benefits to be supplied free of charge to the holder or holders of the card, will be issued if eligibility is established.

Sub-section 84E(1) provides that the Secretary shall, upon application by a person, issue to that person an entitlement card upon being satisfied that the person qualifies for it and sub-section (2) provides that an approved pharmacist, approved medical practitioner or approved hospital authority may also issue entitlement cards to applicants for these cards where the pharmacist, medical practitioner or hospital authority is satisfied that the applicants qualify for them.

Sub-section 84E(3) provides that an application for an entitlement card must be in a form approved by the Secretary, contain prescribed particulars and be accompanied by any prescribed documents, and be signed by the applicant.

Sub-section 84E(4) sets out the matters a person empowered to issue entitlement cards must have regard to before such a card may be issued.

Sub-section 84E(5) sets out the requirement for an approved pharmacist, medical practitioner or hospital authority to retain, for a period of 12 months or such other period as may be prescribed, relevant documents accompanying an application for an entitlement card where the card is subsequently issued. These persons can be required by the Secretary to produce such of these documents as are specified in a notice given by the Secretary (new sub-section (6)).

Sub-section 84E(7) defines a "relevant document", for the purposes of sub-section 84E(5), as being a document containing any information about the number of supplies of pharmaceutical benefits made to a person. This makes clear what documents an approved pharmacist, approved medical practitioner and an approved hospital authority would have to retain.

New Section 84F (Form of entitlement card) provides that an entitlement card shall be in a form approved by the Secretary and must contain particulars which include the relevant entitlement period during which the card is valid and the names of all the holders of the entitlement card.

New sub-section 84F(3) provides that a failure to include particulars of a family member of a holder of an entitlement card at the time the card is issued does not affect the validity of that card.

New Section 84G (Persons covered by entitlement card) establishes who are the persons to be taken to be holders of an entitlement card. Where a person is issued with an entitlement card, that cardholder and any person who is, at the time when the card is issued, a member of that cardholder's family shall also be taken to be a holder of the entitlement card.

New Section 84H (Additional and replacement entitlement cards) provides for the circumstances in which an additional or replacement entitlement card may be issued.

Sub-section 84H(1) provides that where an entitlement card has been issued, an additional card may be issued to any other members of the holder's family in accordance with the regulations.

Sub-section 84H(2) provides that regulations may prescribe the circumstances in which additional cards may be issued, such as where holders of entitlement cards have lost their cards, or have had their cards damaged, stolen or destroyed, or whose particulars have not been included in the entitlement card.

Sub-section 84H(3) provides that where a holder of an entitlement card acquires a new family member after being issued with the entitlement card but during the life of that card, a replacement card may be issued, in accordance with the regulations, to the cardholder so that the new member may be included as a holder of the entitlement card.

Sub-section 84H(4) provides that regulations made for the purposes of sub-sections 84H(1) and (3) may provide for an avenue of appeal to the Administrative Appeals Tribunal in cases where a person refuses to issue either an additional or replacement entitlement card.

New Section 84J (Period of effect of entitlement card) provides that an entitlement card is to be valid from the day of its issue up to the end of the calendar year in which it is issued. If an entitlement card is issued anytime after the proposed commencement date of the provisions, ie 1 November 1986, and before 31 December 1987, it will be valid until 31 December 1987.

New Section 84K (Return of entitlement card) provides that where an entitlement card is issued to a person who is not eligible to receive it, the Secretary may, after giving written notice to the cardholder, require the latter to deliver the card to the Secretary or any other person specified in the notice within the period specified in the notice, being a period of not less than 7 days. Failure to comply is made an offence under new sub-section 84L(3). A person who has received a notice under this section may appeal to the Administrative Appeals Tribunal against a decision seeking the return of his or her entitlement card (Clause 32).

New Section 84L creates the following offences:

for an approved pharmacist, approved medical practitioner or approved hospital authority to knowingly issue an entitlement card to an ineligible person - the conditions of eligibility for a card are provided for in new section 84C, and new section 84E requires that the approved pharmacist, approved medical practitioner or approved hospital authority must be satisfied that the person is eligible before issuing a card

for an approved pharmacist, approved medical practitioner or approved hospital authority to knowingly include in an entitlement card, as the name of a member of a person's family, the name of a person who is not a member of the person's family - new section 84B describes who are to be treated as members of a person's family

for a person, without reasonable excuse, to fail to comply with a notice given to that person under new sub-section 84E(6) or under new section 84K.

(Attention is also drawn to clause 35 of the Bill dealing with prosecution of offences).

Clause 20: Pharmaceutical benefits

This clause amends section 85 of the Principal Act by substituting new provisions to allow the Minister to declare those drugs and medicinal preparations, or classes of drugs and medicinal preparations, to which Part VII of the Principal Act applies. This clause should be read in conjunction with clause 29 of the Bill, the effect of which is to require the agreement of the Pharmaceutical Benefits Advisory Committee to the declaration of new drugs and medicinal preparations or classes of drugs and medicinal preparations. New sub-section 85 (2) also has the effect of removing the British Pharmacopoeia as the basic list of drugs and medicinal preparations from which are drawn selected drugs, and to which are added other drugs, in respect of which pharmaceutical benefits may be payable.

Paragraph 85(2)(b) allows the Minister to declare certain drugs and medicinal preparations, or classes of drugs and medicinal preparations, as drugs for the purposes of Part VII of the Principal Act. The Minister may also declare what additives may be combined with these drugs and medicinal preparations.

New sub-section 85(2A) empowers the Minister to specify the circumstances in which a prescription may be written for certain kinds of pharmaceutical benefits declared by the Minister to be pharmaceutical benefits for the purposes of section 88A of the Principal Act.

New sub-sections 85 (2B), (2C) and (2D) mean that declarations made pursuant to sub-section 85(2) must be gazetted, be tabled before both Houses of Parliament and made subject to possible disallowance and made available for purchase on the date of notification of their publication in the Gazette.

New sub-section 85(2E) provides that evidence of a declaration having been made by the Minister may be given in a court of law by the production of the Gazette containing the declaration.

Clause 21: Limited charges for pharmaceutical benefits

This clause amends section 87 of the Principal Act to increase the basic maximum concessional beneficiary patient contribution for a pharmaceutical benefit from the existing \$2.00 to \$2.50 (plus any special patient contribution), and the basic maximum general patient contribution for a pharmaceutical benefit from \$5.00 to \$10.00 (plus any special patient contribution).

The inclusion in paragraph 87(2A)(a) of a reference to an "entitlement card holder" will mean that an entitlement card holder will not be charged for the supply of a pharmaceutical benefit other than any special patient contribution required to be paid pursuant to a determination made under section 85B of the Principal Act, and any other charges permitted under section 87 of the Act.

The clause also inserts new sub-sections 85(2B), (3A) and (3B).

Sub-section 87(2B) addresses the situation where, due to the increase in patient contribution from, for example, \$5.00 to \$10.00 in the case of drugs supplied upon a general benefit prescription, the aggregate of \$10.00 and any special patient contribution required to be paid by a patient could exceed the Commonwealth price for the pharmaceutical benefit concerned. Sub-section 87(2B) has been inserted to ensure that approved pharmacists and medical practitioners supplying pharmaceutical benefits will not receive a price for that benefit in excess of its Commonwealth price (as defined in section 99 of the Principal Act).

Sub-section 87(3A) provides that approved pharmacists, medical practitioners or hospital authorities shall not supply a pharmaceutical benefit to

- a pensioner or dependant of a pensioner
- a holder of an entitlement card
- a concessional beneficiary or a dependant of a concessional beneficiary

unless they are satisfied that the relevant recipient is eligible to receive it, and by virtue of new sub-section 87(3B) they may refuse to supply pharmaceutical benefits to a beneficiary unless the latter produces evidence, for example an identity card or a pensioner card, that he or she is entitled to the benefit.

Paragraph (j) in sub-clause (1) of this clause omits paragraph 87(4)(a) of the Principal Act so that approved pharmacists may set their own charges for the supply of pharmaceutical benefits after normal trading hours.

The amendment to sub-section 87(5), by paragraph (k) of sub-clause (1), to include a reference to a holder of an entitlement card is necessary to bring that sub-section into line with the new requirement that holders of entitlement cards may not be charged, other than any special patient contribution, for the supply of pharmaceutical benefits before the expiry of their entitlement card.

The addition of new sub-section 87(6), by paragraph (m) of sub-clause (1), is intended to qualify the requirement in sub-section 87(1) that approved pharmacists or medical practitioners may not charge any fees other than that specified under section 87 in order to take account of the removal of controls over charges made for supply of pharmaceutical benefits outside normal trading hours effected under paragraph 21(1)(j) of the Bill.

Sub-clause 21(2) provides that all the changes effected under this clause apply only to supplies of pharmaceutical benefits supplied on or after 1 November 1986.

Clause 22: Repeal of section 88A and substitution of new section 88A - Prescription of certain pharmaceutical benefits authorized only in certain circumstances

This clause repeals section 88A of the Principal Act and substitutes a new section 88A which takes into account the changes made to sub-section 85(2) under Clause 20. These sections allow the Minister to declare what drugs and medicinal preparations may be pharmaceutical benefits under Part VII of the Principal Act, and the circumstances in which certain drugs or medicinal preparations may be prescribed.

Clause 23 - Approvals to be subject to conditions

This clause makes consequential amendments to Section 92A of the Principal Act to take account of the entitlement benefit prescription provisions made under new Division 1A. Section 92A sets out the conditions applying to the grant of approvals to pharmacists and medical practitioners for the supply of pharmaceutical benefits under Part VII of the Principal Act.

The effect of paragraphs 23(a) and (b) is to require that where (in relation to a person identified in amended section 84AA of the Principal Act) an approved pharmacist supplies a pharmaceutical benefit upon a prescription that is communicated to the pharmacist in pursuance of amended paragraph 89(a) of the Principal Act, and the prescription is subsequently reduced to a document in writing, the pharmacist shall record in writing on that document relevant information communicated to him in relation to the status of the person who is the subject of the prescription.

The effect of paragraph 23(c) of the Bill is to provide that the conditions set out in paragraphs 92A(1)(a), (b) and (c) of the Principal Act which do not apply in relation to the supply of pharmaceutical benefits for pensioners should also not apply to the supply of benefits to holders of entitlement cards.

Clause 24: Cancellation by Secretary of approval of pharmacists, etc

This clause amends Section 98 of the Principal Act by replacing sub-section 98(2) with a new provision and by inserting new sub-sections 98(3) and (3A). The effect of the amendments is to allow the Secretary to cancel a pharmacist's or medical practitioner's approval to supply pharmaceutical benefits where:

- (a) an approved pharmacist or approved medical practitioner notifies the Secretary that he or she has ceased to carry on business as a pharmacist or practise as a medical practitioner at premises or in an area in respect of which he or she has been approved for the supply of pharmaceutical benefits, or
- (b) the Secretary is satisfied that the chemist or medical practitioner has ceased to carry on business as a pharmacist, or has ceased to practise as a medical practitioner in premises or an area in respect of which the pharmacist or practitioner was approved, for a period of 6 months.

These amendments overcome a defect in the existing legislation in that the Secretary has no power to cancel approvals to supply benefits where chemists or medical practitioners do not notify the Department of cessation of their business or their practice in an area or premises approved for the purposes of supply of pharmaceutical benefits.

By virtue of amendments made in clause 32 of the Bill, an appeal will lie to the Administrative Appeals Tribunal against the decision of the Minister to cancel an approval under sub-sections 98(3) and (3A).

Clause 25: Cancellation by Minister of approval of hospital

This clause amends section 98AA of the Principal Act by inserting new sub-section 98AA (2) and (3) to allow the Minister to cancel a hospital authority's approval to supply pharmaceutical benefits where the hospital authority gives the Minister notice that it has ceased to conduct a hospital in respect of which it has been approved to supply pharmaceutical benefits, and where the Minister is satisfied that the hospital authority has ceased to conduct a hospital for a period of 6 months or more.

Clause 32 of the Bill provides for an avenue of appeal to the Administrative Appeals Tribunal against a decision of the Minister to cancel an approval under sub-section 98AA(3)

Clause 26 - Function of Tribunal

This clause amends paragraph 98B(2)(a) of the Principal Act to establish that the approved price for a ready-prepared pharmaceutical benefit which is to be taken into account, for the purposes of ascertaining its Commonwealth price, is the approved price applying to that drug on the first day of the month in which it was supplied.

'Approved price' has the same meaning as in sub-section 98B(3) of the Principal Act.

Clause 27: Payment for supply of benefit

Paragraph (a) of this clause amends section 99 of the Principal Act by inserting a reference to an entitlement card prescription in paragraph 99(2)(a) of the Principal Act. The effect of this is to extend the Commonwealth's obligation to pay (subject to the Principal Act) an approved pharmacist or medical practitioner the full Commonwealth price for drugs supplied, in accordance with the Principal Act, free of charge to holders of entitlement cards.

The clause further amends section 99 by substituting the new \$10 general and \$2.50 concessional patient payments for the previously applicable rates of \$5.00 and \$2.00 respectively.

Paragraphs 27(1)(c) and (e) of the Bill provide that where, because no Commonwealth benefit is payable in respect of a supply of a pharmaceutical benefit, a supply of that benefit is deemed (pursuant to sub-sections 99(2A) and (2B) of the Principal Act) not to be a supply under Part VII of the Act, it may nevertheless be a supply for the purposes of qualifying for an entitlement card under new Division 1A.

Clause 28: Unauthorised payments

This clause amends the Principal Act by inserting after section 99 new section 99AA. The new section provides for the recovery of amounts paid by the Commonwealth for unauthorised supplies of pharmaceutical benefits.

New sub-section 99AA(1) empowers the Secretary to require, by notice in writing, repayment to the Commonwealth, from a person who obtained a pharmaceutical benefit and who knows, or should reasonably have known, that he or she is not entitled to receive it, such amounts as have been paid by the Commonwealth to the approved pharmacist, medical practitioner or hospital authority from whom the person wrongfully obtained the pharmaceutical benefit.

Sub-section 99AA(2) provides that the same recovery mechanism should apply to approved pharmacists, medical practitioners or hospital authorities where they have received payment from the Commonwealth in respect of pharmaceutical benefits they have supplied in circumstances where they know, or ought reasonably to have known, that benefits were not payable to them by the Commonwealth.

Sub-section 99AA(3) provides that where the Secretary has by notice in writing requested repayment to the Commonwealth in accordance with sub-sections 99AA(1) and (2), the Commonwealth may recover, in a court, the amount referred to in the notice as a debt owing to the Commonwealth.

Sub-clause (2) of this clause provides that the new section 99AA will apply only to pharmaceutical benefits supplied on or after 1 November 1986 which is the intended date of commencement of the provisions establishing the new pharmaceutical benefits scheme.

Clause 29: Pharmaceutical Benefits Advisory Committee

This clause amends section 101 of the Principal Act to take account of changes to be made by clause 20 of the Bill which enable the Minister to declare which drugs and medicinal preparations are to be listed as pharmaceutical benefits.

New sub-section 101(4) provides that the Minister may not declare a drug or medicinal preparation to be a drug or medicinal preparation in respect of which Part VII of the Principal Act applies unless the Committee has recommended to the Minister that it be so declared. This requirement does not apply in relation to all those drugs and medicinal preparations which were pharmaceutical benefits at the commencement of this provision. New sub-section 101(4A) makes similar provision in regard to the declaration of classes of drugs or medicinal preparations or drugs and medicinal preparations.

Clause 30: Offences

Paragraphs (a) and (b) are amendments consequential upon clause 18 of the Bill.

Paragraphs (c) and (d) of this clause amend section 103 of the Principal Act by inserting new paragraphs 103(5)(aa) and (ba). These new paragraphs make it an offence for a person to make a false or misleading statement in connection with an application for an entitlement card or for a person to obtain the issue of an entitlement card to which that person is not entitled.

Clause 31: Review of certain decisions of Secretary

This clause repeals section 105AAA of the Principal Act in consequence of the amendments made by clause 16 of this Bill. Section 105AAA provided for external review of decisions by the Secretary under Part III of the Principal Act.

Clause 32: Applications for review by Tribunal

This clause inserts in section 105AB of the Principal Act 4 new sub-sections to provide for a right of appeal to the Administrative Appeals Tribunal in the following circumstances:

where the Secretary has refused to issue an entitlement card to a person pursuant to sub-section 84E(1) (new sub-section 105AB(6A))

where the Secretary has required a person to whom an entitlement card is issued to return that card pursuant to section 84K (new sub-section 105AB(6B))

where the Secretary has revoked the approval of an approved pharmacist or medical practitioner after deciding that he or she has ceased to operate for a period of 6 months as a pharmacist in respect of premises approved, or ceased to practise as a practitioner in an area approved, for the purpose of supplying pharmaceutical benefits (new sub-section 105AB(8A))

where the Secretary has revoked the approval of an approved hospital authority after deciding that the authority has ceased to conduct a hospital for a period of 6 months (new sub-section 105AB(8B)).

Clause 33: Statement to accompany notification of decisions

This clause amends section 105AC of the Principal Act in consequence of the repeal made by clause 31 of the Bill.

Clause 34 - Insertion of new section (134E-conduct by directors, servants or agents).

This clause inserts new section 134E into the Principal Act to include a facilitative provision which will enable proof of the knowledge or intention of a body corporate in order to successfully prosecute a corporation, as well as individuals, for offences committed under the Principal Act.

This provision has been inserted on the recommendation of the Attorney-General's Department and appears in other Commonwealth legislation.

Clause 35 - Prosecution of Offences

This clause amends section 135B of the Principal Act to include as indictable offences the new offences created under section 84L. The amendment also will enable the new offences to be heard before a court of summary jurisdiction, and upon a conviction by such a court the maximum penalty which may be imposed is a fine not exceeding \$1,000 or imprisonment for a period of not more than 6 months.

Clause 36 - Schedule

This clause amends paragraph (e) of the Schedule to the Principal Act in consequence of the amendment made by clause 7 of the Bill. The clause removes references to daily bed payments made to private hospitals under the conditions of registration of a health benefits organisation as such references are no longer appropriate given the amendment made by clause 7.

Clause 37: Minor amendments

This clauses provides that the Principal Act is to be amended as set out in Schedules 1 and 2 of the Bill.

Clause 38: Transitional

Sub-clause (1) of this clause provides for transitional arrangements whereby a person who was an approved pharmaceutical chemist under the National Health Act 1953 immediately before the commencement of the amendments made in Schedules 1 and 2 shall be deemed to be an approved pharmacist.

Sub-clauses (2),(3) and (4) of this clause provide that notwithstanding the amendments made in clauses 16, 31 and 33 of the Bill to repeal provisions relevant to the Isolated Patients Travel and Accommodation Assistance Scheme, the repeal will not affect any journeys which commenced before 1 January 1987, the date the repealing provisions take effect. In respect of these journeys, the Principal Act will continue to apply as though no repeal had been effected, thus preserving all entitlements, obligations and conditions.

PART IV - AMENDMENTS OF THERAPEUTIC GOODS ACT 1966Clause 39: Principal Act

This clause identifies the Therapeutic Goods Act 1966 as the Principal Act for the purposes of Part IV of the Bill.

Clause 40: Additional operation of Part

This clause amends section 23B of the Principal Act in consequence of amendments made by clauses 41 and 42.

Clause 41: Insertion of new section (Section 23DA
Notice of, and identification of, particular batches)

This clause inserts new section 23DA into the Principal Act.

At present section 23D of the Principal Act empowers the Secretary to require a manufacturing corporation to provide information about the procedures carried out or to be carried out in the production of a biological product. That biological product must be specified in the notice requesting the information. However there is currently no power to require a corporation to inform the Secretary that it intends to produce a particular biological product. The Secretary is thus unable to specify a particular biological product in a notice if unaware that it is to be produced.

New sub-section 23DA(1) empowers the Secretary to require a manufacturing corporation to give notice on a standing basis of all or specified biological products that it produces or intends to produce. New sub-section 23DA(2) provides that where notice with respect to a biological product has not been given to the Secretary in accordance with the requirements of new sub-section 23DA(1), that corporation shall not supply that biological product in Australia to another person.

New sub-section 23DA(3) requires a corporation to give sufficient information to enable identification of the batch or other quantity of biological product to which the notice relates.

Clause 42: Insertion of new section (Section 23EA Secretary
may require samples to be provided automatically)

This clause inserts new section 23EA into the Principal Act.

Section 23E of the Principal Act presently empowers the Secretary to require a manufacturing corporation to provide information (including samples) about specified batches of specified biological products produced or to be produced by the corporation. However there is no power in section 23E to require a manufacturing corporation to furnish to the Secretary, on a standing basis, samples of biological products produced by the corporation.

New sub-section 23EA(1) empowers the Secretary to require a manufacturing corporation to furnish to the Secretary samples, on a standing basis, from each batch specified or all biological products produced by the corporation.

New sub-section 23EA(2) provides that the Secretary may direct a manufacturing corporation not to supply to a person in Australia any quantity of a biological product from a batch of which the corporation has furnished a sample. Such a direction would be given only where after testing the sample of the biological product it is found not to meet the appropriate standard for that product.

New sub-section 23EA(3) provides that a manufacturing corporation shall not supply a particular biological product from a particular batch to any person in Australia if the corporation has failed to supply a sample from that batch if required by a notice under new sub-section 23EA(1).

New sub-section 23EA(4) provides that a manufacturing corporation shall not supply to another person in Australia a biological product from a particular batch contrary to a notice issued in accordance with sub-section 23EA(2), unless expressly authorised by the Secretary. This sub-section also provides that, in the absence of a notice not to supply a biological product, a corporation shall not supply that product to another person in Australia until 28 days has elapsed since the sample was furnished to the Secretary.

New sub-section 23EA(5) provides that a notice not to supply a biological product may be revoked by the Secretary and new sub-section 23EA(6) provides that a notice authorising the supply of a product contrary to a notice under sub-section 23EA(2) may be revoked by the Secretary.

Clause 43: Regulations may provide for the examination, etc., of goods for therapeutic use

This clause amends section 24 of the Principal Act which provides for the making of regulations relating to the examination, testing and analysing of goods to which the section applies. The amendments extend the application of the section so that it applies:

- (a) to goods for therapeutic use that have been, or are being, manufactured by a prescribed corporation (i.e. a foreign corporation, or a trading corporation formed within the limits of the Commonwealth, within the meaning of placitum 51(xx) of the Constitution);

- (b) to goods for therapeutic use that have been, or are proposed to be, subject of trade or commerce between a State and a Territory or between 2 Territories (as well as among the States);
- (c) to goods for therapeutic use that have been, or are being manufactured in an internal Territory.

Clause 44: Insertion of new section (Section 24A Regulations may provide for inspection of manufacture of goods for therapeutic use)

This clause provides for the making of regulations to enable the inspection of places where goods for therapeutic use are being manufactured to ensure compliance with acceptable standards of manufacturing.

New sub-clause 24A(1) provides that the regulations may make provision relating to the inspection of procedures carried out in the manufacture of therapeutic goods and the inspection of documents relating to those procedures.

New sub-clause 24A(2) provides that the regulations may authorise persons to enter premises to inspect the procedures and documents relating to the manufacture of goods for therapeutic use and the taking of extracts from, or copies of, such documents.

New sub-section 24A(3) defines the term "procedures used in the manufacture of goods for therapeutic use" for the purposes of section 24A.

Clause 45: Service of notices

This clause makes consequential amendments to section 26A of the Principal Act by inserting into that section references to sections 23DA and 23EA which are inserted into Principal Act by clauses 33 and 34 respectively.

Clause 46: Applications for review

This clause amends section 29A of the Principal Act which provides that applications may be made to the Administrative Appeals Tribunal for review of "relevant decisions" (as defined in sub-section 29A(4) of the Principal Act). The amendment expands the term "relevant decision" to include decisions made by the Secretary under new sub-sections 23EA(4) and (5).

PART V - MISCELLANEOUS

Clause 47: Minor amendments to other Acts

This clause provides that the Acts set out in Schedule 3, namely the Commonwealth Serum Laboratories Act 1941, the Health Insurance Act 1973 and the Therapeutic Goods Act 1966, are amended as set out in that Schedule.

Clause 48: Repeal of Act

This clause provides for the repeal of the Hospitals and Health Services Commission (Repeal) Act 1978 which has ceased to have any effect.

Schedule 1

Schedule 1 to the Bill contains minor amendments to the National Health Act 1953. The classes of amendments made in this Schedule are as follows:

amendments of a purely drafting nature, for example, to remove unnecessary phrases such as "of this Act" or to substitute neutral words and expressions for male pronouns.

amendments to substitute references to "pharmaceutical chemist" with "pharmacist".

Schedule 2

Schedule 2 to the Bill identifies sections of the National Health Act 1953 amended pursuant to clause 37 of the Bill. These amendments are consequent upon the omission of the definition of "pharmaceutical chemist" and the insertion of a definition of a "pharmacist" in keeping with current terminology..

Schedule 3 (Clause 39)

Schedule 3 to the Bill identifies sections of three Acts amended pursuant to clause 47 of the Bill. The amendments are as follows -

Provision is made under the Commonwealth Serum Laboratories Act 1961 for the Minister to appoint a Commissioner of the Commonwealth Serum Laboratory as Acting Chairperson of the Commonwealth Serum Laboratory during a vacancy in the office of Chairperson. At present there is no power to do this except during the temporary absence of the Chairperson. Certain consequential amendments in respect of this provision are also made.

Sections 23DN and 23DO of the Health Insurance Act 1973 are amended by the insertion of provisions which preserve the validity of decisions -

- (a) affecting the accreditation of a pathology laboratory, or
- (b) taken on review of an original decision

notwithstanding that the person affected by the decision has not been notified of the right of appeal to the Administrative Appeals Tribunal. The effect of these provisions is to ensure that any dispute over the failure to advise of appeal rights is separate from the relevant decision, which remains in force. Such provisions are frequently included in legislation, and they do not have the effect of protecting decisions from the review procedures by the process of not advising of appeal rights.

Other amendments to the Health Insurance Act 1973 which are of a minor nature.

The Therapeutic Goods Act 1966 is amended to reflect the omission of the expression "pharmaceutical chemist" and its replacement with the expression "pharmacist" in the National Health Act 1953.